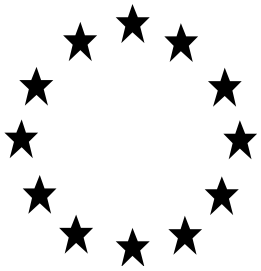
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS



SOPURCLEAN BPF

PT 4

With Decanoic acid & Octanoic acid as A.I.

Case Number in R4BP: BC-PJ019489-22

Evaluating Competent Authority: *Belgium*

Date: 9 July 2019

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ASSESSMENT REPORT

1.1 Summary of the product assessment

1.1.1 Administrative information

1.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
SOPURCLEAN BPF	Belgium

1.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	SOPURA
	Address	Rue de Trazegnies, 199 6180 Courcelles Belgium
Pre-submission phase started on	First communication to ECHA 1st of September 2014.	
Pre-submission phase concluded on	29th of May 2015 Communication number: D(2015)2099	
Authorisation number	To be inserted when authorised	
Date of the authorisation	To be inserted when authorised	
Expiry date of the authorisation	10 years from date of authorisation	

1.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	**SOPURA**	
Address of manufacturer	Rue de Trazegnies 199 6180 COURCELLES BELGIUM	
Location of manufacturing sites	Rue de Trazegnies 199 6180 COURCELLES BELGIUM	PIB de Tyberchamps 14 7180 SENEFFE BELGIUM

Name of manufacturer	***SOPURA Quimica***
Address of manufacturer	SOPURA QUIMICA Pol. Ind. La Canaleta, Av. Júpiter, 7 25300 TARREGA
Location of manufacturing sites	SOPURA QUIMICA Pol. Ind. La Canaleta, Av. Júpiter, 7 25300 TARREGA

1 Please fill in here the identifying product name from R4BP 3.

1.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	**Octanoic acid** (CAS N° 124-07-2)
Name of manufacturer	Emery Oleochemicals [redacted]
Address of manufacturer	[redacted]
Manufacturer plan location	[redacted]
Status of manufacturer	[redacted]

Active substance	**Decanoic acid** (CAS N° 334-48-5)
Name of manufacturer	Emery Oleochemicals [redacted]
Address of manufacturer	[redacted]
Manufacturer plan location	[redacted]
Status of manufacturer	[redacted]

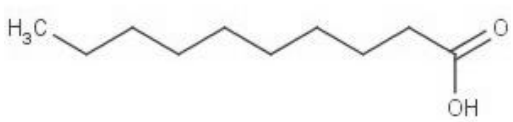
1.1.2 Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

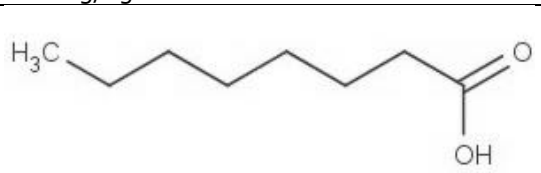
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes **X** (*Septacid BN* & *Septacid BN PS* are part of the ***SOPURCLEAN BPF***)
No **X** (There are additional BPs included in the ***SOPURCLEAN BPF***)

1.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	
IUPAC or EC name	Decanoic acid
EC number	206-376-4
CAS number	334-48-5
Index number in Annex VI of CLP	607-709-00-x
Minimum purity / content	>991 g/kg
Structural formula	
	Mol form.: C10H20O2

Main constituent(s)	
ISO name	
IUPAC or EC name	Octanoic acid
EC number	204-677-5
CAS number	124-07-2

Index number in Annex VI of CLP	607-708-00-4
Minimum purity / content	>996 g/kg
Structural formula	
	Mol form.: C8H16O2

1.1.2.2 Candidate(s) for substitution

The active substances relevant to this application (Decanoic acid & Octanoic acid) do not fulfil the criteria as candidate for substitution.

1.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

The substances listed in the table below are limted to those substances identified as SoCs.

Please see Confidential Annex for additional information, on other co-formulants.

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid	Octanoic acid	Active substance	124-07-2	204-677-5	1.1 (pure >1.0956)	2.7 (pure >2.6892)
Decanoic acid	Decanoic acid	Active substance	334-48-5	206-376-4	0.3 (pure >0.2973)	1.5 (pure >1.4865)
Sulfuric acid	Sulfuric acid	Supporting acid (SoC)	7664-93-9	231-639-5	0	31.2
Phosphoric acid	Phosphoric acid	Supporting acid (SoC)	7664-38-2	231-633-2	0	30.0
Nitric acid	Nitric acid	Supporting acid (SoC)	7697-37-2	231-714-2	0	18.0
Methane sulfonic acid	Methanesulfonic acid	Supporting acid (SoC)	75-75-2	200-898-6	0	20.3
Glycolic acid	Glycol acid	Solvent/ Emulsifier (SoC)	79-14-1	201-180-5	0	4.2
Propionic acid	Propionic acid	Solvent/ emulsifier (SoC)	79-09-4	201-176-3	0	19.5
Lactic acid	2-hydroxypropanoic acid	Solvent/ Emulsifier (SoC)	79-33-4	201-196-2	0	35.2
Citric acid	Trisodium citrate	Solvent/ Emulsifier (SoC)	77-92-9	201-069-1	0	3.0
Other co-formulants	Please see Confidential Annex					

Please note that, according to the decision made during the WG-Eff II 2019, co-formulants i.e. Glycolic Acid (under review in the BPR review program for PT4), Propionic Acid (approved for Annex I-cat.1), L+-Lactic acid (approved for PT4) & Citric Acid (only approved for PT2) cannot be considered to act as active substances in the formulations of the ***SOPURCLEAN BPF*** based on the data currently available.

About the product ***SOPURCLEAN NR*** (Meta SPC 2) which contains high % of Propionic Acid (ie 19.50%) and Lactic Acid (ie 35.20%), the efficacy of the biocidal formulation ***SOPURCLEAN NR*** was compared with a placebo formulation (without both A.S. but with all the co-formulants) via Phase 2/Step 1 efficacy tests in order to determine if lactic and propionic acid contribute to the bactericidal & yeasticidal activity of the whole formulation.

According to the results (please see p. 131-132), Lactic acid and propionic acid, identified as SoC, do not have an impact on the efficacy of the product and therefore cannot be considered to act as active substances in the formulation.

1.1.2.4 Qualitative and quantitative information on the composition of the meta SPC within the biocidal product family

Please see Confidential Annex for information.

1.1.2.5 Information on technical equivalence

Please see Confidential Annex for information.

1.1.2.6 Information on the substance(s) of concern

The biocidal family contains some substances of concern:
Sulfuric acid (N°CAS 7664-93-9), phosphoric acid (N°CAS: 7664-38-2), Nitric Acid (N°CAS: 7697-37-2), Methane Sulfonic Acid (N°CAS: 75-75-2), glycolic acid (N°CAS: 79-14-1), propionic acid (N°CAS: 79-09-4), Lactic Acid (N°CAS: 79-33-4) and Citric Acid (N°CAS: 77-92-9).

Common name	IUPAC name	Function	CASnumber	EC number	Content (%)		Harmonised classification or (self classification)*	SoC reason
					Min	Max		
Sulfuric acid	Sulfuric acid	Supporting acid	7664-93-9	231-639-5	0	31.2	Eye Irrit. 2; H319: 5 % ≤ C < 15 % Skin Corr. 1A; H314: C ≥ 15 % Skin Irrit. 2; H315: 5 % ≤ C < 15 %	Classification Skin Corr 1A
Phosphoric acid	Phosphoric acid	Supporting acid	7664-38-2	231-633-2	0	30.0	Eye Irrit. 2; H319: 10 % ≤ C < 25 % Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % (Acute tox 4 H302)	Classification Eye Damage 1
Nitric acid	Nitric acid	Supporting acid	7697-37-2	231-714-2	0	18.0	Ox. Liq. 2; H272: C ≥ 99 % Ox. Liq. 3; H272: 65 % ≤ C < 99 % Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 % (Acute tox 3 H331)	Classification Eye Damage 1, Acute Tox 4
Methane sulfonic acid	Methanesulfonic acid	Supporting acid	75-75-2	200-898-6	0	20.3	Skin Corr. 1B (STOT SE3 H335)	Classification Eye Damage 1, STOT SE3
Glycolic acid	Glycol acid	Solvent/ emulsifier	79-14-1	201-180-5	0	4.2	(Skin Corr 1B, Acute tox 4 H302 Acute tox 4 H332)	Classification Skin Corr 1B,), Biocidal active substance
Propionic acid	Propionic acid	Solvent/ emulsifier	79-09-4	201-176-3	0	19.5	STOT SE 3; H335: C ≥ 10 % Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H319: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 % STOT SE 3 (SCL ≥10%)	Classification Skin Corr. 1B STOT SE 3
Lactic acid	2-hydroxypropanoic acid	Solvent/ emulsifier	79-33-4	201-196-2	0	35.2	Skin irrit 2 Eye Dam 1	Biocidal active substance
Citric acid	Trisodium citrate	Solvent/ emulsifier	77-92-9	201-069-1	0	3.0	(Eye irrit.2)	Biocidal active substance

Most of those substances participates to the product classification as H314, Causes severe skin burns and eye damage, Category 1. They are the following: Sulfuric Acid, Phosphoric acid, Nitric acid, methane sulfonic acid, glycolic acid and propionic acid.
Lactic acid and citric acid are active substances and as such, according to the guidance on BPR, Volume III, parts B+C, they have to be considered as substances of concern. However, they are only contributing for classification such as H315, H318 and H319, and thus already covered by the classification of H314, including in the risk assessment and the use of PPE.
A few add additional hazards : propionic acid induces H335 with an SLC ≥10%, methane sulfonic acid induces H335 with no specifi SLC (the default value of 20% is thus used). Furthermore, Nitric acid is classified as being Acute Tox 3 (inhal) and is present in concentration high enough to bring the classification of the products at H332. Those additional classification have been taken into account in the structure of the family.

Justification:

a) Sulfuric acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).*
At the concentration used, sulfuric acid is enough to lead to a classification as Skin Corr 1A, which is higher than the classification provided by the active substance. As such, it must thus be considered as a substance of concern.

Please note that Sulfuric acid has no environmental classification.

b) Phosphoric Acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).*
At the concentration used, phosphoric acid is enough to lead to a classification as Eye Damage 1, which is higher than the classification provided by the active substance. As such, it must thus be considered as a substance of concern.

Please note that Phosphoric acid has no environmental classification.

c) Nitric Acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).*
At the concentration used, Nitric acid is enough to lead to a classification as Eye Damage 1 and Acute Toxicity Cat. 4 (inhalation) which is higher than the classification

provided by the active substance. As such, it must thus be considered as a substance of concern.

Please note that Nitric acid has no environmental classification.

d) Methane Sulfonic Acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).*
At the concentration used, methane Sulfonic acid is enough to lead to a classification as Eye Damage 1 and STOT SE 3, which is higher than the classification provided by the active substance. As such, it must thus be considered as a substance of concern.

Please note that Methane Sulfonic Acid has no environmental classification.

e) Glycolic Acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-*

formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).
At the concentration used, Glycolic acid is enough to lead to a classification as Eye Damage 1, which is higher than the classification provided by the active substance. As such, it must thus be considered as a substance of concern.
Regarding the environment, Glycolic Acid is registered as active substance in the Review programme for PT 2, 3 and 4. However Glycolic Acid is currently under review and no assessment report is available. Moreover it has no environmental harmonised classification.
For more information, please refer to the Confidential Annex.

f) Propionic Acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation. It should be noted that impurities might affect the classification of any such substances. This criterion partly overlaps with the requirements of Art 3(f) of the BPR. Ultimately, this criterion will additionally identify classified co-formulants that contribute, by additivity, to the classification of the biocidal product. It is noted that since the additivity principle of Directive 1999/45/EC or CLP Regulation applies only to acute toxicity and irritation/corrosivity, SoCs identified by this criterion would be co-formulants classified for these endpoints, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves, but that together with other co-formulants/active substance(s) contribute to the classification of the product. Conversely, as the additivity principle of Directive 1999/45/EC or CLP Regulation does not apply to the other toxicological hazards under the scope of these legislations, co-formulants classified for these other hazards, which are present in the biocidal product at concentrations insufficient to trigger the classification of the product by themselves are not considered SoCs on the basis of this criterion. Concentrations for classified substances taken into consideration when determining the classification of the product are specified in the relevant legislation (Directive 1999/45/EC and CLP Regulation).*
At the concentration used, Propionic acid is enough to lead to a classification as STOT SE 3 (SCL: C≥10%), which is higher than the classification provided by the active substance. As such, it must thus be considered as a substance of concern.

Please note that Propionic Acid has no environmental classification.

It is to be noted that propionic acid is also an active substance included in Annex I of the BPR. Due to this inclusion in the Annex I of the BPR, being an active substance does not lead to an automatic categorisation as substance of concern.

g) Lactic Acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report (CAR) (with agreed reference values) is available*

(including draft final CARs for Product Types other than the one of the actual biocidal product under evaluation). This criterion identifies other active substances in the biocidal product that act as co-formulants (e.g. in-can preservatives). It is noted that active substances (acting as co-formulants in a product) should be regarded as SoCs because, due to their intrinsic biological activity, they are likely to possess toxicological activity. It is also noted that as many active substances do not hold harmonised classifications under the CLP Regulation, they may fail to be identified as SoCs by the first two indents of Art 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%.

Regarding the environment, Lactic Acid is registered as active substance in the Review programme for PT 1, 2, 3 and 4. It is not included in the Annex I of the BPR and, as such, must thus be considered as a substance of concern. However Lactic Acid has no environmental classification.
For more information, please refer to the Confidential Annex.

Regarding toxicology, Lactic Acid is an approved active substance and as such must be considered as a substance of concern.
The NOAEC of lactic acid is 10%. Based on the "Risk characterisation of local effects in the absence of systemic effects (2009)" guidance, we can use an AF of only 10. This leads to an AEC of 1%.
The Guidance on the BPR: Volume III, parts B+C in appendix 4.5, page 290 mention that the risk is thus acceptable if some conditions are met, such as:
- Reversible effects
- Installed RMM at place
- Trained workers
- Use of appropriate PPE

Since the use of coverall, gloves and goggles is recommended, that the use is happening at low frequencies (disinfection only) with dilution happening, the RMM currently in place are enough to make this risk acceptable.

h) Citric Acid

According to the Guidance on BPR: Volume II Parts B+C, a substance corresponding to the following condition has to be considered as substance of concern: *Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report (CAR) (with agreed reference values) is available (including draft final CARs for Product Types other than the one of the actual biocidal product under evaluation). This criterion identifies other active substances in the biocidal product that act as co-formulants (e.g. in-can preservatives). It is noted that active substances (acting as co-formulants in a product) should be regarded as SoCs because, due to their intrinsic biological activity, they are likely to possess toxicological activity. It is also noted that as many active substances do not hold harmonised classifications under the CLP Regulation, they may fail to be identified as SoCs by the first two indents of Art 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%.*

Regarding the environment, Citric Acid is registered as active substance in the Review programme for PT 2. It is not included in the Annex I of the BPR and, as such, must thus be considered as a substance of concern.
However Citric Acid has no environmental classification.
For more information, please refer to the Confidential Annex.

Conclusion:

Most of those substances are considered substances of concern due to their classification as H314, and none present a classification for acute/chronic toxicity and/or CMR effects. Since the family is already classified as H314, and all scenarios take this into account, including with the use of PPE when required, it was deemed not necessary to perform further evaluation on the substances of concern.
The remaining two substance of concern are lactic acid and citric acid, who are considered as substance of concern due to their status as active substances. However, since both are classified only for local effect such as H315, H318 and H319, inferior to the classification of H314 already obtained by the family, and all scenarios take this into account, including with the use of PPE when required, it was deemed not necessary to perform further evaluation on the substances of concern.
Regarding environment, the substances considered due to their classification or because they are registered as active substance showed no risk and were not considered to be of concern.
A few add additional hazards: propionic acid induces H335 with an SLC ≥10%, methane sulfonic acid induces H335 with no specifi SLC (the default value of 20% is thus used). Furthermore, Nitric acid is classified as being Acute Tox 3 (inhal) and is present in concentration high enough to bring the classification of the products at H332. Those additional classification have been taken into account in the structure of the family.

For more information about other con-formulants, please refer to the Confidential Annex.

1.1.2.7 Type of formulation

SL: Soluble concentrate Applicable to all Biocidal products of the ***SOPURCLEAN BPF***.

1.1.3 Hazard and precautionary statements

Classification and labelling of the Meta SPC 1 products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Corrosion Cat.1A Metal Corrosion Cat.1
Hazard statement	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals
Labelling	
Signal words	Danger
Hazard statements	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals
Precautionary statements	P403 + P233 – Store in a well-ventilated place. Keep container tightly closed. P260 – Do not breathe vapours P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P390 Absorb spillage to prevent material damage P280 – Wear eye protection, face protection, protective clothing, protective gloves P301+P330+P331 – IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P234 – Keep only in original packaging P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
GHS Pictogram	GHS05 

Note that P-phrases listed were selected based on existing CLP preference rules for selecting P- phrases.

Classification and labelling of the meta SPC 2 products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Corrosion Cat.1A Metal Corrosion Cat.1 Specific Target Organ Toxicity, Single Exposure, Respiratory Tract Irritation
Hazard statement	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals H335: May cause respiratory irritation
Labelling	
Signal words	Danger
Hazard statements	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals H335: May cause respiratory irritation
Precautionary statements	P403 + P233 – Store in a well-ventilated place. Keep container tightly closed. P260 – Do not breathe vapours P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P280 – Wear eye protection, face protection, protective clothing, protective gloves P301+P330+P331 – IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P234 – Keep only in original packaging P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
GHS Pictogram	GHS05, GHS07 

Note that P-phrases listed were selected based on existing CLP preference rules for selecting P- phrases.

Classification and labelling of the meta SPC 3 products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Corrosion Cat.1A Acute Tox Cat. 4 Metal Corrosion Cat.1
Hazard statement	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals H332: Harmful if inhaled
Labelling	
Signal words	Danger
Hazard statements	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals H332: Harmful if inhaled
Precautionary statements	P403 + P233 – Store in a well-ventilated place. Keep container tightly closed. P260 – Do not breathe vapours P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P390 Absorb spillage to prevent material damage P280 – Wear eye protection, face protection, protective clothing, protective gloves P301+P330+P331 – IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P234 – Keep only in original packaging P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
GHS Pictogram	GHS05, GHS07 

Note that P-phrases listed were selected based on existing CLP preference rules for selecting P- phrases.

Classification and labelling of the meta SPC 4 products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Corrosion Cat.1A STOT SE 3 Metal Corrosion Cat.1
Hazard statement	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals H335: May cause respiratory irritation
Labelling	
Signal words	Danger
Hazard statements	H314: Cause severe skin burns and eye damage, H290: May be corrosive to metals H335: May cause respiratory irritation
Precautionary statements	P403 + P233 – Store in a well-ventilated place. Keep container tightly closed. P260 – Do not breathe vapours P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P390 Absorb spillage to prevent material damage P280 – Wear eye protection, face protection, protective clothing, protective gloves P301+P330+P331 – IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P234 – Keep only in original packaging P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
GHS Pictogram	GHS05, GHS07 

Note that P-phrases listed were selected based on existing CLP preference rules for selecting P- phrases.

1.1.4 Authorised use(s)

1.1.4.1 Use description

Meta SPC1

Use # 1 – Disinfection : Cleaning In Place (CIP) with circulation

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	For disinfection of pipes, tanks, etc …: - Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) - Circulation in a closed CIP system
Application rate(s) and frequency	For an effect on bacteria and on yeasts: Dilution rate: 1.5%v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 2%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)
Category(ies) of users	Industrial or Trained professional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. **Depending on BP specific weight.*

1.1.4.2 Use-specific instructions for use[2]

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

[2] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

1.1.4.3 Use-specific risk mitigation measures

<u>During the mixing and loading & application phase:</u> - Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (containers containing the product are connected to CIP via installed pipes; connections with dry coupling) - Treated equipment (vessels) and dosing equipment have to be rinsed

1.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific instructions.

Use # 2 – Disinfection : Dipping/soaking procedures

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	<u>For disinfection of non-porous surfaces / small parts (spare parts, tools, valves, hoses,...) used along the food manufacturing process</u>: - Concentrated product pumped in the bath and tap water added to reach the required use concentration - Immersion
Application rate(s) and frequency	<u>For an effect on bacteria and on yeasts:</u> Dilution rate: 1.5%v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 2%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)

Category(ies) of user(s)	Industrial or Trained professional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* Bulk delivery. *Depending on BP specific weight.

1.1.4.7 Use-specific instructions for use

The dipping solution must replaced by a fresh solution when it becomes visually polluted, and in all cases daily.

1.1.4.8 Use-specific risk mitigation measures

During the post application phase: Equipment is rinsed.

1.1.4.9 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.10 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.11 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific instructions.

Meta SPC2

Use # 1 – Disinfection : Cleaning In Place (CIP) with circulation

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts

Field of use	Indoor (Food & Feed areas)
Application method(s)	For disinfection of pipes, tanks, etc … - Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) - Circulation in a closed CIP system
Application rate(s) and frequency	<u>For an effect on bacteria and on yeasts:</u> Dilution rate: 1 %v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 1.5%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or Trained professional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* Bulk delivery. **Depending on BP specific weight.*

1.1.4.12 Use-specific instructions for use

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

1.1.4.13 Use-specific risk mitigation measures

<u>During the mixing and loading & application phase:</u> Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling)

1.1.4.14 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.15 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.16 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific instructions.

Use # 2 – Disinfection : Spraying

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	For disinfection of hard non-porous surfaces/items in contact with food processing: - Diluted biocidal product sprayed via a low pressure spraying device
Application rate(s) and frequency	For an effect on bacteria and on yeasts: Dilution rate: 1%v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 1.5%. Maximum application rate : 100 mL/m² Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or Trained professional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* Bulk delivery. **Depending on BP specific weight.*

1.1.4.17 Use-specific instructions for use

Please see general directions for use.

1.1.4.18 Use-specific risk mitigation measures

Fully automated process where workers are not present during spraying. Workers only re-enter in the work area when spraying solution has been drained.

1.1.4.19 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.20 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.21 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific instructions.

Use # 3 – Disinfection : Manual Disinfection

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	<u>For disinfection of non-porous small parts and surfaces/items used along the food manufacturing process:</u> - Diluted biocidal product sprayed via a low pressure spraying device - After the optimal disinfection contact time, the small parts will be wiped/mopped/brushed.
Application rate(s) and frequency	<u>For an effect on bacteria and on yeasts:</u> Dilution rate: 1%v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 1.5%. Maximum application rate : 100 mL/m² Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or Trained professional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*.

	• IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery **Depending on BP specific weight.*

1.1.4.22 Use-specific instructions for use

Make sure to wet surfaces completely.

1.1.4.23 Use-specific risk mitigation measures

No use-specific instructions.

1.1.4.24 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.25 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.26 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please see general directions for use.

Use # 4 – Disinfection : Dipping/soaking

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	<u>For disinfection of hard non-porous surfaces/small parts (spare parts, tools, valves, hoses,...) used along the food manufacturing process</u>: - Concentrated product pumped in the bath and tap water added to reach the required use concentration - Immersion
Application rate(s) and frequency	<u>For an effect on bacteria and on yeasts:</u> Dilution rate: 1%v/v

	In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 1.5%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C.
Category(ies) of user(s)	Industrial or Trained professional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. **Depending on BP specific weight.*

1.1.4.27 Use-specific instructions for use

The dipping solution must replaced by a fresh solution when it becomes visually polluted, and in all cases daily.

1.1.4.28 Use-specific risk mitigation measures

No use-specific instructions.

1.1.4.29 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.30 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.31 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific instructions.

Meta SPC3

Use # 1 – Disinfection : Cleaning In Place (CIP)

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant

Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	For disinfection of pipes, tanks, etc … - Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) - Circulation in a closed CIP system
Application rate(s) and frequency	<u>For an effect on bacteria and on yeasts:</u> Dilution rate: 1.5 %v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 2%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or Trained professional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* Bulk delivery. **Depending on BP specific weight.*

1.1.4.32 Use-specific instructions for use

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

1.1.4.33 Use-specific risk mitigation measures

<u>During the mixing& loading and application phases :</u> - Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (containers containing the product are connected to CIP via installed pipes; connections with dry coupling) **<u>During the mixing& loading phase :</u>** - Wear respiratory Mask.

1.1.4.34 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.35 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.36 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific instructions.

Meta SPC4

Use # 1 – Disinfection : Cleaning In Place (CIP)

Product Type	4
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	For disinfection of pipes, tanks, etc … - Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) - Circulation in a closed CIP system
Application rate(s) and frequency	For an effect on bacteria and on yeasts: Dilution rate: 1.5 %v/v In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 2%. Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial or Trained profeessional users
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* Bulk delivery. **Depending on BP specific weight.*

1.1.4.37 Use-specific instructions for use

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

1.1.4.38 Use-specific risk mitigation measures

<u>During the mixing and loading & application phase:</u> - Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling).

1.1.4.39 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific instructions.

1.1.4.40 Where specific to the use, the instructions for safe disposal of the product and its packaging

No use-specific instructions.

1.1.4.41 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific instructions.

1.1.5 General directions for use for all BP in BPF

1.1.5.1 Instructions for use[3]

<u>Main steps</u>: **For an effect on bacteria and on yeasts** • <u>Rinsing & cleaning before disinfection:</u> Not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). *For disinfection procedures in slaughterhouses, a cleaning step (with a cold alkaline solution) before disinfection is always mandatory.* • <u>Disinfecting cycle:</u> - Dilution of the concentrated product in tap water before use For products of Meta SPC 1, 3 and 4 : 1.5%

[3] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 2%.
Always check that the diluted products have a pH < 2.

For products of Meta SPC 2 : 1.0%
In case of outbreaks caused by *Pediococcus damnosus*, the products must be used at 1.5%.

- Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C).

- Disinfection procedures by dipping (for products of Meta SPC1 and 2):
The dipping solution must replaced by a fresh solution when it becomes visually polluted, and in all cases daily.

- Disinfection by CIP procedures (with circulation):
In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

- Final rinsing (with drinking water): may be skipped for products of Meta SPC 2 (i.e. *Sopurclean NR*)

1.1.5.2 Risk mitigation measures

Use in well ventilated places.

During the mixing& loading and application phases : A protective coverall shall be worn. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). The use of eye protection during handling of the product is mandatory. Wear face protection.

1.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Particulars of likely direct or indirect adverse effects:

- Severe chemical burns and/or corrosion of the eyes, mucosae, respiratory and digestive tract with the risk of perforation and intense pain. (The absence of visual oral burns does not exclude esophageal burns).
- If aspiration and/or ingestion occurs this may induce chemical pneumonia and metabolic acidosis.

First aid instructions:

- Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
- In case of inhalation : Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures.
- In case of eye exposure : Seek medical attention immediately. **ALWAYS** check for and remove contact lenses. Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. (Keep a bottle of water at hand).
- In case of skin contact : Obtain medical attention. Remove contaminated clothing and shoes. Wash affected area with plenty of water. **NO** scrubbing.

- In case of mouth contact or ingestion : Do **NOT** induce vomiting, if the individual is conscious, able to swallow saliva without coughing and ingestion occurred in less than one hour proceed to mouth wash with plenty of water. Take to hospital.
- **NEVER** administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.
- Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
- If symptoms persist or worsen bring individual to a healthcare center, bring packaging or label whenever possible.
- NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- In case of ingestion assess realizing an endoscopic procedure.
- The use of ipecac syrup, neutralization and activated charcoal is not advised.
- Symptomatic and supportive treatment.
- **WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER**

Emergency measures to protect the environment:

• Prevent entry into sewers and public waters.
• Clean up any spills as soon as possible, using an absorbent material (earth, sand, ...) to collect the spill. Use suitable disposal containers.

1.1.5.4 Instructions for safe disposal of the product and its packaging

Keep only in the original packaging tightly closed in a cool and well-ventilated place
Keep products away from direct sunlight, source of heat and ignition.
The biocidal product must be stored at temperatures below +30°C.
Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

1.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Storage conditions:

• Store in a clean area allowing recuperation of leaks and effusion.

• Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep container closed when not in use.
• Handle in accordance with good industrial hygiene and safety procedures.

Packaging material: Use approved materials suitable for corrosive liquids.

Shelf-life :
12 months in its original packaging for all the products of the SOPURCLEAN BPF.

1.1.6 Other information

Application codes: UA-APP

In order to guarantee efficacy of future products in Meta SPC 1, any new product with a total active substance concentration below 3%, and with co-formulant levels different from those in ***SopurCIP EC***, will need to be introduced by a change application and supported by new efficacy data (decision made in Eff *ad-hoc* follow up from 10/05/2019).

1.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Jerrycan	10 to 12.5 kg	HDPE	HDPE screw cap	Professional	Yes
Jerrycan	20 to 25 kg	HDPE	HDPE screw cap	Professional	Yes
Drum	200 to 250 kg	HDPE	HDPE screw cap	Professional	Yes
Drum	600 to 750 kg	HDPE	HDPE screw cap	Professional	Yes
IBC	1100 to 1250 kg	HDPE	HDPE screw cap	Professional	Yes

Products are also delivered in bulk.

1.1.8 Documentation

1.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the different biocidal products described within this application.

1.1.8.2 Access to documentation

The applicant is owner of the data submitted in function of this product application. Additionally, the applicant is also owner of all the data described in the active substance dossier as the applicant was participant in the review program. Consequently, the applicant is listed as an approved supplier on the Art. 95 list. A letter of access is therefore not applicable.

1.1.8.3 Similar conditions of use

Extract from outcome of pre-submission consultation (Communication number: D(2015)2099:

"The biocidal product family SOPURCLEAN is deemed eligible for Union authorisation.
Reasons
Based on the information provided by the applicant it appears that the application could meet the basic requirement of Article 42(1) of the Biocidal Products Regulation. No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards the eligibility of the prospective application

for Union authorisation on the grounds that the biocidal product family SOPURCLEAN falls outside of the scope of the BPR, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union. "

For detailed comments reference is made to the Annex of the original document received as outcome of the pre-submission session.

1.2 Assessment of the biocidal product (family)

1.2.1 Intended use(s) as applied for by the applicant

Table 1. SOPURCLEAN Biocidal Product Family

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal products of the BPF are disinfectants intended to be used with same application methods in various food & feed industries: manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products. For every kind of industry, a specific combination of product-application is selected, based on best available practice based on type of deposit, frequency of cleaning and available cleaning practice.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	Four application methods: (Will be detailed at the *meta* SPC level) - CIP procedures with circulation - Spraying of surfaces - Soaking baths - Manual disinfection of all kind of surfaces
Application rate(s) and frequency	Rates will be based on hygiene requirements during processing of food but concentrations varying from 1.0 up to 2%v/v will be used.
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. **Depending on BP specific weight.*

Meta SPC1: Product ***SOPURCIP EC*** as representative product

Table 2. Use # 1 – Cleaning In Place (CIP)

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal will be (semi-) automatically dosed in the CIP vessel either by volume or conductivity measurements. The solution will circulate in the closed equipment, pipes, tanks, etc. for disinfection. After disinfection the solution will be recovered in an adequate CIP vessel for re-use.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	Main steps: • Pre-rinsing & cleaning (by high & low pressure spraying): not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). • Disinfecting cycle(s): dilute the concentrated product in tap water to reach the required use dilution. • Final rinsing: rinse carefully the treated equipment (vessels) and the pumping pipes used with drinking water. *In case of re-use of the disinfectant solution for CIP, the active substance concentration must be measured and restored to its intended level before re-use*.
Application rate(s) and frequency	The disinfectant solution will be used in a closed CIP system and solution will be recovered for re-use. If needed, the recovered use concentration is adjusted based on the active substance content level. For an effect on bacteria and yeast: Dilution rate: 1.5%v/v Specific for outbreaks caused by *Pediococcus damnosus*: dilution rate of 2% Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C) Frequency (indicative): about 300 runs/year within the CIP circuit will be done.
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

With regard to the CIP use, the following best practices for recovery and re(use) of a CIP solution are applicable:

In order to guarantee a re(use) of the recovered CIP solution, it is required that the rinsing and cleaning process, prior to the disinfection is under control.

Table 3. Best practices for recovery and re(use) of a CIP solution

Step	Process	Frequency of the check
1	Control of the rinsing efficiency prior to the detergency step: • Control of pressure / flow rate • Visual inspection of the removal of the deposits	• Random • 1 per month
2	Control of the cleaning efficiency (often caustic) via: • Control of pressure / flow rate • Concentration control of the use concentration of the detergent (often caustic) • Visual inspection of the removal of the deposits	• Random • Each CIP • 1 per month
3	Control of the post-rinsing efficiency prior to the detergency / disinfection step: • Control of pressure / flow rate.	
4	Control of the cleaning / disinfection efficiency: • Microbiological control.	• Appropriate sampling plan.
5	Control of the cleaning/disinfecting solution: • Control of the use concentration of the BP in the CIP storage vessel via direct or indirect control method. • Mandatory adjustment of use concentration prior to disinfection.	• Each CIP • Each CIP (manual or automatic)
6	Visual inspection of the use control	• Each CIP
7	When appropriate, check if deposit(s) in the use solution	• As appropriate
8	Replacement of the use solution is mandatory when insufficient microbiological results are obtained based on the HACCP standards in place.	

Table 4. Use # 2 – Dipping/soaking

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of small parts (spare parts, tools, valves, hoses,...) used along the food manufacturing process. The small parts are submerged in soaking baths containing a biocide solution.

Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	Main steps: • Pre-rinsing & cleaning: not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). • Disinfecting cycle(s): the concentrated product is pumped in the bath and tap water is added to reach the required use solution. The equipment to be disinfected is then soaked in the bath. Loading and unloading of the to be disinfected items is typically manually. The baths are closed during the application (soaking) phase. • Final rinsing: rinse carefully the treated devices (tools, spare parts) and the pumping pipes used with drinking water. *The dipping solution is replaced by a fresh solution when it becomes visually polluted, and in all cases daily."*
Application rate(s) and frequency	For an effect on bacteria and yeast: Dilution rate: 1.5%v/v Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C)
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

Meta SPC2: Product *SOPURCLEAN NR as* representative product

Table 5. Use # 1 – Cleaning In Place (CIP)

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal will be (semi-) automatically dosed in the CIP vessel either by volume or conductivity measurements. The solution will circulate in the closed equipment, pipes, tanks, etc. for disinfection. After disinfection the solution will be recovered in an adequate CIP vessel for re-use.
Target organism (including development stage)	Bacteria Yeasts

Field of use	Indoor (Food & Feed areas)
Application method(s)	Main steps: • Pre-rinsing & cleaning (by high & low pressure spraying): not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). • Disinfecting cycle(s): dilute the concentrated product in tap water to reach the required use dilution. • Final rinsing: may be skipped. *In case of re-use of the disinfectant solution for CIP, the active substance concentration must be measured and restored to its intended level before re-use*.
Application rate(s) and frequency	The disinfectant solution will be used in a closed CIP system and solution will be recovered for re-use. If needed, the recovered use concentration is adjusted. For an effect on bacteria and on yeasts: Dilution rate: 1%v/v Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C Frequency (indicative): about 300 runs/year within the CIP circuit will be done.
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

Table 6. Use # 2 – Spraying

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of hard surfaces in contact with food processing. The diluted solution is sprayed on the surface via a low pressure spraying device.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	Main steps: • Pre-rinsing & cleaning (by high & low pressure spraying): not mandatory (even if a pre-rinsing is always recommended and usually performed by the users).

	• Disinfecting cycle(s): dilute the concentrated product in tap water and spray with a low pressure device on the equipment (tanks, ..) that must be treated. • Final rinsing: may be skipped.
Application rate(s) and frequency	<u>For an effect on bacteria and on yeasts:</u> Dilution rate: 1%v/v Maximum application rate : 100 mL/m² Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

Table 7. Use # 3 – Dipping/soaking

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of small parts (spare parts, tools, valves, hoses,...) used along the food manufacturing process. The small parts are submerged in soaking baths containing a biocide solution.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	<u>Main steps:</u> • Pre-rinsing & cleaning: not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). • Disinfecting cycle(s): the concentrated product is pumped in the bath and tap water is added to reach the required use solution. The equipment to be disinfected is then soaked in the bath. *Loading and unloading of the to be disinfected items is typically manually. The baths are closed during the application (soaking) phase.* • Final rinsing: may be skipped. *The dipping solution is replaced by a fresh solution when it becomes visually polluted, and in all cases daily.*
Application rate(s) and frequency	<u>For an effect on bacteria and on yeasts:</u> Dilution rate: 1%v/v

	Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

Table 8. Use # 4 – Manual Disinfection

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal product will be used for the disinfection of small parts and surfaces used along the food manufacturing process. The small parts will be manually cleaned.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	Main steps: • Pre-rinsing & cleaning: not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). • Disinfecting cycle(s): dilute the concentrated product in tap water before use. Apply the use solution on the surface that is to be treated and use appropriate cleaning tools, e.g. mops, cloths, brushes, on hard surfaces to achieve disinfection. *The use solution is applied by spraying and the user has to wait 15 min (optimal contact time) before mopping/wiping.* • Final rinsing: may be skipped. After the treatment, the surfaces are ready to be re-used
Application rate(s) and frequency	For an effect on bacteria and on yeasts: Dilution rate: 1%v/v Maximum application rate : 100 mL/m² Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*.

	• IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

Meta SPC3: Product *SOPURCLEAN OP N as* representative product

Table 9. Use # 1 – Cleaning In Place (CIP)

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal will be (semi-) automatically dosed in the CIP vessel either by volume or conductivity measurements. The solution will circulate in the closed equipment, pipes, tanks, etc. for disinfection. After disinfection the solution will be recovered in an adequate CIP vessel for re-use.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	Main steps: • Pre-rinsing & cleaning (by high & low pressure spraying): not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). • Disinfecting cycle(s): dilute the concentrated product in tap water to reach the required use dilution. • Final rinsing: rinse carefully the treated equipment (vessels) and the pumping pipes used with drinking water. *In case of re-use of the disinfectant solution for CIP, the active substance concentration must be measured and restored to its intended level before re-use*."
Application rate(s) and frequency	The disinfectant solution will be used in a closed CIP system and solution will be recovered for re-use. If needed, the recovered use concentration is adjusted based on the active substance content level. For an effect on bacteria and yeast: Dilution rate: 1.5%v/v Specific for outbreaks caused by *Pediococcus damnosus:* dilution rate of 2% Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C) Frequency (indicative): about 300 runs/year within the CIP circuit will be done.
Category(ies) of user(s)	Industrial / Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*.

	• Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

Meta SPC4: Product *SOPURCLEAN CIP OP as* representative product

Table 10. Use # 1 – Cleaning In Place (CIP)

Product Type(s)	4
Where relevant, an exact description of the authorised use	The biocidal will be (semi-) automatically dosed in the CIP vessel either by volume or conductivity measurements. The solution will circulate in the closed equipment, pipes, tanks, etc. for disinfection. After disinfection the solution will be recovered in an adequate CIP vessel for re-use.
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor (Food & Feed areas)
Application method(s)	Main steps: • Pre-rinsing & cleaning (by high & low pressure spraying): not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). • Disinfecting cycle(s): dilute the concentrated product in tap water to reach the required use dilution. • Final rinsing: rinse carefully the treated equipment (vessels) and the pumping pipes used with drinking water. *In case of re-use of the disinfectant solution for CIP, the active substance concentration must be measured and restored to its intended level before re-use*."
Application rate(s) and frequency	The disinfectant solution will be used in a closed CIP system and solution will be recovered for re-use. If needed, the recovered use concentration is adjusted based on the active substance content level. For an effect on bacteria and yeasts: Dilution rate: 1.5%v/v Specific for outbreaks caused by *Pediococcus damnosus*: dilution rate of 2% Contact time: minimum 15 minutes at +4°C (and above, up to +20-25°C) Frequency (indicative): about 300 runs/year within the CIP circuit will be done.
Category(ies) of user(s)	Industrial / Trained professional

Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg*. • Jerrycan (PE-HD), containing: 20 to 25 kg*. • Drums (PE-HD) containing 200 to 250 kg*. • Containers (PE-HD) containing 600 to 750 kg*. • IBC (Internal bulk containers, PE-HD) containing 1100 to 1250 kg* • Bulk delivery. *Depending on BP specific weight.

1.2.2 Physical, chemical and technical properties

Please refer to the confidential PAR for additional information about the function of the different co-formulants.

Meta SPC1: Product information on *SOPURCLEAN BN, SOPURCLEAN BN PS and SOPURCIP EC* is presented in this PAR for Meta SPC 1.

APCP data is available for all products within Meta SPC 1.

In function of the readability and transparency of the PAR, only details on the 'new' products ***SOPURCLEAN BN*, SOPURCLEAN BN PS and *SOPURCIP EC*** have been presented in the PAR. Nevertheless, the APCP information on the other ('old') products of Meta SPC 1 is available and presented in the IUCLID.

Sopurclean BN

Table 11. Physical, chemical and technical properties – Sopurclean BN (meta SPC 1)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.1 Physical state at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	liquid	Study report. Physico-chemical characteristics of the SOPURCLEAN BN. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 A. 2015/02/23
Colour at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	limpid colourless	Study report. Physico-chemical characteristics of the SOPURCLEAN BN. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 A. 2015/02/23
Odour at +20°C and 101.3 kPa	ITLMA 81 internal method (odour)	Biocidal product as such (100%)	Vinegar	Study report. Physico-chemical characteristics of the SOPURCLEAN BN. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 A. 2015/02/23

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.2 Acidity / alkalinity	Method according to CIPAC MT 75 (determination of PH values)	100.0	Sopurclean BN was found to have a pH < 2 at 20°C (average 6 individual results) Acidity (% m/m H_2SO_4): 38.7%	Study report. Physico-chemical characteristics of the SOPURCLEAN BN. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 A. 2015/02/23. Study report. Determination of acidity SOPURCLEAN PRODUCTS. Semal E. 2019. Unpublished. Sopura Laboratory. 2019/04/09.
3.3 Relative density / bulk density	According to IT-LCT-02 (internal guideline) According to OECD guideline 109 (density of liquids and solids) The density was assessed via a calibrated automated densimeter.	Biocidal product as such (100%)	The density of Sopurclean BN is 1.288 kg/L (average 6 individual results)	Study report. Physico-chemical characteristics of the SOPURCLEAN BN. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 A. 2015/02/23
3.4 Storage stability test – **low temperature stability test for liquids**	According to CIPAC method MT 39.2. 100 mL of the material is put in a measuring cylinder and in the refrigerator at 0 ±1°C. After 48h the amount of separated material is noted. After, the cylinder is allowed to reach room temperature and again the amount of separated material is noted.	Biocidal product as such (100%)	Separated material : 0 mL => ***Sopurclean BN*** is considered stable at 0°C during 48 hours (2 trials).	Study report. Stability at 0°C of the Sopurclean BN Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 S. Company owner: Sopura SA 2015/03/26
3.4 Storage stability test – **accelerated storage**	IT-LMA-54 (internal method) IT-LMA-22V03 EN 1276 EN 1650	Biocidal product as such (100%)	**Octanoic acid** T_0 = 1.89 % (w/w) T_{8w} = 1.61 % (w/w) **Decanoic acid** T_0 = 1.24 % (w/w)	Study report. Stability study in accelerate conditions (40°C) ***Sopurclean BN*** - Product code: 1333 Servais D. 2015. Unpublished. Sopura

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	The test item was put in a flask made of PEHD and stored at 40°C for 12 weeks in accelerating conditions. Analyses were performed at the beginning and then at 3, 6, 8 and 12 weeks.		T_{8w} = 1.11 % (w/w) After 12 weeks at 40°C the appearance of the biocidal product and the container remained unchanged. However, loss of the active matter appeared to be more than 10%. Nevertheless, the product remained conform for the biocidal activity at 0.75 %v. The biocidal product ***Sopurclean BN*** must be stored at temperatures below +30°C.	Laboratory. Company owner: Sopura S.A. Report date: 2015/08/06
3.4 Storage stability test – **long term storage at ambient temperature**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)	Biocidal product as such (100%)	The stability of ***Sopurclean BN*** in a commercial HDPE container was assessed for 24 months according to the guidelines: **Octanoic acid (% w/w):** T_0 = 1.89 T_{3m} = 1.78 T_{6m} = 1.68 T_{12m} = 1.67 T_{24m} = 1.21 **Decanoic acid (% w/w):** T_0 = 1.24 T_{3m} = 1.20 T_{6m} = 1.12 T_{12m} = 1.11 T_{24m} = 0.83 The loss of active matter was well below 10 % up to 3 months storage. After 6 months, the 10% cut-off was slightly exceeded for	Stability study in normal conditions (20°C) ***SOPURCLEAN BN.*** Servais 2016/11/10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			octanoic and after 12 months for decanoic acid. The appearance of the product and the container did not change after 24 months. The storage stability study was performed in a recipient from the same material, but with a different volume (125 ml instead of liters) from the commercially available recipients. Applicant indicated that the active substances decay is related with absorption to the plastic of the recipient, and not actual degradation, and this effect is probably enhanced by the small size of the testing packaging. As the loss of active ingredient after 12 months was only slightly above 10 %, the shelf-life of ***Sopurclean BN*** was set to 12 months at Room T°C..	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Data waiving	Biocidal product as such (100%)	All products of the Sopurclean family are packed in HD-PE (high density polyethylene) which has a high resistance to	Waiver effect of the light on products of the bpf. S. Verschaeve 2015/08/07

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			light because of its composition and additionally for acid products, red pigmented HD-PE is used allowing to protect more the chemical products to potential light effects. For this reason it would not be justified to evaluate light effect of those products.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Data waiving		As the biocidal products of the SOPURCLEAN BPF are liquids, humidity is not considered to be a relevant issue. With regard to the effect of temperature on the characteristics of the product, reference is made to the results of the storage stability tests at 0°C and the accelerated storage stability tests. These indicate that under the intended conditions of use and storage the content of the active substance and its technical characteristics remain within specifications.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and	Biocidal product as such (100%)	The appearance of the product and the container did not change after 24 months.	Stability study in normal conditions (20°C) SOPURCLEAN BN. Servais 2016/11/10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
container material	assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)			
3.5 Wettability	No solid			
3.5 Suspensibility, spontaneity and dispersion stability	No suspension			
3.5 Wet sieve analysis and dry sieve test	No suspension			
3.5 Emulsifiability, re-emulsifiability and emulsion stability	Data waiving		The product formulations of the SOPURCLEAN BPF can all be characterized as acidic water solutions of organic short chain fatty acids, maintained in solution by means of hydrothropic substances. Those substances have the ability to maintain hydrophobic molecules in an aqueous solution in dispersion.	Non emulsion statement and stability, 2017, Verschaeve (*please refer to confidential PAR for justification*).
3.5 Disintegration time	No tablets			
3.5 Particle size distribution, content of dust/fines, attrition, friability	No particles			
3.5 Persistent foaming	According to CIPAC: 47.1	2%v of the biocidal product	The persistence of foaming of Sopurclean BN in a 100 mL cylinder was determined to be 5mL or 5% at 20°C (average 6 individual	Study report Physico-chemical characteristics of the SOPURCLEAN BN Loghmanian A. 2015 Unpublished. Sopura Laboratory. Report no: VAL 84 A. Company owner Sopura S.A.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			results) after 1 min	Report date: 2015/02/23
3.5 Flowability/Pourability/Dustability	No particles			
3.5 Burning rate — smoke generators	No smoke generators			
3.5 Burning completeness — smoke generators	No smoke generators			
3.5 Composition of smoke — smoke generators	No smoke generators			
3.5 Spraying pattern — aerosols	No aerosols			
3.6 Physical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.6 Chemical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.7 Degree of dissolution and dilution stability	Other: MT41 dilution stability of herbicide aqueous solutions Dilute the specified amount of the formulation or otherwise use 5 mL, to 100 mL with standard water and allow the solution to stand for 18h at 20°C. At the end of this time, note if any material separates.	1% v/v of the biocidal product	No separated material was observed after 18 hours. Therefore, the diluted solution is considered stable.	Study report. Val84 X: Dilution stability of a Sopurclean BN solution. Loghmanian A. 2015. Unpublished. Testing laboratory: Sopura Laboratory. Report no.: VAL84 X. Company owner: Sopura S.A. 2015/08/06
3.8 Surface tension	The method used is IT-LMA-18 (internal	1 g/l	31.5 mN/m at 20°C.	Study report. Physico-chemical characteristics of the

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	method), in accordance with OECD 115 method, EC A5 surface tension: ring method)			SOPURCLEAN BN. Loghmanian A. 2015 Unpublished. Testing laboratory: Sopura Laboratory. Report no.: VAL 84 A. Company owner: Sopura S.A. 2015/02/12
3.9 Viscosity	An internal method was used: IT-LMA-14V04 which is in accordance with the OECD 114 method (viscosity of liquids)	Biocidal product as such (100%)	The viscosity of Sopurclean BN is 12.9 and 8.7 mPa/s at respectively 20 and 40°C. (average of 6 individual results)	Study report. Measure of viscosity SOPURCLEAN BN. Semal E. 2019. Unpublished. Testing laboratory: Sopura Laboratory. Report no.:-, Company owner: Sopura S.A. 2019/04/01

Sopurclean BN PS

Table 12. Physical, chemical and technical properties – Sopurclean BN PS (meta SPC 1)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.1 Physical state at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	liquid	Study report. Physico-chemical characteristics of the SOPURCLEAN BN PS. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 B. 2015/02/23
Colour at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	limpid colourless	Study report. Physico-chemical characteristics of the SOPURCLEAN BN PS. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 B. 2015/02/23
Odour at +20°C and 101.3 kPa	ITLMA 81 internal method (odour)	Biocidal product as such (100%)	Vinegar	Study report. Physico-chemical characteristics of the SOPURCLEAN BN PS. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 B. 2015/02/23
3.2 Acidity / alkalinity	Method according to CIPAC MT 75 (determination of PH values)	100.0	Sopurclean BN PS was found to have a pH < 2 at 20°C (average 6 individual results)	Study report. Physico-chemical characteristics of the SOPURCLEAN BN PS. Loghmanian A. 2015. Unpublished. Sopura

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Acidity (% m/m H_2SO_4): 23.0%	Laboratory. Report no: VAL 084 B. 2015/02/23 Study report. Determination of acidity SOPURCLEAN PRODUCTS. Semal E. 2019. Unpublished. Sopura Laboratory. 2019/04/09.
3.3 Relative density / bulk density	According to IT-LCT-02 (internal guideline) According to OECD guideline 109 (density of liquids and solids) The density was assessed via a calibrated automated densimeter.	Biocidal product as such (100%)	The density of Sopurclean BN PS is 1.218 kg/L (average 6 individual results)	Study report. Physico-chemical characteristics of the SOPURCLEAN BN PS. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 B. 2015/02/23
3.4 Storage stability test – **low temperature stability test for liquids**	According to CIPAC method MT 39.2. 100 mL of the material is put in a measuring cylinder and in the refrigerator at 0 ±1°C. After 48h the amount of separated material is noted. After, the cylinder is allowed to reach room temperature and again the amount of separated material is noted.	Biocidal product as such (100%)	Separated material : 0 mL => Sopurclean BN PS is considered stable at 0°C during 48 hours (2 trials).	Study report. Stability at 0°C of the Sopurclean BN PS Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 T. Company owner: Sopura SA 2015/03/26
3.4 Storage stability test – **accelerated storage**	IT-LMA-54 (internal method) IT-LMA-22V03 EN 1276 EN 1650 The test item was put in a flask made of PEHD and stored at 40°C for 12 weeks in accelerating	Biocidal product as such (100%)	After 12 weeks at 40°C the appearance of the biocidal product and the container remained unchanged. However, loss of the active matter appeared to be more than 10%.	Study report. Stability study in accelerate conditions (40°C) Sopurclean BN PS - Product code: 852 Servais D. 2015 Unpublished. Sopura Laboratory. Company owner: Sopura S.A. Report date: 2015/08/06

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	conditions. Analyses were performed at the beginning and then at 3, 6, 8 and 12 weeks.		Nevertheless, the product remained conform for the biocidal activity at 0.75 %v. The biocidal product ***Sopurclean BN-PS*** must be stored at temperatures below +30°C.	
3.4 Storage stability test – **long term storage at ambient temperature**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)	Biocidal product as such (100%)	The stability of ***Sopurclean BN-PS*** in a commercial HDPE container was assessed for 12 months according to the guidelines: **Octanoic acid (% w/w):** T_0 = 1.85 T_{12m} = 1.68 **Decanoic acid (% w/w):** T_0 = 1.20 T_{12m} = 1.11 The loss of active matter was below 10 % after 12 months. The appearance of the product and the container did not change after 12 months.	Stability study in normal conditions (20°C) SOPURCLEAN BN PS. Servais 2016/11/10
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Data waiving	Biocidal product as such (100%)	All products of the Sopurclean family are packed in HD-PE (high density polyethylene) which has a high resistance to light because of its composition and additionally for acid products, red pigmented HD-PE is used allowing to	Waiver effect of the light on products of the bpf. S. Verschaeve 2015/08/07

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			protect more the chemical products to potential light effects. For this reason it would not be justified to evaluate light effect of those products.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Data waiving		As the biocidal products of the SOPURCLEAN BPF are liquids, humidity is not considered to be a relevant issue. With regard to the effect of temperature on the characteristics of the product, reference is made to the results of the storage stability tests at 0°C and the accelerated storage stability tests. These indicate that under the intended conditions of use and storage the content of the active substance and its technical characteristics remain within specifications.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and	Biocidal product as such (100%)	The appearance of the product and the container did not change after 24 months.	Stability study in normal conditions (20°C) SOPURCLEAN BN PS. Servais 2016/11/10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	biocidal products. (ENV/JM/MONO (2015)32)			
3.5 Wettability	No solid			
3.5 Suspensibility, spontaneity and dispersion stability	No suspension			
3.5 Wet sieve analysis and dry sieve test	No suspension			
3.5 Emulsifiability, re-emulsifiability and emulsion stability	Data waiving		The product formulations of the SOPURCLEAN BPF can all be characterized as acidic water solutions of organic short chain fatty acids, maintained in solution by means of hydrothropic substances. Those substances have the ability to maintain hydrophobic molecules in an aqueous solution in dispersion.	Non emulsion statement and stability, 2017, Verschaeve (*please refer to confidential PAR for justification*).
3.5 Disintegration time	No tablets			
3.5 Particle size distribution, content of dust/fines, attrition, friability	No particles			
3.5 Persistent foaming	According to CIPAC: 47.1	1%v of the biocidal product	The persistence of foaming of Sopurclean BN PS in a 100 mL cylinder was determined to be 5mL or 5% at 20°C (average 6 individual results) after 1 min	Study report. Physico-chemical characteristics of the SOPURCLEAN BN PS. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 B. 2015/02/23
3.5 Flowability/Pourability/Dustability	No particles			
3.5 Burning rate — smoke generators	No smoke generators			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.5 Burning completeness — smoke generators	No smoke generators			
3.5 Composition of smoke — smoke generators	No smoke generators			
3.5 Spraying pattern — aerosols	No aerosols			
3.6 Physical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.6 Chemical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.7 Degree of dissolution and dilution stability	Other: MT41 dilution stability of herbicide aqueous solutions Dilute the specified amount of the formulation or otherwise use 5 mL, to 100 mL with standard water and allow the solution to stand for 18h at 20°C. At the end of this time, note if any material separates.	2% v/v of the biocidal product	No separated material was observed after 18 hours. Therefore, the diluted solution is considered stable.	Study report. Val84 Y: Dilution stability of a Sopurclean BN PS solution. Loghmanian A. 2015. Unpublished. Testing laboratory: Sopura Laboratory. Report no.: VAL84 Y. Company owner: Sopura S.A. 2015/08/06
3.8 Surface tension	The method used is IT-LMA-18 (internal method), in accordance with OECD 115 method, EC A5 surface tension: ring method)	1 g/l	28.5 mN/m at 20°C.	Study report. Physico-chemical characteristics of the SOPURCLEAN BN PS. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 B. 2015/02/23

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.9 Viscosity	An internal method was used: IT-LMA-14V04 which is in accordance with the OECD 114 method (viscosity of liquids)	Biocidal product as such (100%)	The viscosity of Sopurclean BN PS is 11.8 and 7.1 mPa/s at respectively 20 and 40°C. (average of 6 individual results)	Study report. Measure of viscosity SOPURCLEAN BN PS. Semal E. 2019. Unpublished. Testing laboratory: Sopura Laboratory. Report no.:-, Company owner: Sopura S.A. 2019/04/01

Sopurcip EC

Table 13. Physical, chemical and technical properties – Sopurcip EC (meta SPC 1)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.1 Physical state at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	Liquid	Study report. Physico-chemical characteristics of the SOPURCIP EC. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 B. 2015/02/23
Colour at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	Limpid, light yelllow	Study report. Physico-chemical characteristics of the SOPURCIP EC Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 J. 2015/02/23
Odour at +20°C and 101.3 kPa	ITLMA 81 internal method (odour)	Biocidal product as such (100%)	Aromatic	Study report. Physico-chemical characteristics of the SOPURCIP EC Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 J. 2015/02/23
3.2 Acidity / alkalinity	Method according to CIPAC MT 75 (determination of PH values)	100.0	Sopurcip EC was found to have a pH < 2 at 20°C (average 6 individual results) Acidity (%m/m H_2SO_4): 18.5%	Study report. Physico-chemical characteristics of the SOPURCIP EC. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 J. 2015/02/23 Study report. Determination of acidity SOPURCLEAN PRODUCTS. Semal E. 2019. Unpublished. Sopura Laboratory. 2019/04/09.
3.3 Relative density / bulk density	According to IT-LCT-02	Biocidal product as such (100%)	1.153 kg/L (average 6	Study report. Physico-chemical characteristics of the SOPURCIP EC.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	(internal guideline) According to OECD guideline 109 (density of liquids and solids) The density was assessed via a calibrated automated densimeter.		individual results)	Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 084 J 2015/02/23
3.4 Storage stability test – **low temperature stability test for liquids**	According to CIPAC method MT 39.2. 100 mL of the material is put in a measuring cylinder and in the refrigerator at 0 ±1°C. After 48h the amount of separated material is noted. After, the cylinder is allowed to reach room temperature and again the amount of separated material is noted.	Biocidal product as such (100%)	Separated material : 0 mL => Stable at 0°C during 48 hours (2 trials).	Study report. Stability at 0°C of the Sopurcip EC Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84 V. Company owner: Sopura SA 2015/03/30
3.4 Storage stability test – **accelerated storage**	IT-LMA-54 (internal method) IT-LMA-22V03 EN 1276 EN 1650 The test item was put in a flask made of PEHD and stored at 40°C for 12 weeks in accelerating conditions. Analyses were performed at the beginning and then at 3, 6, 8 and 12 weeks.	Biocidal product as such (100%)	**Octanoic acid** T_0 = 1.05 % (w/w) T_{8w} = 0.89 % (w/w) **Decanoic acid** T_0 = 0.70 % (w/w) T_{8w} = 0.58 % (w/w) After 12 weeks at 40°C the appearance of the biocidal product and the container remained unchanged. However, loss of the active matter appeared to be more than 10%.	Study report. Stability study in accelerate conditions (40°C) Sopurcip EC - Product code: 1560 Servais D 2015 Unpublished Sopura Laboratory Company owner: Sopura S.A. Report date: 2015/08/06

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Nevertheless, the product remained conform for the biocidal activity at 1%v.	
3.4 Storage stability test – **long term storage at ambient temperature**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)	Biocidal product as such (100%)	The stability of ***SOPURCIP EC*** in a commercial HDPE container was assessed for 24 months according to the guidelines: **Octanoic acid (% w/w):** T_0 = 1.05 T_{3m} = 0.98 T_{6m} = 0.94 T_{12m} = 0.93 T_{24m} = 0.59 **Decanoic acid (% w/w):** T_0 = 0.70 T_{3m} = 0.66 T_{6m} = 0.62 T_{12m} = 0.62 T_{24m} = 0.37 The loss of active matter was well below 10 % up to 3 months storage. After 6 months, the 10% cut-off was slightly exceeded for octanoic and after 12 months for decanoic acid. The appearance of the product and the container did not change after 24 months. The storage stability study was performed in a recipient from the same material, but	Stability study in normal conditions (20°C) ***SOPURCIP EC***. Servais 2016/11/10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			with a different volume (125 ml instead of litters) from the commercially available recipients. Applicant indicated that the active substances decay is related with absorption to the plastic of the recipient, and not actual degradation, and this effect is probably enhanced by the small size of the testing packaging. As the loss of active ingredient after 12 months was only slightly above 10 %, the shelf-life of ***SOPURCIP EC*** was set to 12 months at Room T°C..	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Data waiving	Biocidal product as such (100%)	All products of the Sopurclean family are packed in HD-PE (high density polyethylene) which has a high resistance to light because of its composition and additionally for acid products, red pigmented HD-PE is used allowing to protect more the chemical products to potential light effects. For this	Waiver effect of the light on products of the bpf. S. Verschaeve 2015/08/07

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			reason it would not be justified to evaluate light effect of those products.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Data waiving		As the biocidal products of the SOPURCLEAN BPF are liquids, humidity is not considered to be a relevant issue. With regard to the effect of temperature on the characteristics of the product, reference is made to the results of the storage stability tests at 0°C and the accelerated storage stability tests. These indicate that under the intended conditions of use and storage the content of the active substance and its technical characteristics remain within specifications.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal	Biocidal product as such (100%)	The appearance of the product and the container did not change after 24 months.	Stability study in normal conditions (20°C) SOPURCIP EC. Servais 2016/11/10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	products. (ENV/JM/MONO (2015)32)			
3.5 Wettability	No solid			
3.5 Suspensibility, spontaneity and dispersion stability	No suspension			
3.5 Wet sieve analysis and dry sieve test	No suspension			
3.5 Emulsifiability, re-emulsifiability and emulsion stability	Data waiving		The product formulations of the SOPURCLEAN BPF can all be characterized as acidic water solutions of organic short chain fatty acids, maintained in solution by means of hydrothropic substances. Those substances have the ability to maintain hydrophobic molecules in an aqueous solution in dispersion.	Non emulsion statement and stability, 2017, Verschaeve (*please refer to confidential PAR for justification*).
3.5 Disintegration time	No tablets			
3.5 Particle size distribution, content of dust/fines, attrition, friability	No particles			
3.5 Persistent foaming	According to CIPAC:MT 47.1	1.5%v of the biocidal product	The persistence of foaming of SOPURCIP EC in a glass cylinder of 100 mL was determined to be 10mL or 10% at 20°C (average 6 individual results) after 1 min	Study report Physico-chemical characteristics of the SOPURCIP EC Bougard F 2015 Unpublished Sopura Laboratory Report no: VAL 84 J Company owner Sopura S.A. Report date: 2015/02/23
3.5 Flowability/Pourability/Dustability	No particles			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.5 Burning rate — smoke generators	No smoke generators			
3.5 Burning completeness — smoke generators	No smoke generators			
3.5 Composition of smoke — smoke generators	No smoke generators			
3.5 Spraying pattern — aerosols	No aerosols			
3.6 Physical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.6 Chemical compatibility	Data waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.7 Degree of dissolution and dilution stability	Other: MT41 dilution stability of herbicide aqueous solutions Dilute the specified amount of the formulation or otherwise use 5 mL, to 100 mL with standard water and allow the solution to stand for 18h at 20°C. At the end of this time, note if any material separates.	1.5% v/v of the biocidal product	No separated material was observed after 18 hours. Therefore, the diluted solution is considered stable.	Study report. Val84 Y: Dilution stability of a Sopurcip EC solution. Loghmanian A. 2015. Unpublished. Testing laboratory: Sopura Laboratory. Report no.: VAL84 AA. Company owner: Sopura S.A. 2015/08/06
3.8 Surface tension	The method used is IT-LMA-18 (internal method), in accordance with OECD 115	1 g/l	32.0 mN/m at 20°C	Study report. Physico-chemical characteristics of the SOPURCIP EC. Loghmanian A. 2015 Unpublished.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	method, EC A5 surface tension: ring method)			Testing laboratory: Sopura Laboratory. Report no.: VAL 84 J. Company owner: Sopura S.A. 2015/02/23
3.9 Viscosity	An internal method was used: IT-LMA-14V04 which is in accordance with the OECD 114 method (viscosity of liquids)	Biocidal product as such (100%)	The viscosity of Sopurcip EC is < 6.7 and < 6.7 mPa/s at respectively 20 and 40°C. (average of 6 individual results)	Study report. Measure of viscosity SOPURCIP EC. Semal E. 2019. Unpublished. Testing laboratory: Sopura Laboratory. Report no.:-, Company owner: Sopura S.A. 2019/04/01

Note on long-term stability – JUSTIFICATION for the products of Meta SPC 1, 3 & 4
The shelf-life of the of Meta SPC 1, 3 & 4 products was set to 12 months at Room T°C. The biocidal products must be sotred at temperatures lower than +30°C. Please see the detailed justification with results and tables in the Confidential annex.

Conclusion on the physical, chemical and technical properties of the product
Products such as *Sopurclean BN and Sopurclean BN PS* are limpid, colourless liquids with a vinegar odour. Other products measured at +20°C and 101.3kPa for instance *Sopurcip EC* appear as a limpid light yellow liquid with an aromatic smell. The pH of all products is < 2. The acidity of the products is 38.7% (*Sopurclean BN*), 23.0% (*Sopurclean BN PS*) and 18.5% (*Sopurcip EC*) The density measured at +20°C is around 1.288 (*Sopurclean BN*), 1.218 kg/L (*Sopurclean BN PS*) and 1.153 kg/L (*Sopurcip EC*). After 12 weeks at +40°C the appearance of the biocidal product and the container remain unchanged. The products stay stable during accelerated storage and at low temperature (+0°C during 48h). The concentrated and diluted products are also stable. All products of the ***Sopurclean BPF*** are packed in HD-PE (high density polyethylene) which has a high resistance to light. The shelf life is 12 months for all products at +20°C. Persistence of foaming was determined to be around 5 to 10 % at low concentrations (2% *Sopurclean BN,* 1% for *Sopurclean BN PS* and 1.5%v *Sopurcip EC*). None of the Biocidal products, part of the ***Sopurclean BPF***, are intended to be used with other products, so physical and chemical compatibility with other products is not relevant. The surface tension of the products is 31.5, 28.5 and 32.0 mN/m at +20°C at 1 g/L for *Sopurclean BN, Sopurclean BN PS* and *Sopurcip EC* respectively. The viscosity of the pure product of respectively *Sopurclean BN, Sopurclean BN PS* and *Sopurcip EC* is 12.9, 11.8 and < 6.7 mPa/s at 20°C and 8.7, 7.1 and <6.7 mPa/s at 40°C.

Meta SPC2: Product *SOPURCLEAN NR* as representative product

Table 14. Physical, chemical and technical properties – Sopurclean NR (meta SPC 2)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.1 Physical state at +20 °C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	Liquid	Study report. Physico-chemical characteristics of the SOPURCLEAN NR. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL CLDI068A. 2015/05/06
Colour at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	limpid colourless	Study report. Physico-chemical characteristics of the SOPURCLEAN NR. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL CLDI068A. 2015/05/06
Odour at +20°C and 101.3 kPa	ITLMA 81 internal method (odour)	Biocidal product as such (100%)	sour-smell of rancid butter	Study report. Physico-chemical characteristics of the SOPURCLEAN NR Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL CLDI068A. 2015/05/06
3.2 Acidity / alkalinity	Method according to CIPAC MT 75 (determinatio n of PH values)	100.0	Sopurclean NR was found to have a pH < 2 at 20°C (average 6 individual results) Acidity (%m/m H_2SO_4): 34.4%	Study report. Physico-chemical characteristics of the SOPURCLEAN NR. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL CLDI068A. 2015/05/06 Study report. Determination of acidity SOPURCLEAN PRODUCTS. Semal E. 2019. Unpublished. Sopura Laboratory. 2019/04/09.
3.3 Relative density / bulk density	According to IT-LCT-02 (internal guideline) According to OECD guideline 109 (density of liquids and solids) The density was assessed via a calibrated automated densimeter.	Biocidal product as such (100%)	The density of Sopurclean NR is 1.104 kg/L (average 6 individual results)	Study report. Physico-chemical characteristics of the SOPURCLEAN NR. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL CLDI068A. 2015/05/06
3.4 Storage stability test – **low temperature**	According to CIPAC method MT 39.2.	Biocidal product as such (100%)	Separated material : 0 mL => Sopurclean NR is	Study report. Stability at 0°C of the Sopurclean NR Loghmanian A. 2015. Unpublished. Sopura

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
stability test for liquids	100 mL of the material is put in a measuring cylinder and in the refrigerator at 0 ±1°C. After 48h the amount of separated material is noted. After, the cylinder is allowed to reach room temperature and again the amount of separated material is noted.		considered stable at 0°C during 48 hours (2 trials).	Laboratory. Report no: CLDI068C Company owner: Sopura SA 2015/05/07
3.4 Storage stability test – **accelerated storage**	IT-LMA-54 (internal method) IT-LMA-22V03 EN 1276 EN 1650 The test item was put in a flask made of PEHD and stored at 54°C for 2weeks away from light	Biocidal product as such (100%)	**Octanoic acid** T_0 = 2.60 % (w/w) T_{2w} = 2.56 % (w/w) **Decanoic acid** T_0 = 0.31 % (w/w) T_{8w} = 0.33 % (w/w) After 2 weeks at 54°C the appearance of the biocidal product and the container remained unchanged. The loss of the active matter appeared to be less than 10%. Based on this study, it is suggested that the product remained stable over times.	Study report. Stability study in accelerate conditions (40°C) Sopurclean NR - Product code: 1563 Servais D 2015 Unpublished Sopura Laboratory Company owner: Sopura S.A. Report date: 2015/08/06
3.4 Storage stability test – **long term storage at ambient temperature**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment	Biocidal product as such (100%)	The stability of ***SOPURCLEAN NR*** in a commercial HDPE container was assessed for 12 months according to the guidelines: **Octanoic acid (% w/w):**	Stability study in normal conditions (20°C) ***SOPURCLEAN NR***. Servais 2016/04/26

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)		T_0 = 2.61 T_{3m} = 2.41 T_{6m} = 2.40 T_{12m} = 2.38 **Decanoic acid (% w/w):** T_0 = 0.28 T_{3m} = 0.28 T_{6m} = 0.27 T_{12m} = 0.26 The loss of active matter was well below 10 % after 12 months. The appearance of the product and the container did not change after 12 months. The shelf-life of ***SOPURCLEAN NR*** was set to 12 months at Room T°C..	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Data waiving	Biocidal product as such (100%)	All products of the Sopurclean family are packed in HD-PE (high density polyethylene) which has a high resistance to light because of its composition and additionally for acid products, red pigmented HD-PE is used allowing to protect more the chemical products to potential light effects. For this reason it would not be justified to evaluate light effect of those products.	Waiver effect of the light on products of the bpf. S. Verschaeve 2015/08/07
3.4 Effects on content of the active substance and technical characteristics of	Data waiving		As the biocidal products of the SOPURCLEAN BPF are liquids, humidity is not	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
the biocidal product – **temperature and humidity**			considered to be a relevant issue. With regard to the effect of temperature on the characteristics of the product, reference is made to the results of the storage stability tests at 0°C and the accelerated storage stability tests. These indicate that under the intended conditions of use and storage the content of the active substance and its technical characteristics remain within specifications.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)	Biocidal product as such (100%)	The appearance of the product and the container did not change after 12 months.	Stability study in normal conditions (20°C) SOPURCLEAN NR. Servais 2016/04/26
3.5 Wettability	No solid			
3.5 Suspensibility, spontaneity and dispersion stability	No suspension			
3.5 Wet sieve analysis and dry sieve test	No suspension			
3.5 Emulsifiability, re-emulsifiability	Data waiving		The product formulations of	Non emulsion statement and stability, 2017,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and emulsion stability			the SOPURCLEAN BPF can all be characterized as acidic water solutions of organic short chain fatty acids, maintained in solution by means of hydrothropic substances. Those substances have the ability to maintain hydrophobic molecules in an aqueous solution in dispersion.	Verschaeve (*please refer to confidential PAR for justification*).
3.5 Disintegration time	No tablets			
3.5 Particle size distribution, content of dust/fines, attrition, friability	No particles			
3.5 Persistent foaming	According to CIPAC: MT 47.1	2%v of the biocidal product	The persistence of foaming of Sopurclean NR in a 100 mL cylinder was determined to be 0 mL or 0% at 20°C (average 6 individual results) after 1 min	Study report Physico-chemical characteristics of the SOPURCLEAN NR Loghmanian A 2015 Unpublished Sopura Laboratory Report no: CLDI068A Company owner Sopura S.A. Report date: 2015/05/06
3.5 Flowability/Pourability/Dustability	No particles			
3.5 Burning rate — smoke generators	No smoke generators			
3.5 Burning completeness — smoke generators	No smoke generators			
3.5 Composition of smoke — smoke generators	No smoke generators			
3.5 Spraying pattern — aerosols	No aerosols			
3.6 Physical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Biocidal Product Family are intended to be used with other products.	
3.6 Chemical compatibility	Data waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.7 Degree of dissolution and dilution stability	Other: MT41 dilution stability of herbicide aqueous solutions Dilute the specified amount of the formulation or otherwise use 5 mL, to 100 mL with standard water and allow the solution to stand for 18h at 20°C. At the end of this time, note if any material separates.	2% v/v of the biocidal product	No separated material was observed after 18 hours. Therefore, the diluted solution is considered stable.	Study report. CLDI068B: Dilution stability of a Sopurclean NR solution. Loghmanian A. 2015. Unpublished. Testing laboratory: Sopura Laboratory. Report no.: CLDI068B. Company owner: Sopura S.A. 2015/08/06
3.8 Surface tension	The method used is IT-LMA-18 (internal method), in accordance with OECD 115 method, EC A5 surface tension: ring method)	1 g/l	55.1 mN/m at 20°C.	Study report CLDI068A. Physico-chemical characteristics of the SOPURCLEAN NR. CLDI068A Loghmanian A. 2015 Unpublished. Testing laboratory: Sopura Laboratory. Report no.: CLDI068A. Company owner: Sopura S.A. 2015/05/06
3.9 Viscosity	An internal method was used: IT-LMA-14V04 which is in	Biocidal product as such (100%)	The viscosity of Sopurclean NR is 15.1 and 9.5 mPa/s at respectively 20	Study report. Measure of viscosity SOPURCLEAN NR. Semal E. 2019. Unpublished.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	accordance with the OECD 114 method (viscosity of liquids)		and 40°C. (average of 6 individual results)	Testing laboratory: Sopura Laboratory. Report no.:-, Company owner: Sopura S.A. 2019/04/01

Conclusion on the physical, chemical and technical properties of the product
Sopurclean NR is a limpid, colourless liquid with an aromatic odour. The pH value is <2, the acidity 34.4%. The density of *Sopurclean NR* is 1.104 kg/L After 12 weeks at +40°C the appearance of the biocidal product and the container remained unchanged. *Sopurclean NR* is considered stable at +0°C during 48 hours. The shelf life is 12 months. All products of the ***Sopurclean BPF*** are packed in HD-PE (high density polyethylene) which has a high resistance to light. With a concentration of 2 %v, the persistence of foaming was determined to be 0 mL or 0%. There is no evaluation for the physical or chemical compatibility of the product because products of the ***Sopurclean BPF*** are never intended to be used with other products. *Sopurclean NR* has a surface tension of 55.1 mN/m at +20°C at 1.0 g/l and the pure product has a viscosity of 15.1 and 9.5 mPa/s at 20 and 40°C respectively.

Meta SPC3: Product information on *SOPURCLEAN OP-N is provided.*

Table 15. Physical, chemical and technical properties – Sopurclean OP N (Meta SPC 3)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.1 Physical state at +20 °C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	Liquid	Study report. Physico-chemical characteristics of the SOPURCLEAN OP N. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84C. 2015/02/23
Colour at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	colourless	Study report. Physico-chemical characteristics of the SOPURCLEAN OP N. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84C. 2015/02/23
Odour at +20°C and 101.3 kPa	ITLMA 81 internal method (odour)	Biocidal product as such (100%)	Aromatic odour	Study report. Physico-chemical characteristics of the SOPURCLEAN OP N. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84C. 2015/02/23
3.2 Acidity / alkalinity	Method according to CIPAC MT 75 (determination of PH values)	100.0	Sopurclean OP N was found to have a pH < 2 at 20°C (average 6 individual results)	Study report. Physico-chemical characteristics of the SOPURCLEAN OP N. Loghmanian A. 2015. Unpublished. Sopura

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Acidity (%m/m H_2SO_4): 16.6%	Laboratory. Report no: VAL84C. 2015/02/23 Study report. Determination of acidity SOPURCLEAN PRODUCTS. Semal E. 2019. Unpublished. Sopura Laboratory. 2019/04/09.
3.3 Relative density / bulk density	According to IT-LCT-02 (internal guideline) According to OECD guideline 109 (density of liquids and solids) The density was assessed via a calibrated automated densimeter.	Biocidal product as such (100%)	The density of Sopurclean OP N is 1.160 kg/L (average 6 individual results)	Study report. Physico-chemical characteristics of the SOPURCLEAN OP N. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84C. 2015/02/23
3.4 Storage stability test – **low temperature stability test for liquids**	According to CIPAC method MT 39.2. 100 mL of the material is put in a measuring cylinder and in the refrigerator at 0 ±1°C. After 48h the amount of separated material is noted. After, the cylinder is allowed to reach room temperature and again the amount of separated material is noted.	Biocidal product as such (100%)	Separated material : 0 mL => Sopurclean OP N is considered stable at 0°C during 48 hours (2 trials).	Study report. Stability at 0°C of the Sopurclean OP N Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84U Company owner: Sopura SA 2015/03/27
3.4 Storage stability test – **accelerated storage**	IT-LMA-54 (internal method) IT-LMA-22V03 EN 1276 EN 1650	Biocidal product as such (100%)	After 12 weeks at 40°C the appearance of the biocidal product and the container remained unchanged.	Study report. Stability study in accelerate conditions (40°C) Sopurclean OP N - Product code: 1216 Servais D 2015 Unpublished

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	The test item was put in a flask made of PEHD and stored at 54°C for 2weeks away from light		However, loss of the active matter appeared to be more than 10%. Nevertheless, the product remained conform for the biocidal activity at 1%v.	Sopura Laboratory Company owner: Sopura S.A. Report date: 2015/08/06
3.4 Storage stability test – **long term storage at ambient temperature**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)	Biocidal product as such (100%)	The stability of ***SOPURCLEAN OP N*** in a commercial HDPE container was assessed for 12 months according to the guidelines: **Octanoic acid (% w/w):** T_0 = 1.78 T_{12m} = 1.66 **Decanoic acid (% w/w):** T_0 = 1.15 T_{12m} = 1.10 The loss of active matter was less than 10 % after 12 months. The appearance of the product and the container did not change after 12 months. Therefore, shelf-life of the product is set at 12 months at Room T°C..	Study report. Stability study in normal conditions (20°C) SOPURCLEAN OP N. Servais D. 2015. Unpublished. Sopura Laboratory Company owner: Sopura S.A. 2016/11/10
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Data waiving	Biocidal product as such (100%)	All products of the Sopurclean family are packed in HD-PE (high density polyethylene) which has a high resistance to light because of its composition and additionally for acid products, red pigmented HD-PE is used	Waiver effect of the light on products of the BPF. S. Verschaeve 2015/08/07

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			allowing to protect more the chemical products to potential light effects. For this reason it would not be justified to evaluate light effect of those products.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Data waiving		As the biocidal products of the SOPURCLEAN BPF are liquids, humidity is not considered to be a relevant issue. With regard to the effect of temperature on the characteristics of the product, reference is made to the results of the storage stability tests at 0°C and the accelerated storage stability tests. These indicate that under the intended conditions of use and storage the content of the active substance and its technical characteristics remain within specifications.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability	Biocidal product as such (100%)	The appearance of the product and the container did not change after 12 months.	Study report. Stability study in normal conditions (20°C) SOPURCLEAN OP N. Servais D. 2015. Unpublished. Sopura Laboratory Company owner: Sopura S.A. 2016/11/10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)			
3.5 Wettability	No solid			
3.5 Suspensibility, spontaneity and dispersion stability	No suspension			
3.5 Wet sieve analysis and dry sieve test	No suspension			
3.5 Emulsifiability, re-emulsifiability and emulsion stability	Data waiving		The product formulations of the SOPURCLEAN BPF can all be characterized as acidic water solutions of organic short chain fatty acids, maintained in solution by means of hydrothropic substances. Those substances have the ability to maintain hydrophobic molecules in an aqueous solution in dispersion.	Non emulsion statement and stability, 2017, Verschaeve (*please refer to confidential PAR for justification*).
3.5 Disintegration time	No tablets			
3.5 Particle size distribution, content of dust/fines, attrition, friability	No particles			
3.5 Persistent foaming	According to CIPAC: MT 47.1	1%v of the biocidal product	The persistence of foaming of Sopurclean OP N in a 100 mL cylinder was determined to be 10 mL or 10% at 20°C (average 6 individual results) after 1 min	Study report. Physico-chemical characteristics of the SOPURCLEAN OP N. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84C. 2015/02/23
3.5 Flowability/Pourability/Dustability	No particles			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.5 Burning rate — smoke generators	No smoke generators			
3.5 Burning completeness — smoke generators	No smoke generators			
3.5 Composition of smoke — smoke generators	No smoke generators			
3.5 Spraying pattern — aerosols	No aerosols			
3.6 Physical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.6 Chemical compatibility	Data waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.7 Degree of dissolution and dilution stability	Other: MT41 dilution stability of herbicide aqueous solutions Dilute the specified amount of the formulation or otherwise use 5 mL, to 100 mL with standard water and allow the solution to stand for 18h at 20°C. At the end of this time, note if any material separates.	2% v/v of the biocidal product	No separated material was observed after 18 hours. Therefore, the diluted solution is considered stable.	Study report. VAL84 Z: Dilution stability of a Sopurclean OP N solution. Loghmanian A. 2015. Unpublished. Testing laboratory: Sopura Laboratory. Report no.: VAL84 Z Company owner: Sopura S.A. 2015/08/06
3.8 Surface tension	The method used is IT-LMA-18 (internal method), in accordance	1 g/l	28.4 mN/m at 20°C.	Study report. Physico-chemical characteristics of the SOPURCLEAN OP N. Loghmanian A. 2015. Unpublished. Sopura

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	with OECD 115 method, EC A5 surface tension: ring method)			Laboratory. Report no: VAL84C. 2015/02/23
3.9 Viscosity	An internal method was used: IT-LMA-14V04 which is in accordance with the OECD 114 method (viscosity of liquids)	Biocidal product as such (100%)	The viscosity of Sopurclean OP N is < 6.7 mPa/s both at 20 and 40°C. (average of 6 individual results)	Study report. Measure of viscosity SOPURCLEAN OP N. Semal E. 2019. Unpublished. Testing laboratory: Sopura Laboratory. Report no.:-, Company owner: Sopura S.A. 2019/04/01

Conclusion on the physical, chemical and technical properties of the product
Sopurclean OP N is a colourless liquid with an aromatic odour. The pH value is <2, the acidity 16.6%. The density of *Sopurclean OP N* is 1.160 kg/L After 12 weeks at +40°C the appearance of the biocidal product and the container remained unchanged. *Sopurclean OP N* is considered stable at +0°C during 48 hours. The shelf life is 12 months. All products of the ***Sopurclean BPF*** are packed in HD-PE (high density polyethylene) which has a high resistance to light. With a concentration of 2 %v, the persistence of foaming was determined to be 10 mL or 10%. There is no evaluation for the physical or chemical compatibility of the product because products of the ***Sopurclean BPF*** are never intended to be used with other products. *Sopurclean OP N* has a surface tension of 28.4 mN/m at +20°C at 1.0 g/l and the pure product has a viscosity of <6.7 mPa/s both at 20 and 40°C.

Meta SPC4: Product information on *SOPURCLEAN CIP OP is provided.*

Table 16. Physical, chemical and technical properties – Sopurclean CIP OP (meta SPC 4)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.1 Physical state at +20 °C and 101.3 kPa	No specific method has been used to analyse the colour and the physical state.	Biocidal product as such (100%)	Liquid	Study report. Physico-chemical characteristics of the SOPURCLEAN CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84K. 2015/02/23
Colour at +20°C and 101.3 kPa	No specific method has been used to analyse the colour and	Biocidal product as such (100%)	Light yellow	Study report. Physico-chemical characteristics of the SOPURCLEAN CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	the physical state.			Report no: VAL84K. 2015/02/23
Odour at +20°C and 101.3 kPa	ITLMA 81 internal method (odour)	Biocidal product as such (100%)	Aromatic odour	Study report. Physico-chemical characteristics of the SOPURCLEAN CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84K. 2015/02/23
3.2 Acidity / alkalinity	Method according to CIPAC MT 75 (determination of PH values)	100.0	Sopurclean CIP OP was found to have a pH < 2 at 20°C (average 6 individual results) Acidity (%m/m H_2SO_4): 21.5%	Study report. Physico-chemical characteristics of the SOPURCLEAN CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84K. 2015/02/23 Study report. Determination of acidity SOPURCLEAN PRODUCTS. Semal E. 2019. Unpublished. Sopura Laboratory. 2019/04/09.
3.3 Relative density / bulk density	According to IT-LCT-02 (internal guideline) According to OECD guideline 109 (density of liquids and solids) The density was assessed via a calibrated automated densimeter.	Biocidal product as such (100%)	The density of Sopurclean CIP OP is 1.170 kg/L (average 6 individual results)	Study report. Physico-chemical characteristics of the SOPURCLEAN CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84K. 2015/02/23
3.4 Storage stability test – **low temperature stability test for liquids**	According to CIPAC method MT 39.2. 100 mL of the material is put in a measuring cylinder and in the refrigerator at 0 ±1°C. After 48h the amount of separated material is noted. After, the cylinder is	Biocidal product as such (100%)	Separated material : 0 mL => Sopurclean CIP OP is considered stable at 0°C during 48 hours (2 trials).	Study report. Stability at 0°C of the Sopurclean CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL 84W Company owner: Sopura SA 2015/XX/XX

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	allowed to reach room temperature and again the amount of separated material is noted.			
3.4 Storage stability test – **accelerated storage**	IT-LMA-54 (internal method) IT-LMA-22V03 EN 1276 EN 1650 The test item was put in a flask made of PEHD and stored at 54°C for 2weeks away from light	Biocidal product as such (100%)	After 12 weeks at 40°C the appearance of the biocidal product and the container remained unchanged. However, loss of the active matter appeared to be more than 10%. Nevertheless, the product remained conform for the biocidal activity at 0.75%v.	Study report. Stability study in accelerate conditions (40°C) Sopurclean CIP OP - Product code: 1063 Servais D. 2015. Unpublished Sopura Laboratory Company owner: Sopura S.A. Report date: 2015/08/06
3.4 Storage stability test – **long term storage at ambient temperature**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MONO (2015)32)	Biocidal product as such (100%)	The stability of ***SOPURCLEAN CIP OP*** in a commercial HDPE container was assessed for 12 months according to the guidelines: **Octanoic acid (% w/w):** T_0 = 1.83 T_{12m} = 1.65 **Decanoic acid (% w/w):** T_0 = 1.21 T_{12m} = 1.09 The loss of active matter was less than 10 % after 12 months. The appearance of the product and the container did not change after 12 months. Therefore, shelf-life of the product is set at	Study report. Stability study in normal conditions (20°C) ***SOPURCLEAN CIP OP***. Servais D. 2015. Unpublished. Sopura Laboratory Company owner: Sopura S.A. 2016/11/10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			12 months at Room T°C.	
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Data waiving	Biocidal product as such (100%)	All products of the Sopurclean family are packed in HD-PE (high density polyethylene) which has a high resistance to light because of its composition and additionally for acid products, red pigmented HD-PE is used allowing to protect more the chemical products to potential light effects. For this reason it would not be justified to evaluate light effect of those products.	Waiver effect of the light on products of the BPF. S. Verschaeve 2015/08/07
3.4 Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Data waiving		As the biocidal products of the SOPURCLEAN BPF are liquids, humidity is not considered to be a relevant issue. With regard to the effect of temperature on the characteristics of the product, reference is made to the results of the storage stability tests at 0°C and the accelerated storage stability tests. These indicate that under the intended conditions of use and storage the content of the active substance and its technical characteristics remain within specifications.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
3.4 Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT41: Dilution stability of solution herbicide aqueous solution OECD: series on testing and assessment N°223: Guidance document for storage stability testing of plant protection and biocidal products. (ENV/JM/MO NO (2015)32)	Biocidal product as such (100%)	The appearance of the product and the container did not change after 12 months.	Study report. Stability study in normal conditions (20°C) SOPURCLEAN CIP OP. Servais D. 2015. Unpublished. Sopura Laboratory Company owner: Sopura S.A. 2016/11/10
3.5 Wettability	No solid			
3.5 Suspensibility, spontaneity and dispersion stability	No suspension			
3.5 Wet sieve analysis and dry sieve test	No suspension			
3.5 Emulsifiability, re-emulsifiability and emulsion stability	Data waiving		The product formulations of the SOPURCLEAN BPF can all be characterized as acidic water solutions of organic short chain fatty acids, maintained in solution by means of hydrothropic substances. Those substances have the ability to maintain hydrophobic molecules in an aqueous solution in dispersion.	Non emulsion statement and stability, 2017, Verschaeve (*please refer to confidential PAR for justification*).
3.5 Disintegration time	No tablets			
3.5 Particle size distribution, content of	No particles			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
dust/fines, attrition, friability				
3.5 Persistent foaming	According to CIPAC: MT 47.1	1%v of the biocidal product	The persistence of foaming of Sopurclean CIP OP in a 100 mL cylinder was determined to be 10 mL or 10% at 20°C (average 6 individual results) after 1 min	Study report. Physico-chemical characteristics of the SOPURCLEAN CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84K. 2015/02/23
3.5 Flowability/Pourability/Dustability	No particles			
3.5 Burning rate — smoke generators	No smoke generators			
3.5 Burning completeness — smoke generators	No smoke generators			
3.5 Composition of smoke — smoke generators	No smoke generators			
3.5 Spraying pattern — aerosols	No aerosols			
3.6 Physical compatibility	Data Waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.6 Chemical compatibility	Data waiving		None of the Biocidal Products part of the Sopurclean Biocidal Product Family are intended to be used with other products.	
3.7 Degree of dissolution and dilution stability	Other: MT41 dilution stability of herbicide aqueous solutions Dilute the specified amount of the formulation or otherwise use 5 mL, to 100 mL with standard	1% v/v of the biocidal product	No separated material was observed after 18 hours. Therefore, the diluted solution is considered stable.	Study report. VAL84 AB: Dilution stability of a Sopurclean CIP OP solution. Loghmanian A. 2015. Unpublished. Testing laboratory: Sopura Laboratory. Report no.: VAL84 AB Company owner: Sopura S.A. 2015/08/06

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	water and allow the solution to stand for 18h at 20°C. At the end of this time, note if any material separates.			
3.8 Surface tension	The method used is IT-LMA-18 (internal method), in accordance with OECD 115 method, EC A5 surface tension: ring method)	1 g/l	29.7 mN/m at 20°C.	Study report. Physico-chemical characteristics of the SOPURCLEAN CIP OP. Loghmanian A. 2015. Unpublished. Sopura Laboratory. Report no: VAL84K. 2015/02/23
3.9 Viscosity	An internal method was used: IT-LMA-14V04 which is in accordance with the OECD 114 method (viscosity of liquids)	Biocidal product as such (100%)	The viscosity of Sopurclean CIP OP is 7.7 and 6.9 mPa/s at respectively 20 and 40°C. (average of 6 individual results)	Study report. Measure of viscosity SOPURCLEAN CIP OP. Semal E. 2019. Unpublished. Testing laboratory: Sopura Laboratory. Report no.:-, Company owner: Sopura S.A. 2019/04/01

Conclusion on the physical, chemical and technical properties of the product
Sopurclean CIP OP is a light yellow liquid with an aromatic odour. The pH value is <2, the acidity 21.5%. The density of *Sopurclean CIP OP* is 1.170 kg/L After 12 weeks at +40°C the appearance of the biocidal product and the container remained unchanged. *Sopurclean CIP OP* is considered stable at +0°C during 48 hours. The shelf life is 12 months. All products of the ***Sopurclean BPF*** are packed in HD-PE (high density polyethylene) which has a high resistance to light. With a concentration of 1 %v, the persistence of foaming was determined to be 10 mL or 10%. There is no evaluation for the physical or chemical compatibility of the product because products of the ***Sopurclean BPF*** are never intended to be used with other products. *Sopurclean CIP OP* has a surface tension of 29.7 mN/m at +20°C at 1.0 g/l and the pure product has a viscosity of 7.7 and 6.9 mPa/s at 20 and 40°C respectively.

1.2.3 Physical hazards and respective characteristics

Meta SPC1: Product information on *SOPURCLEAN BN and SOPURCIP EC* is presented in this PAR for Meta SPC 1.

APCP data is available for all products within Meta SPC 1. In function of the readability and transparency of the PAR, only details on the products ***SOPURCLEAN BN*** **and** ***SOPURCIP EC*** have been presented in the PAR. These two products were selected as they differ the most with regard to active substance content. Nevertheless, the APCP information on the other products of Meta SPC 1 is available and presented in the IUCLID.

SOPURCLEAN BN

Table 17. Physical hazards and respective characteristics - Sopurclean BN (meta SPC 1)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
4.1 Explosiveness	Data Waiving		Non explosive. **JUSTIFICATION :** The current waiver statement in the PAR indicates that none of the biocidal products 'contain ingredients which possess explosive properties', and is The waiving is based on available data for all components of the mixtures either published by ECHA, ADR,… or from their SDS. The screening procedure (CLP section 2.1 Annex I) was followed to evaluate if y/n the formulations (mixtures) do have reasons to be submitted to tests for explosive properties. Based on those criteria, it is considered that the mixtures should be considered as being non-explosive.	
4.2 Flammability	Other: Council Regulation (EC) 440/2008 EC method A.9 (flash point)	Biocidal product as such (100%)	Not flammable. The test item presents no flash point until 130°C.	study report SOPURCLEAN BN: Determination of the flashpoint Briosschi M. 2015 Unpublished Testing laboratory ChemService report no Company owner SOPURA Company

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				study no CH-295/2015 Brioschi M. 2015-05-21
4.3 Flammable aerosols	No aerosol			
4.4 Oxidising properties	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC 1, 2, 3 and 4 contain ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.5 Gases under pressure	No gas			
4.6 Flammable liquids	Data Waiving		According to CLP (EC 1272/2008) regulation **none** of the Biocidal Products covered by the Sopurclean Biocidal Product family fulfil the criteria to be classified as a flammable liquid.	
4.7 Flammable solids	No solid			
4.8 Self-reactive substances and mixtures	Data waiving		The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties.	
4.9 Pyrophoric liquids	Data Waiving		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C.	
4.10 Pyrophoric solids	No solid			
4.11 Self-heating substances and mixtures	Data Waiving		Self-heating applies only to solids. Test method is not applicable to liquids.	
4.12 Substances and mixtures which in contact with water emit flammable gases	Data waiving		This test is not deemed necessary as the products are not flammable liquids. This is based on the justification mentioned in section 2.14.4.1 of the CLP Regulation where it is mentioned that the classification procedure for this class is not needed if: (a) the chemical structure of the	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			substance or mixture does not contain metals or metalloids; or (b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or (c) the substance or mixture is known to be soluble in water to form a stable mixture. As all 3 criteria are considered fulfilled, no test requirements are identified for any of the BPs within the SOPURCLEAN BPF and there is no need to classify these products within this hazard class.	
4.13 Oxidising liquids	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC1, 2, 3 and 4 contains ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.14 Oxidising solids	No solids			
4.15 Organic peroxides	No organic peroxides			
4.16 Corrosive to metals	C1: test for determining the corrosive properties of liquids and solids that may become liquid during transport as dangerous goods of Class 8, packing group III.	Biocidal product as such (100%) Dilution of biocidal product (2% v/v)	***SOPURCLEAN BN*** diluted shows uniform corrosive attack on mild steel and aluminium but did not exhibit a loss of weight of more than 26,5 % after an exposure time of 14 days, which would result in classification. The criterion for localised corrosion was not evaluated.	Study report Val 084N Corrosion test for SOPURCLEAN BN. Loghmanian A. 2015 Unpublished. Testing laboratory: Sopura Laboratory. 2015-03-10
4.17 Auto-ignition temperatures of products (liquids and gases)	Data Waiving		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C.	S. Verschaeve. 7/8/2015)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			In addition, the individual ingredients of the biocidal products of the Sopurclean family do all have auto-ignition temperatures far above 400°C (based on the information listed on the ECHA dissemination database) are not classified as flammable liquids, or information requirements for both endpoint determinations have been waived. If chemically speaking, some ingredients of the biocidal products covered by the Sopurclean family would be classified as flammable/combustible liquids which ignite, burn easy at normal working temperatures, and have relatively low flashpoints data requirements for those endpoints will be re-evaluated. Evaluation of these endpoints would then be justified in function of their relevance for fire hazard risk management. However, based on the currently available information and the composition of the Sopurclean family products additional testing is not deemed necessary. (waiver auto-ignition temperature Sopurclean.	
4.17 Relative self-ignition temperature for solids	No solid			
4.17 Dust explosion hazard	No dust			

Sopurcip EC

Table 18. Physical hazards and respective characteristics – Sopurcip EC (meta SPC 1)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
4.1 Explosiveness	Data waiving		Non explosive. **JUSTIFICATION :** The current waiver statement in the PAR indicates that none of the biocidal products 'contain ingredients which possess explosive properties', and is The waiving is based on available data for all components of the mixtures either published by ECHA, ADR,… or from their SDS. The screening procedure (CLP section 2.1 Annex I) was followed to evaluate if y/n the formulations (mixtures) do have reasons to be submitted to tests for explosive properties. Based on those criteria, it is considered that the mixtures should be considered as being non-explosive.	
4.2 Flammability	Other: Council Regulation (EC) 440/2008 EC method A.9 (flash point)	Biocidal product as such (100%)	Not flammable. The test item presents no flash point until 130°C.	Study report Sopurcip EC Determination of the flashpoint Briosschi M. 2015 Unpublished Testing laboratory ChemService report no Company owner SOPURA Company study no CH-298/2015 Brioschi M. 2015-05-21
4.3 Flammable aerosols	No aerosol			
4.4 Oxidising properties	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC 1, 2, 3 and 4 contain ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.5 Gases under pressure	No gas			
4.6 Flammable liquids	Data waiving		According to CLP (EC 1272/2008) regulation	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			none of the Biocidal Products covered by the Sopurclean Biocidal Product family fulfil the criteria to be classified as a flammable liquid.	
4.7 Flammable solids	No solid			
4.8 Self-reactive substances and mixtures	Data waiving		The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties.	
4.9 Pyrophoric liquids	Data Waiving		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C.	
4.10 Pyrophoric solids	No solid			
4.11 Self-heating substances and mixtures	Data Waiving		Self-heating applies only to solids. Test method is not applicable to liquids.	
4.12 Substances and mixtures which in contact with water emit flammable gases	Data waiving		This test is not deemed necessary as the products are not flammable liquids. This is based on the justification mentioned in section 2.14.4.1 of the CLP Regulation where it is mentioned that the classification procedure for this class is not needed if: (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or (b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or (c) the substance or mixture is known to be soluble in water to form a stable mixture. As all 3 criteria are considered fulfilled, no test requirements are identified for any of the BPs within the SOPURCLEAN BPF and	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			there is no need to classify these products within this hazard class.	
4.13 Oxidising liquids	Data Waiving		Non oxidising None of the Biocidal product part of the meta SPC1, 2, 3 and 4 contains ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.14 Oxidising solids	No solids			
4.15 Organic peroxides	No organic peroxides			
4.16 Corrosive to metals	C1: test for determining the corrosive properties of liquids and solids that may become liquid during transport as dangerous goods of Class 8, packing group III.	Biocidal product as such (100%) Dilution of biocidal product (1.5% v/v)	***Sopurcip EC*** diluted shows uniform corrosive attack on mild steel and aluminium but did not exhibit a loss of weight of more than 26,5 % after an exposure time of 14 days, which would result in classification. The criterion for localised corrosion was not evaluated.	Study report corrosion test for SOPURCIP EC. Report no VAL 84 P Loghmanian A. 2015 Unpublished. Testing laboratory: Sopura Laboratory. 2015-03-10
4.17 Auto-ignition temperatures of products (liquids and gases)	Data Waiving		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C. In addition, the individual ingredients of the biocidal products of the Sopurclean family do all have auto-ignition temperatures far above 400°C (based on the information listed on the ECHA dissemination database) are not classified as flammable liquids, or information requirements for both endpoint determinations have been waived. If chemically speaking, some ingredients of the	S. Verschaeve. 7/8/2015)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			biocidal products covered by the Sopurclean family would be classified as flammable/combustible liquids which ignite, burn easy at normal working temperatures, and have relatively low flashpoints data requirements for those endpoints will be re-evaluated. Evaluation of these endpoints would then be justified in function of their relevance for fire hazard risk management. However, based on the currently available information and the composition of the Sopurclean family products additional testing is not deemed necessary. (waiver auto-ignition temperature Sopurclean.	
4.17 Relative self-ignition temperature for solids	No solid			
4.17 Dust explosion hazard	No dust			

Conclusion on the physical hazards and respective characteristics of the product
Sopurclean BN and *Sopurcip EC* are not explosive, not flammable or combustible and are non-oxidising products. They don't have a flashpoint below 130°C. The products are corrosive to metals.

Meta SPC2: Product ***SOPURCLEAN NR*** as representative product

Table 19. Physical hazards and respective characteristics - Sopurclean NR (meta SPC 2)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
4.1 Explosiveness	Data Waiving		Non explosive. **JUSTIFICATION :** The current waiver statement in the PAR indicates that none of the biocidal products 'contain ingredients which possess explosive properties', and is	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The waiving is based on available data for all components of the mixtures either published by ECHA, ADR,… or from their SDS. The screening procedure (CLP section 2.1 Annex I) was followed to evaluate if y/n the formulations (mixtures) do have reasons to be submitted to tests for explosive properties. Based on those criteria, it is considered that the mixtures should be considered as being non-explosive.	
4.2 Flammability	Other: Council Regulation (EC) 440/2008 EC method A.9 (flash point)	Biocidal product as such (100%)	Not flammable. The test item presents no flash point until 130°C.	study report SOPURCLEAN NR: Determination of the flashpoint Briosschi M. 2015 Unpublished Testing laboratory ChemService report no Company owner SOPURA Company study no CH-300/2015 Brioschi M. 2015-05-21
4.3 Flammable aerosols	No aerosol			
4.4 Oxidising properties	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC 1, 2, 3 and 4 contain ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.5 Gases under pressure	No gas			
4.6 Flammable liquids	Data waiving		According to CLP (EC 1272/2008) regulation **none** of the Biocidal Products covered by the Sopurclean Biocidal Product family fulfil the criteria to be classified as a flammable liquid.	
4.7 Flammable solids	No solid			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
4.8 Self-reactive substances and mixtures	Data waiving		The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties.	
4.9 Pyrophoric liquids	Data Waiving		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C.	
4.10 Pyrophoric solids	No solid			
4.11 Self-heating substances and mixtures	Data Waiving		Self-heating applies only to solids. Test method is not applicable to liquids.	
4.12 Substances and mixtures which in contact with water emit flammable gases	Data waiving		This test is not deemed necessary as the products are not flammable liquids. This is based on the justification mentioned in section 2.14.4.1 of the CLP Regulation where it is mentioned that the classification procedure for this class is not needed if: (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or (b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or (c) the substance or mixture is known to be soluble in water to form a stable mixture. As all 3 criteria are considered fulfilled, no test requirements are identified for any of the BPs within the SOPURCLEAN BPF and there is no need to classify these products within this hazard class.	
4.13 Oxidising liquids	Data Waiving		Non oxidising.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			None of the Biocidal product part of the meta SPC1, 2, 3 and 4 contains ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.14 Oxidising solids	No solids			
4.15 Organic peroxides	No organic peroxides			
4.16 Corrosive to metals	C1: test for determining the corrosive properties of liquids and solids that may become liquid during transport as dangerous goods of Class 8, packing group III.		***SOPURCLEAN NR*** diluted shows uniform corrosive attack on mild steel and aluminium but did not exhibit a loss of weight of more than 26,5 % after an exposure time of 14 days, which would result in classification. The criterion for localised corrosion was not evaluated.	Study report CLDI068 D Corrosion test for Sopurclean NR Loghmanian A. 2015 Unpublished. Testing laboratory: Sopura Laboratory. 2015-05-20
4.17 Auto-ignition temperatures of products (liquids and gases)	Waiver		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C. In addition, the individual ingredients of the biocidal products of the Sopurclean family do all have auto-ignition temperatures far above 400°C (based on the information listed on the ECHA dissemination database) are not classified as flammable liquids, or information requirements for both endpoint determinations have been waived. If chemically speaking, some ingredients of the biocidal products covered by the Sopurclean family would be classified as flammable/combustible liquids which ignite,	S. Verschaeve. 7/8/2015)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			burn easy at normal working temperatures, and have relatively low flashpoints data requirements for those endpoints will be re-evaluated. Evaluation of these endpoints would then be justified in function of their relevance for fire hazard risk management. However, based on the currently available information and the composition of the Sopurclean family products additional testing is not deemed necessary. (waiver auto-ignition temperature Sopurclean.	
4.17 Relative self-ignition temperature for solids	No solid			
4.17 Dust explosion hazard	No dust			

Conclusion on the physical hazards and respective characteristics of the product
Sopurclean NR is not explosive, is not flammable or combustible. It does not have a flashpoint below 130°C. It is not oxidising. It is corrosive to metal.

Meta SPC3: Product information on ***SOPURCLEAN OP-N*** *is provided.*

Table 20. Physical hazards and respective characteristics - Sopurclean OP N (meta SPC 3)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
4.1 Explosiveness	Data Waiving		Non explosive. **JUSTIFICATION :** The current waiver statement in the PAR indicates that none of the biocidal products 'contain ingredients which possess explosive properties', and is The waiving is based on available data for all components of the mixtures either published by ECHA, ADR,… or from their SDS. The screening procedure (CLP section 2.1 Annex I) was followed to evaluate if y/n the formulations (mixtures) do have reasons to be submitted to tests for explosive properties. Based on those criteria, it is considered that the mixtures should be considered as being non-explosive.	
4.2 Flammability	Other: Council Regulation (EC) 440/2008 EC method A.9 (flash point)	Biocidal product as such (100%)	Not flammable. The test item presents no flash point until 130°C.	study report SOPURCLEAN OP-N: Determination of the flashpoint Briosschi M. 2015 Unpublished Testing laboratory ChemService report no Company owner SOPURA Company study no CH-297/2015 Brioschi M. 2015-05-21
4.3 Flammable aerosols	No aerosol			
4.4 Oxidising properties	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC 1, 2, 3 and 4 contain ingredients which possess oxidising properties. Therefore,	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			further testing is not deemed necessary.	
4.5 Gases under pressure	No gas			
4.6 Flammable liquids	Data waiving		According to CLP (EC 1272/2008) regulation **none** of the Biocidal Products covered by the Sopurclean Biocidal Product family fulfil the criteria to be classified as a flammable liquid.	
4.7 Flammable solids	No solid			
4.8 Self-reactive substances and mixtures	Data waiving		The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties.	
4.9 Pyrophoric liquids	Data Waiving		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C.	
4.10 Pyrophoric solids	No solid			
4.11 Self-heating substances and mixtures	Data Waiving		Self-heating applies only to solids. Test method is not applicable to liquids.	
4.12 Substances and mixtures which in contact with water emit flammable gases	Data waiving		This test is not deemed necessary as the products are not flammable liquids. This is based on the justification mentioned in section 2.14.4.1 of the CLP Regulation where it is mentioned that the classification procedure for this class is not needed if: (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or (b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or (c) the substance or mixture is	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			known to be soluble in water to form a stable mixture. As all 3 criteria are considered fulfilled, no test requirements are identified for any of the BPs within the SOPURCLEAN BPF and there is no need to classify these products within this hazard class.	
4.13 Oxidising liquids	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC1, 2, 3 and 4 contains ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.14 Oxidising solids	No solids			
4.15 Organic peroxides	No organic peroxides			
4.16 Corrosive to metals	Waiver		***SOPURCLEAN OP N*** diluted shows uniform corrosive attack on mild steel and aluminium but did not exhibit a loss of weight of more than 26,5 % after an exposure time of 14 days, which would result in classification. The criterion for localised corrosion was not evaluated	
4.17 Auto-ignition temperatures of products (liquids and gases)	Waiver		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C. In addition, the individual ingredients of the biocidal products of the Sopurclean family do all have auto-ignition temperatures far above 400°C (based on the information listed on the ECHA dissemination database) are not classified as flammable liquids, or information requirements for both	S. Verschaeve. 7/8/2015)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			endpoint determinations have been waived. If chemically speaking, some ingredients of the biocidal products covered by the Sopurclean family would be classified as flammable/combustible liquids which ignite, burn easy at normal working temperatures, and have relatively low flashpoints data requirements for those endpoints will be re-evaluated. Evaluation of these endpoints would then be justified in function of their relevance for fire hazard risk management. However, based on the currently available information and the composition of the Sopurclean family products additional testing is not deemed necessary. (waiver auto-ignition temperature Sopurclean.	
4.17 Relative self-ignition temperature for solids	No solid			
4.17 Dust explosion hazard	No dust			

Conclusion on the physical hazards and respective characteristics of the product
Sopurclean OP N is not explosive, is not flammable or combustible. It does not have flashpoint below 130°C. It is not oxidising. It is corrosive to metal.

Meta SPC4: Product information on ***SOPURCLEAN CIP OP*** *is provided.*

Table 21. Physical hazards and respective characteristics - Sopurclean CIP OP (meta SPC 4)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
4.1 Explosiveness	Data Waiving		Non explosive. **JUSTIFICATION :** The current waiver statement in the PAR indicates that none of the biocidal products 'contain ingredients which possess explosive properties', and is The waiving is based on available data for all components of the mixtures either published by ECHA, ADR,… or from their SDS. The screening procedure (CLP section 2.1 Annex I) was followed to evaluate if y/n the formulations (mixtures) do have reasons to be submitted to tests for explosive properties. Based on those criteria, it is considered that the mixtures should be considered as being non-explosive.	
4.2 Flammability	Other: Council Regulation (EC) 440/2008 EC method A.9 (flash point)	Biocidal product as such (100%)	Not flammable. The test item presents no flash point until 130°C.	study report SOPURCLEAN CIP OP: Determination of the flashpoint Briosschi M. 2015 Unpublished Testing laboratory ChemService report no Company owner SOPURA Company study no CH-299/2015 Brioschi M. 2015-05-21
4.3 Flammable aerosols	No aerosol			
4.4 Oxidising properties	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC 1, 2, 3 and 4 contain ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.5 Gases under pressure	No gas			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
4.6 Flammable liquids	Data waiving		According to CLP (EC 1272/2008) regulation **none** of the Biocidal Products covered by the Sopurclean Biocidal Product family fulfil the criteria to be classified as a flammable liquid.	
4.7 Flammable solids	No solid			
4.8 Self-reactive substances and mixtures	Data waiving		The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties.	
4.9 Pyrophoric liquids	Data Waiving		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C.	
4.10 Pyrophoric solids	No solid			
4.11 Self-heating substances and mixtures	Data Waiving		Self-heating applies only to solids. Test method is not applicable to liquids.	
4.12 Substances and mixtures which in contact with water emit flammable gases	Data waiving		This test is not deemed necessary as the products are not flammable liquids. This is based on the justification mentioned in section 2.14.4.1 of the CLP Regulation where it is mentioned that the classification procedure for this class is not needed if: (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or (b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or (c) the substance or mixture is known to be soluble in water to form a stable mixture. As all 3 criteria are considered fulfilled,	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			no test requirements are identified for any of the BPs within the SOPURCLEAN BPF and there is no need to classify these products within this hazard class.	
4.13 Oxidising liquids	Data Waiving		Non oxidising. None of the Biocidal product part of the meta SPC1, 2, 3 and 4 contains ingredients which possess oxidising properties. Therefore, further testing is not deemed necessary.	
4.14 Oxidising solids	No solids			
4.15 Organic peroxides	No organic peroxides			
4.16 Corrosive to metals	C1: test for determining the corrosive properties of liquids and solids that may become liquid during transport as dangerous goods of Class 8, packing group III.		***SOPURCLEAN CIP OP*** diluted shows uniform corrosive attack on mild steel and aluminium but did not exhibit a loss of weight of more than 26,5 % after an exposure time of 14 days, which would result in classification. The criterion for localised corrosion was not evaluated.	Study report CLDI068 D Corrosion test for SOPURCLEAN CIP OP Loghmanian A. 2015 Unpublished. Testing laboratory: Sopura Laboratory. 2015-05-20
4.17 Auto-ignition temperatures of products (liquids and gases)	Waiver		All the products of the Sopurclean family are classified as not flammable or not combustible and do not have flash points below 120°C. In addition, the individual ingredients of the biocidal products of the Sopurclean family do all have auto-ignition temperatures far above 400°C (based on the information listed on the ECHA dissemination database) are not classified as flammable liquids, or information requirements for both endpoint determinations have been waived.	S. Verschaeve. 7/8/2015)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			If chemically speaking, some ingredients of the biocidal products covered by the Sopurclean family would be classified as flammable/combustible liquids which ignite, burn easy at normal working temperatures, and have relatively low flashpoints data requirements for those endpoints will be re-evaluated. Evaluation of these endpoints would then be justified in function of their relevance for fire hazard risk management. However, based on the currently available information and the composition of the Sopurclean family products additional testing is not deemed necessary. (waiver auto-ignition temperature Sopurclean.	
4.17 Relative self-ignition temperature for solids	No solid			
4.17 Dust explosion hazard	No dust			

Conclusion on the physical hazards and respective characteristics of the product
Sopurclean CIP OP is not explosive, is not flammable or combustible. It does not have flashpoint below 130°C. It is not oxidising. It is corrosive to metal.

1.2.4 Methods for detection and identification

In the table below the analytical methods have been provided for: Sopurcip EC, Sopurclean BN, Sopurclean BN PS, Sopurclean CIP OP, Sopurclean OP N, Sopurclean NR. The information on Septacid BN and Septacid BN PS have been reviewed in the active substance approval phase and can be found there.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
octanoic acid decanoic acid	EEC guideline SANCO/3030/99 Rev. 4 and OECD GC 202 GC Agilent 6890 GC-FID GC column HP5 30m x 0.53 x 1.2µm Oven 95°C to 110°C Injection 250°C Detection 250°C Ramp 80°C/min Injection volume 3µl Ret. Time Octanoic acid 1.24 min, Nonanoic acid 1.87 min, Decanoic acid 2.73 min	5 concentrations 3 repetitions	>0.99 (75% - 125%)	No interfering substances in formulation	100 100	97-103 97-103	<2.68 2.93		SOPURCIP EC Validation report of the method of fatty acids content determination in Sopurcip EC by GC FID. Servais D. Unpublished report no VAL 084-L 2015-02-19 EEC guideline SANCO/3030/99 rev. 4 and OECD GD 202
octanoic acid decanoic acid	EEC guideline SANCO/3030/99 Rev. 4 and OECD GC 202 GC Agilent 6890 GC-FID GC column HP5 30m x 0.53 x 1.2µm Oven 95°C to 110°C Injection 250°C Detection 250°C Ramp 80°C/min Injection volume 3µl	5 concentrations 3 repetitions	>0.99 (75% - 125%)	No interfering substances in formulation	100 100	97-103 97-103	<2.45 2.61		SOPURCLEAN BN Validation report of the method of fatty acids content determination in Sopurclean BN by GC FID. Servais D. Unpublished report no VAL 084-M 2015-03-25 EEC guideline

	Ret. Time Octanoic acid 1.24 min, Nonanoic acid 1.87 min, Decanoic acid 2.73 min								SANCO/3030 /99 rev. 4 and OECD GD 202
octanoic acid decanoic acid	EEC guideline SANCO/3030/99 Rev. 4 and OECD GC 202 GC Agilent 6890 GC-FID GC column HP5 30m x 0.53 x 1.2µm Oven 95°C to 110°C Injection 250°C Detection 250°C Ramp 80°C/min Injection volume 3µl Ret. Time Octanoic acid 1.24 min, Nonanoic acid 1.87 min, Decanoic acid 2.73 min	5 concentrations 3 repetitions	>0.99 (75% - 125%)	No intefering substances in formulation	100 100	97-103 97-103	<2.45 2.61		SOPURCLEAN BN PS Validation report of the method of fatty acids content determination in Sopurclean BN PS by GC FID. Servais D. Unpublished report no VAL 084-R 2015-03-25 EEC guideline SANCO/3030 /99 rev. 4 and OECD GD 202
octanoic acid decanoic acid	EEC guideline SANCO/3030/99 Rev. 4 and OECD GC 202 GC Agilent 6890 GC-FID GC column HP5 30m x 0.53 x 1.2µm Oven 95°C to 110°C Injection 250°C Detection 250°C Ramp 80°C/min Injection volume 3µl Ret. Time Octanoic acid 1.24 min, Nonanoic acid 1.87 min, Decanoic acid 2.73 min	5 concentrations 3 repetitions	>0.99 (75% - 125%)	No intefering substances in formulation	100 100	97-103 97-103	<2.45 <2.61		SOPURCLEAN CIP OP Validation report of the method of fatty acids content determination in Sopurclean CIP OP. Servais D. Unpublished report no VAL 084-I 2015-03-25 EEC guideline SANCO/3030 /99 rev. 4 and OECD GD 202
octanoic acid	EEC guideline SANCO/3030/99	5 concentrations	>0.99 (75%	No intefering	100	97-103	<2.45		SOPURCLEAN OP N

decanoic acid	Rev. 4 and OECD GC 202 GC Agilent 6890 GC-FID GC column HP5 30m x 0.53 x 1.2µm Oven 95°C to 110°C Injection 250°C Detection 250°C Ramp 80°C/min Injection volume 3µl Ret. Time Octanoic acid 1.24 min, Nonanoic acid 1.87 min, Decanoic acid 2.73 min	3 repetitions	- 125%)	substances in formulation	100	97-103	<2.61		Validation report of the method of fatty acids content determination in Sopurclean OP N. Servais D. Unpublished report no VAL 084-G 2014-12-04 EEC guideline SANCO/3030/99 rev. 4 and OECD GD 202
octanoic acid decanoic acid	EEC guideline SANCO/3030/99 Rev. 4 and OECD GC 202 GC Agilent 6890 GC-FID GC column HP5 30m x 0.53 x 1.2µm Oven 95°C to 110°C Injection 250°C Detection 250°C Ramp 80°C/min Injection volume 3µl Ret. Time Octanoic acid 1.24 min, Nonanoic acid 1.87 min, Decanoic acid 2.73 min	5 concentrations 3 repetitions	>0.99 (75% - 125%)	No intefering substances in formulation	100 100	97-103 97-105	<2.24 2.75		SOPURCLEAN NR Validation report of the method of fatty acids content determination in Sopurclean NR by GC FID. Servais D. Unpublished report no VAL 084-AD 2015-04-17 EEC guideline SANCO/3030/99 rev. 4 and OECD GD 202

Data waiver metabolites: The potential metabolites are fatty acids and do not represent a significant risk. The other ingredients of the formulation do not have a classification requiring a specific analytical method. This endpoint refers to the analytical methods for detection and identification of toxicologically and ecotoxicologically relevant components of the biocidal product.

Data waiver soil: Based on the use of the products indoor, there is inherently negligible emission to the environment expected, therefore development of an analytical method for soil is not deemed necessary. If contamination of soil would

happen, an analytical method is described in the adsorption/desorption screening test. The adsorption/desorption screening test showed that decanoic acid is very fast degraded in soil (DT50 < 2 days), therefore it is very unlikely that a significant amount would be found in soil.

Data waiver air: Based on the use of the products indoor, there is inherently negligible emission to the environment expected, therefore development of an analytical method for air is not deemed necessary. The vapour pressure of the ASs is low, therefore no significant concentrations of ASs in air are expected to occur.

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD n= 3		
decanoic acid *0.1 µg/l* *1 µg/l* *2.5 µg/l* **1 mg/l**	Enrichment: In-situ derivation with dimethylsulfate (DMST) and then loading of a C-18ec Cartridge with either the test solution for calibration or surface water containing decanoic acid. After loading elution with 2 mL methylene chlorid. Method ID: GC/MS		0-5 mg/l r2 = 0.9994	100 mg/L standard Accuracy of 71.6%	*111.5* *91.5* *95.9*		**1.14**	LOD < 0.1 µg/L	Methodenvalidierung 0.1 µg/L for decanoic acid and octanoic acid; Böhler Analytik Ges.m.b.H., 2006, Böhler analytik Ges.m.b.H. Study no. A4.2/01b

Data waiver body fluids: Decanoic acid is naturally present in body fluids and tissues in man and animals, it is therefore impossible to develop a method for the general and regular determination of decanoic acid. In principle, for very specific cases, a distinction between endogen and external application may be possible via an analysis of isotope ratio in decanoic acid.

Data waiver body food and feed: Decanoic acid occurs in nature and is part of the human diet, it occurs as free acid in food items. Without an exact knowledge of the natural content of decanoic acid in food before the application of the biocidal product it is impossible to differentiate between the natural and residual decanoic acid.

Note that no analytical methods have been provided for the SoCs as, within the ACPC working group, this was found to be unnecessary. Additionally, the products of the BPF are composed of combinations of different types of acids having clearly identified

detergency functions (sulfuric, nitric, phosphoric, methane sulfonic, propionic, lactic, citric, glycolic, acidic), classified as organic and mineral acids.
They do not have any "chemical potential" to interfere with other ingredients, which could chemically create a decrease or increase of one of the constituents, and as a consequence generate by-products. (which could occur with strong oxidizers for instance).
The development of methods to identify such a mineral acid (e.g. detection of the mineral part) or an organic one (e.g. ia GC/HPLC/MS) would not have any added value as no by-products are generated.
More easier methods, like titration methods, would not distinguish the different acids and are therefore not considered as valid for the identification of by-products.

Conclusion on the methods for detection and identification of the product
Octanoic acid and decanoic acid present in products of the *SOPURCLEAN BPF* are separated with an Alltech column AT-225 10mx0.53mmx01.2µm and detected with a GC-FID (oven 120°C, injection 200°C, detection 250°C, ramp 80°C/min). The method is linear (75% - 125%), specific and the recovery is fine (< 3% RSD). To analyse decanoic acid in water, the available method is based on the in-situ methylation of strongly polar organic acids in natural waters. Pre-concentration with aC-18ec Cartridge gives the required sensitivity of < 0.1 µg/L in natural water. Analysis is performed with GC/MS by detection and integrations of the peak-area of the specific peaks in the mass spectra. The reasoning in the various data waivers from the applicant for other analytical methods can be considered as acceptable.

1.2.5 Efficacy against target organisms

1.2.5.1 Function and field of use

SOPURCLEAN BPF

Main Group 01: Disinfectants
Product Type 4: Food & feed Area

All the biocidal products within the entire ***SOPURCLEAN BPF*** are liquid concentrates to dilute in tap water.

They are disinfectants intended to be used as "Food and feed area disinfectants PT4" by professional and industrial users in various food & feed industries (PT4): manufacture of drinks, manufacture of dairy food, slaughterhouse meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

According to the product and the intended use, four use procedures are considered:
1) CIP (cleaning in place) with circulation
2) Spraying of surfaces (conveyors, external machines, inside of cold storages/freezers,…)
3) Soaking/dipping for small stainless steel connections, valves, …
4) Manual disinfection of surfaces

Since the assessment of efficacy performances on the basis of an overall "worst case" for the entire BPF is not possible, the assessment is focused at *meta* SPC level, taking into consideration the composition of the products and the different uses described in each *meta* SPC.

Meta SPC1

Main Group 01: Disinfectants
Product Type 4: Food & feed Area

The *meta* SPC 1 includes biocidal products which contain the 2 active substances:

- ***Octanoic Acid***
  CAS N° 124-07-2 & EC-N° 204-677-5
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 1 at the concentration range 1.10 – 1.80 % w/w.
- ***Decanoic Acid***
  CAS N° 334-48-5 & EC N° 206-376-4
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 1 at the concentration range 0.70 – 1.50 % w/w.

All the biocidal products within the *meta* SPC1 are liquid concentrates to dilute in tap water and intended to be used by professional and industrial users in various food & feed industries (PT4): manufacture of drinks, manufacture of dairy food, slaughterhouse meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

All the biocidal products within this *meta* SPC1 are combined cleaning-disinfectants and are intended to be used for the following uses:

1) CIP (cleaning in place) with circulation

2) Soaking/dipping for small stainless steel connections, valves, …

Choice of the representative product for all the biocidal products of the *meta* SPC 1:

The product ***SOPURCIP EC*** has been chosen to represent all the biocidal products of the *meta* SPC 1, 3 and 4.
Please see additional information and justification in the Confidential Annex.

Meta SPC2

Main Group 01: Disinfectants
Product Type 4: Food & feed Area

The *meta* SPC 2 refers to one biocidal product only i.e. ***SOPURCLEAN NR*** which contain the 2 active substances:

- ***Octanoic Acid***
  CAS N° 124-07-2 & EC-N° 204-677-5
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 2 at the concentration of 2.7 % w/w.
- ***Decanoic Acid***
  CAS N° 334-48-5 & EC N° 206-376-4
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 2 at the concentration of 0.3 % w/w.

The biocidal product ***SOPURCLEAN NR*** is a liquid concentrate to dilute in tap water and intended to be used by professional and industrial users in various food & feed industries (PT4): manufacture of drinks, manufacture of dairy food, slaughterhouse meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

The biocidal product ***SOPURCLEAN NR*** is either combined cleaning-disinfectants or disinfectants intended to be used as "Food and feed area disinfectants PT4" by professionals for the following uses:

1) CIP (cleaning in place) with circulation
2) Spraying of surfaces (conveyors, external machines, inside of cold storages/freezers, …)
3) Soaking/dipping for small stainless steel connections, valves, …
4) Manual disinfection of surfaces by wiping/mopping : the disinfection solution is applied by spraying and the user has to wait 15 min (optimal contact time) before wiping/mopping.

Choice of the representative product for all the biocidal products of *meta* SPC 2:

The product ***SOPURCLEAN NR*** is the one and only product supported in the *meta* SPC 2 and therefore the representative product for the Meta SPC 2.

Please see additional information in the Confidential Annex.

Meta SPC3

Main Group 01: Disinfectants
Product Type 4: Food & feed Area

The *meta* SPC 3 includes biocidal products which contain the 2 active substances:

- ***Octanoic Acid***
  CAS N° 124-07-2 & EC-N° 204-677-5
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 3 at the concentration of 1.80 % w/w.
- ***Decanoic Acid***
  CAS N° 334-48-5 & EC N° 206-376-4
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 3 at the concentration of 1.20 % w/w.

The biocidal product ***SOPURCLEAN OP-N*** is a liquid concentrate to dilute in tap water and intended to be used by professional and industrial users in various food & feed industries (PT4): manufacture of drinks, manufacture of dairy food, slaughterhouse meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

The biocidal product ***SOPURCLEAN OP-N*** is a combined cleaning-disinfectant intended to be used for CIP (cleaning in place) procedures with circulation.

The product ***SOPURCIP EC*** has been chosen to represent the biocidal product of the *meta* SPC 3 (Please refer to the justification included in the section related to Meta SPC1).

Please see additional information in the Confidential Annex.

Meta SPC4

Main Group 01: Disinfectants
Product Type 4: Food & feed Area

The *meta* SPC 4 includes biocidal products which contain the 2 active substances:

- ***Octanoic Acid***
  CAS N° 124-07-2 & EC-N° 204-677-5
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 4 at the concentration of 1.80 % w/w.
- ***Decanoic Acid***
  CAS N° 334-48-5 & EC N° 206-376-4
  Authorised for the PT4 "food and feed area disinfectants" from 01/09/2015
  Used in the Meta SPC 4 at the concentration of 1.20 % w/w.

The biocidal product ***SOPURCLEAN CIP-OP*** is a liquid concentrate to dilute in tap water and intended to be used by professional and industrial users in various food &

feed industries (PT4): manufacture of drinks, manufacture of dairy food, slaughterhouse meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

The biocidal product ***SOPURCLEAN CIP-OP*** is a combined cleaning-disinfectant intended to be used for CIP (cleaning in place) procedures with circulation.

The product ***SOPURCIP EC*** has been chosen to represent the biocidal product of the *meta* SPC 4 (Please refer to the justification included in the section related to Meta SPC1).

Please see additional information in the Confidential Annex.

1.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

All the biocidal products within the entire ***SOPURCLEAN BPF*** are intended to have a bactericidal activity (only vegetative bacteria – excluding mycobacteria and spore-forming bacteria) and a yeasticidal activity.

1.2.5.3 Effects on target organisms, including unacceptable suffering

1- Impact of decanoic acid (2nd active substance) on the efficiency of the BP:

The issue about the contribution of Decanoic Acid to the efficiency of the formulation was raised following ECHA's request after the initial UA-pre submission in April 2015.

In order to solve the issue about the contribution of both Active Substances to the efficiency of the formulation, the Applicant has provided efficacy tests (performed according to the EN 1276 including the 4 representative mandatory bacteria) to compare the product ***SOPURCLEAN NR*** (full composition - OA at 2.7% and DA at 0.3%) & a dummy product ***SOPURCLEAN NR-wo DA*** (which only contains OA at 2.7%). This test is performed to demonstrate the additional efficacy effect i.e. the "added-value of Decanoic acid (0.3%v/v) to the Biocidal Product.

Please see the tables with the results in the Confidential Annex.

According to the results, decanoic acid does contribute to achieve the bactericidal & yeasticidal activity of the whole formulation.
Since the representative product for meta SPC 1, i.e. ***SOPURCIP EC***, contains a lower concentration of octanoic acid (1.1 to 1.8%) than the product ***SOPURCLEAN NR***, the results described above are therefore also relevant for the representative product for meta SPC 1, i.e. ***SOPURCIP EC.***

2-Role of the acids:

Please see detailed information in the Confidential Annex.

3- Impact of co-formulants on the efficiency of the BPs:

*Meta SPC 1/3/4 co-formulants**
Co-formulants i.e. Glycolic Acid (under review in the BPR review program for PT4), Propionic Acid (approved for Annex I-cat.1), L+-Lactic acid (approved for PT4) & Citric Acid (only approved for PT2) cannot be considered to act as active substances in the formulations of the ***SOPURCLEAN BPF*** based on the data currently available.
* The non-efficacy of the other acids has been evaluated in the AS dossiers (+ Meta 2).

Meta SPC 2 co-formulants
Lactic acid and propionic acid, identified as SoC, can have an impact on the efficacy of the product. Based on the data currently available however, co-formulants (lactic acid, propionic acid and phosphoric acid) cannot be considered to act as active substances in the formulations of the ***SOPURCLEAN BPF***.

To demonstrate this, the efficacy of the biocidal formulation ***SOPURCLEAN NR*** was compared with a placebo formulation (without both A.S. but with all the co-formulants) via Phase 2/Step 1 efficacy tests.
According to the results, lactic and propionic acid do not contribute to the bactericidal & yeasticidal activity of the whole formulation.

Please see the composition of the placebo formulation & the tables with the results in the Confidential Annex.

Please note that by the time this PAR was written and finalised, the discussion at EU level about co-formulants is still ongoing. The applicant considers however that currently (at the time of data submission) the submitted information is sufficient to confirm the non-biocidal function (efficacy) of the co-formulants. The submitting applicant cannot be held responsible for all future potential regulatory changes which are put in place between the dossier submission data and final approval stage.

4- More limiting & critical interfering substance for the representative products:

Orienting efficacy tests (quantitative suspension pre-testing) were performed in order to determine the most limiting interfering substance amongst 5 interfering substances i.e. saccharose, milk, yeasts, erythrocytes and albumin (relevant for main food industries).
Quantitative suspension efficacy tests have been performed according to the EN 1276 standard using the product *SOPURCIP EC* (representative product for *meta* SPC1, 3 & 4 products) and the product *SOPURCLEAN NR* (representative product for *meta* SPC2 products) under intended use conditions (i.e. 15 min at +4°C).

At 1.5% (use concentration), the most limiting & critical interfering substance for the product ***SOPURCIP EC*** (representative product for meta SPC1;3 & 4 products) is yeasts (10%), simulating dirty conditions in breweries.

At 1.0% (use concentration), the most limiting & critical interfering substance for the product ***SOPURCLEAN NR*** (representative product for meta SPC2 products) is BSA+RBC (simulating dirty conditions in slaughterhouses) instead of Skimmed Milk.
However, considering that blood is always a very difficult I.S. to deal with, the BE eCA is of the opinion that a disinfection procedure in slaughterhouses does mandatory require a cleaning step (with a cold alkaline solution).
As the consequence, the BE eCA and the Applicant agreed to take into account the 2nd most limiting I.S. i.e. Skimmed Milk.
Please see additional information in the Confidential Annex.

Meta SPC1, 3 and 4:

According to the claims above and the Annex 4 of the *Guidance on Efficacy Assessment for Product Types 1-5*, efficacy tests performed according to suspension and surface standards have to be submitted:
- Phase 2/Step 1 efficacy tests are mandatory for products intended to be used for CIP with circulation procedures (EN 1276 and EN 1650-yeasts standards).
- Phase 2/Step 1 (EN 1276 and EN 1650-yeasts standards) and Phase 2/Step 2 (EN 13697 standard) efficacy tests are mandatory for products intended to be used for soaking/dipping procedures.

N.B.: *The Applicant has considered the "worst case" testing conditions (meaning dirty conditions) to perform all the efficacy tests. Consequently, this allows the Applicant to not mention nor recommend upfront rinsing or cleaning on the label. For this reason, only results in dirty conditions are reported below.*
Furthermore, since all the products of the BPF are claimed as yeasticidal and not fungicidal disinfectants, only the results with yeasts are reported below.

Since the applicant has been placing fatty acid based products on the market in Belgium for more than two decades there is a lot of "historical" efficacy data available on several products present in the ***Sopurclean BPF***, not only on the "key" products being SOPURCIP EC (meta SPC1) and SOPURCLEAN NR (meta SPC2).
In function of this authorisation application however, only the data relevant to these two key products are presented below as these are considered sufficient to draw conclusions on efficacy of these two meta SPC.

The relevant data on ***Sopurcip EC*** are presented as follows :

1. Key data:

Since the biocidal products within meta SPC1, 3 & 4 are intended to be used on surfaces (including inner surfaces using CIP) in various food & feed industries including the disinfection of cold surfaces, the Applicant has performed & provided efficacy tests using the product *SOPURCIP EC* at +4°C ("worst case" situation) with a 15 min contact time (to mimic the practical use conditions) and with 10 g/L Yeast Extract as interfering substance ("worst case" situation).

a. Bacterial suspension test EN1276: obligatory and complementary strains

Name of the document	Sopurcip EC-bact-suspension-CH59115_RT_KEY Technical Report No. CH – 591/2015 Rev.1				
EN Standard Used	EN 1276 : 2009/2010				
Test-Product	***SOPURCIP EC***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	1 - 1.5 – 2 – 2.5 %	15 min	+4°C	10 g/l Yeast Extract	YES
Target Organisms	**Name**		**Strain**	**Log Reduction**	
	Pseudomonas aeruginosa		ATCC 15442	Log↘ = 5.09 > 5 at 1.0 %	
	E.coli		ATCC 10536	Log↘ = 5.09 > 5 at 1.0 %	
	Staphylococcus aureus		ATCC 6538	Log↘ = 5.04 > 5 at 1.5 %	
	Enterococcus hirae		ATCC 10541	Log↘ = 5.03 > 5 at 1.0 %	
	Lactobacillus brevis		DSM 6235	Log↘ = 5.06 > 5 at 1.0 %	
	Pediococcus damnosus		ATCC 29358	Log↘ = 5.17 > 5 at 2.0 %	
	Enterobacter cloacae		DSM 6234	Log↘ = 5.00 > 5 at 1.0 %	
	Salmonella typhimurium		ATCC 13311	Log↘ = 5.00 > 5 at 1.0 %	
	Listeria monocytogenes		ATCC 19111	Log↘ = 5.01 > 5 at 1.0 %	
	Campylobacter jejuni		ATCC 33291	Log↘ = 5.05 > 5 at 1.0 %	
Conclusion as reported	According to EN 1276 (2009/2010), the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity in 15 minutes at +4°C under dirty conditions for breweries (10 g/l Yeast Extract). With the same use conditions, the product ***SOPURCIP EC*** is also active against *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Listeria monocytogenes and Campylobacter jejuni* (must be adjusted to 2% for *Pediococcus damnosus*).				
Remarks	Nothing to mention				
RMS conclusion	**Reliability 1: Key study** According to EN 1276 (2009/2010) relevant for CIP procedures, the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni and Listeria monocytogenes*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Yeast Extract). To be active against *Pediococcus damnosus*, the product ***SOPURCIP EC*** must be used at 2%.				

b. Fungal suspension test EN1650: obligatory and complementary strains

Name of the document	Sopurcip EC-fung-suspension-CH59215_RT_KEY Technical Report No. CH – 592/2015 Rev.1
EN Standard Used	EN 1650 : 2008/2013
Test-Product	***SOPURCIP EC***

Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	1 - 1.5 – 2 – 2.5 %	15 min	+4°C	10 g/l Yeast Extract	YES

Target Organisms	**Name**	**Strain**	**Log Reduction**
	Candida albicans	ATCC 10231	Log↘ = 4.33 > 4 at 1.5 %
	Saccharomyces cerevisiae	ATCC 9763	Log↘ = 4.16 > 4 at 1.0 %
	Saccharomyces cerevisiae diastaticus	DSM 70487	Log↘ = 4.10 > 4 at 1.0 %

Conclusion as reported	According to EN 1650 (2008/2013), the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses yeasticidal activity in 15 minutes at +4°C under dirty conditions for breweries (10 g/l Yeast Extract). With the same use conditions, the product ***SOPURCIP EC*** is also active against *Saccharomyces cerevisiae.*
Remarks	Nothing to mention
RMS conclusion	**Reliability 1: Key study** According to EN 1650 (2008/2013), relevant for CIP procedures, the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses yeasticidal activity (including *Saccharomyces cerevisiae.and Saccharomyces cerevisiae diastaticus.* in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Yeast Extract).

c. Bacterial surface test EN13697: obligatory and complementary strains

Name of the document	Sopurcip EC-bact-non-porous surface-CH58915_RT_KEY Technical Report No. CH – 589/2015 Rev 1
EN Standard Used	EN 13697 : 2015
Test-Product	***SOPURCIP EC***

Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	1 - 1.5 – 2 – 2.5 %	15 min	+4°C	10 g/l Yeast Extract	YES

Target Organisms	**Name**	**Strain**	**Log Reduction**
	Pseudomonas aeruginosa	ATCC 15442	Log↘ = 4.52 > 4 at 1.0 %
	E.coli	ATCC 10536	Log↘ = 4.30 > 4 at 1.0 %
	Staphylococcus aureus	ATCC 6538	Log↘ = 4.68 > 4 at 1.5 %
	Enterococcus hirae	ATCC 10541	Log↘ = 4.17 > 4 at 1.0 %
	Lactobacillus brevis	DSM 6235	Log↘ = 4.44 > 4 at 1.0 %
	Pediococcus damnosus	ATCC 29358	Log↘ = 4.40 > 4 at 1.0 %
	Enterobacter cloacae	DSM 6234	Log↘ = 4.33 > 4 at 1.0 %
	Salmonella typhimurium	ATCC 13311	Log↘ = 4.17 > 4 at 1.0 %
	Listeria monocytogenes	ATCC 19111	Log↘ = 4.01 > 4 at 1.0 %
	Campylobacter jejuni	ATCC 33291	Log↘ = 4.03 > 4 at 1.0 %

Conclusion as reported	According to EN 13697 (2015), the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity in 15 minutes at +4°C under dirty conditions for breweries (10 g/l Yeast Extract). With the same use conditions, the product ***SOPURCIP EC*** is also active against *Lactobacillus brevis, Pediococcus damnosus, Enterobacter cloacae, Salmonella typhimurium, Listeria monocytogenes and Campylobacter jejuni*.
Remarks	Nothing to mention
RMS conclusion	**Reliability 1: Key study** According to EN 13697 (2015) relevant for surface disinfection by soaking/dipping procedures, the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter*

	jejuni, *Listeria monocytogenes and Pediococcus damnosus*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Yeast Extract).

d. Fungal surface test EN13697: obligatory and complementary strains

Name of the document	Sopurcip EC-fung-non-porous surface-CH59015_RT_KEY Technical Report No. CH – 590/2015 Rev 1				
EN Standard Used	EN 13697 : 2015				
Test-Product	***SOPURCIP EC***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	1 - 1.5 – 2 – 2.5 %	15 min	+4°C	10 g/l Yeast Extract	YES
Target Organisms	**Name**			**Strain**	**Log Reduction**
	Candida albicans			ATCC 10231	Log↘ = 3.32 > 3 at 1.5 %
	Saccharomyces cerevisiae			ATCC 9763	Log↘ = 3.02 > 3 at 1.0 %
	Saccharomyces cerevisiae diastaticus			DSM 70487	Log↘ = 3.23 > 3 at 1.5 %
Conclusion as reported	According to EN 13697 (2015), the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses fungicidal activity in 15 minutes at +4°C under dirty conditions for breweries (10 g/l Yeast Extract). With the same use conditions, the product ***SOPURCIP EC*** is also active against *Saccharomyces cerevisiae.*				
Remarks	Nothing to mention				
RMS conclusion	**Reliability 1: Key study** According to EN 13697 (2015) relevant for surface disinfection by soaking/dipping procedures, the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses yeasticidal activity (including *Saccharomyces cerevisiae.and Saccharomyces cerevisiae diastaticus)* in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Yeast Extract).				

According to the results of the 4 efficacy tests provided by the Applicant and summarised above, the product ***SOPURCIP EC***:

- Can be used during CIP procedures and possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni* and *Listeria monocytogenes*) and yeasticidal activity (including *Saccharomyces cerevisiae* and *Saccharomyces cerevisiae diastaticus*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Yeast Extract) when diluted at 1.5 % (v/v), in hard water.
- Can be used for surface disinfection by soaking/dipping procedures and possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni*, and *Listeria monocytogenes*) and yeasticidal activity (including *Saccharomyces cerevisiae* and *Saccharomyces cerevisiae diastaticus*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Yeast Extract) when diluted at 1.5 % (v/v), in hard water.
- In case of outbreaks caused by *Pediococcus damnosus*, the product ***SOPURCIP EC*** must be used at 2% (in 15 min at +4°C under dirty conditions) during CIP and soaking/dipping procedures.

2. Supporting information:

Since SOPURCLEAN products are on the market for more than two decades in Belgium, a lot of data have been generated in the past by the Applicant with the BPs for which an authorisation was sought in Belgium.
As a purpose of clarity, all relevant data generated in the past are shown below as supportive information.

a. Bacterial suspension test EN 1276 (1997)

Name of the document	6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276-(1997)-IN GENERAL USE CONDITIONS-SOPURCIP_EC-20150120				
EN Standard Used	EN 1276 : 1997				
Test-Product	***SOPURCIP EC***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.75 - 1 - 1.5 %	5 min	+20°C	3 g/l BSA: Dirty	YES
Target Organisms	**Name**		**Strain**	**Log Reduction**	
	Pseudomonas aeruginosa		ATCC 15442	Log↘ > 5 at 0.75 % - 5 min - +20°C – Dirty	
	E.coli		ATCC 10536	Log↘ > 5 at 0.75 % - 5 min - +20°C – Dirty	
	Staphylococcus aureus		ATCC 6538	Log↘ > 5 at 1 % - 5 min - +20°C – Dirty	
	Enterococcus hirae		ATCC 8043	Log↘ > 5 at 1 % - 5 min - +20°C – Dirty	
Conclusion as reported	According to EN 1276 (1997), the product ***SOPURCIP EC***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity in 5 minutes at 20°C under dirty conditions (3 g/L bovine albumin).				
Remarks	- The study, from 02/2015, has been performed according to the 1997 version of the EN 1276 standard: in-force standard versions should have been used. **=> Reliability 2**				
RMS conclusion	According to EN 1276 (1997), the product ***SOPURCIP EC***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity in 5 minutes at 20°C under dirty conditions (3 g/L bovine albumin).				

b. Bacterial suspension test EN 1276 (1997) practical conditions & strains

Name of the document	6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276-(1997)-IN PRACTICAL USE CONDITIONS-SOPURCIP_EC-20150120				
EN Standard Used	EN 1276 : 1997				
Test-Product	***SOPURCIP EC***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.75 - 1 - 1.5 %	15 min	+10°C	10 g/l YE: Dirty	YES
Target Organisms	**Name**		**Strain**	**Log Reduction**	
	Pseudomonas aeruginosa		ATCC 15442	Log↘ > 5 at 1 % - 15 min - +10°C – Dirty	
	E.coli		ATCC 10536	Log↘ > 5 at 0.75 % - 15 min - +10°C – Dirty	
	Lactobacillus brevis		DSM 6235	Log↘ > 5 at 1 % - 15 min - +10°C – Dirty	
	Pediococcus damnosus		ATCC 43013	Log↘ > 5 at 1 % - 15 min - +10°C – Dirty	
Conclusion as reported	According to EN 1276 (1997), the product ***SOPURCIP EC***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity in 15 minutes at 10°C under dirty conditions. (10 g/L Yeast Extract - breweries)				
Remarks	- The study, from 02/2015, has been performed according to the 1997 version of the EN 1276 standard: in-force standard versions should have been used. - *Enterococcus hirae* and *Staphylococcus aureus* not tested as representative microorganisms, as all the representative microorganisms should have been. However, *Enterococcus hirae* is not relevant for the food industry. Since *Staphylococcus aureus* is not included in the test and since it seems to be the most resistant microorganism for the product under evaluation, the test is considered as valid (and well performed) but the test results could be taken into account only as supportive information.				
RMS conclusion	Supportive information				

c. Fungal suspension test EN 1650 (1997)

Name of the document	6_7-EVALUATION-OF-THE-FUNGICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1650-(1997)-IN GENERAL USE CONDITIONS-SOPURCIP_EC-20150120				
EN Standard Used	EN 1650 : 1997				
Test-Product	***SOPURCIP EC***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	7.5 - 10 - 12.5 %	15 min	+20°C	3 g/l BSA: Dirty	YES
Target Organisms	**Name**	**Strain**		**Log Reduction**	
	Candida albicans	ATCC 10231		Log↘ > 4 at 7.5 % - 15 min - +20°C – Dirty	
Conclusion as reported	According to EN 1650 (1997), the product ***SOPURCIP EC***, when diluted at 7.5 % (v/v), in hard water, possesses yeasticidal activity in 15 minutes at 20°C under dirty conditions (3 g/L bovine albumin).				
Remarks	- The study, from 02/2015, has been performed according to the 1997 version of the EN 1650 standard: in-force standard versions should have been used. - For all the tests performed under dirty conditions in function of the yeasticidal activity, no non-efficacious concentration has been included. Furthermore, as mentioned in standards (§5.4.2), all the efficacy tests may include at least one non-efficacious concentration and 2 efficacious concentrations in order to be sure that we have the lowest possible effective concentration. In addition, comparing the results with the results obtained for the bactericidal activity, it's surprising that a so high concentration should be applied to achieve the yeasticidal activity ! Test considered as valid (and well-performed)				
RMS conclusion	Supportive information				

d. Fungal suspension test EN 1650 (1997) practical conditions & strains

Name of the document	6_7-EVALUATION-OF-THE-FUNGICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1650-(1997)-IN GENERAL USE CONDITIONS-SOPURCIP_EC-20150120				
EN Standard Used	EN 1650 : 1997				
Test-Product	***SOPURCIP EC***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.75 ; 1 and 1.5 %	15 min	+10°C	10 g/l YE: Dirty	YES
Target Organisms	**Name**	**Strain**		**Log Reduction**	
	Saccharomyces cerevisiae	ATCC 9763		Log↘ > 4 at 1 % - 15 min - +10°C – Dirty	
	Saccharomyces cerevisiae diastaticus	DSM 70487		Log↘ > 4 at 0.75 % - 15 min - +10°C – Dirty	
Conclusion as reported	According to EN 1650 (1997), the product ***SOPURCIP EC***, when diluted at 1 % (v/v), in hard water, possesses an yeasticidal activity against *Saccharomyces cerevisiae* in 15 minutes at 10°C under dirty conditions (10 g/L Yeast Extract - breweries).				
Remarks	- The study, from 02/2015, has been performed according to the 1997 version of the EN 1650 standard: in-force standard versions should have been used! - *Candida albicans* not tested as representative microorganisms! - According to the results from the test reported just above, it's surprising that a such low concentration should be applied to achieve the activity against *Saccharomyces sp*. : because, in term of susceptibility to biocides, Saccharomyces sp. is *Candida albicans*. - Since *Candida albicans* is not included in the test, the test is considered as valid (and well performed) but the test results could be taken into account only as supportive information.				
RMS conclusion	Supportive information				

According to the results of the 4 efficacy tests provided by the Applicant (as supportive information) and summarised above:

- The product ***SOPURCIP EC*** is bactericidal (suspension) in the following conditions: 1% - +20°C – 5 min - in dirty conditions,

- The product ***SOPURCIP EC*** is yeasticidal (suspension) in the following conditions: 7.5% - + 20°C – 15 min – in dirty conditions.

Meta SPC2:

According to the claims above and the Annex 4 of the *Guidance on Efficacy Assessment for Product Types 1-5*, efficacy tests performed according to suspension and surface standards have to be submitted:
- Phase 2/Step 1 efficacy tests are mandatory for products intended to be used for CIP with circulation procedures (EN 1276 and EN 1650-yeasts standards).
- Phase 2/Step 1 (EN 1276 and EN 1650-yeasts standards) and Phase 2/Step 2 (EN 13697 standard) efficacy tests are mandatory for products intended to be used on surfaces during soaking/dipping, spraying (conveyors, external machines, inside of cold storages/freezers, …) or manual cleaning procedures.

N.B.: *The Applicant has considered the "worst case" testing conditions (meaning dirty conditions) to perform all the efficacy tests. Consequently this allows the Applicant to not mention nor recommend upfront rinsing or cleaning on the label. For this reason only results in dirty conditions are reported below.*
Furthermore, since all the products of the BPF are claimed as yeasticidal and not fungicidal disinfectants, only the results with yeasts are reported below.

1. Key data:

Since the biocidal products within meta SPC2 are intended to be used on surfaces (including inner surfaces using CIP) in various food & feed industries including the disinfection of cold surfaces, the Applicant has performed & provided efficacy tests using the product SOPURCLEAN NR at +4°C ("worst case" situation) with a 15 min contact time (to mimic the "worst" practical use conditions) and with 10 g/L Milk as interfering substance ("worst case" situation).

a. Bacterial suspension test EN1276: obligatory and complementary strains

Name of the document	Sopurclean NR-bact-suspension-CH59515_RT_R1_KEY				
EN Standard Used	EN 1276 : 2009/2010				
Test-Product	***SOPURCLEAN NR*** With Octanoic acid 2.7 % w/w & Decanoic acid 0.28 % w/w (-7% < 10%) From Certificate of Analysis joined to the efficacy report				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.5 - 1 - 1.5 – 2 %	15 min	+4°C	10 g/l MILK	YES
Target Organisms	**Name**		**Strain**	**Log Reduction**	
	Pseudomonas aeruginosa		ATCC 15442	Log↘ = 5.01 > 5 at 0.5 %	
	E.coli		ATCC 10536	Log↘ = 5.10 > 5 at 0.5 %	
	Staphylococcus aureus		ATCC 6538	Log↘ = 5.08 > 5 at 1.0 %	
	Enterococcus hirae		ATCC 10541	Log↘ = 5.01 > 5 at 0.5 %	
	Lactobacillus brevis		DSM 6235	Log↘ = 5.06 > 5 at 1.0 %	
	Pediococcus damnosus		ATCC 29358	Log↘ = 5.17 > 5 at 1.5 %	
	Enterobacter cloacae		DSM 6234	Log↘ = 5.00 > 5 at 1.0 %	

	Salmonella typhimurium	ATCC 13311	Log↘ = 5.00 > 5 at 0.5 %
	Listeria monocytogenes	ATCC 19111	Log↘ = 5.02 > 5 at 1.0 %
	Campylobacter jejuni	ATCC 33291	Log↘ = 5.02 > 5 at 0.5%
Conclusion as reported	According to EN 1276 (2009/2010), the product ***SOPURCLEAN NR***, when diluted at 1.0 % (v/v), in hard water, possesses bactericidal activity in 15 minutes at +4°C under dirty conditions for dairies (10 g/l MILK). With the same use conditions, the product ***SOPURCLEAN NR*** is also active against *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Listeria monocytogenes and Campylobacter jejuni* (must be adjusted to 1.5% for *Pediococcus damnosus*).		
Remarks	Nothing to mention		
RMS conclusion	**Reliability 1: Key study** According to EN 1276 (2009/2010) relevant for CIP procedures, the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni and Listeria monocytogenes*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Milk). To be active against *Pediococcus damnosus*, the product ***SOPURCLEAN NR*** must be used at 1.5%.		

b. Fungal suspension test EN1650: obligatory and complementary strains

Name of the document	Sopurclean NR-fung-suspension- corrected CH59615_RT_R1_KEY				
EN Standard Used	EN 1650 : 2008/2013				
Test-Product	***SOPURCLEAN NR***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.5 - 1 - 1.5 – 2 %	15 min	+4°C	10 g/l MILK	YES
Target Organisms	**Name**			**Strain**	**Log Reduction**
	Candida albicans			ATCC 10231	Log↘ = 4.35 > 4 at 1.0 %
	Saccharomyces cerevisiae			ATCC 9763	Log↘ = 4.13 > 4 at 0.5 %
	Saccharomyces cerevisiae diastaticus			DSM 70487	Log↘ = 4.08 > 4 at 0.5 %
Conclusion as reported	According to EN 1650 (2008/2013), the product ***SOPURCLEAN NR***, when diluted at 1.0 % (v/v), in hard water, possesses yeasticidal activity in 15 minutes at +4°C under dirty conditions for dairies (10 g/l Milk). With the same use conditions, the product ***SOPURCLEAN NR*** is also active against *Saccharomyces cerevisiae.*				
Remarks	Nothing to mention				
RMS conclusion	**Reliability 1: Key study** According to EN 1650 (2008/2013), relevant for CIP procedures, the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses yeasticidal activity (including *Saccharomyces cerevisiae*.and *Saccharomyces cerevisiae diastaticus)* in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Milk).				

c. Bacterial surface test EN13697: obligatory and complementary strains

Name of the document	Sopurclean NR-bact-non-porous surface-CH59315_RT_R1_KEY				
EN Standard Used	EN 13697 : 2015				
Test-Product	***SOPURCLEAN NR***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.5 - 1 - 1.5 – 2 %	15 min	+4°C	10 g/l MILK	YES
	Name			**Strain**	**Log Reduction**

Target Organisms	*Pseudomonas aeruginosa*	ATCC 15442	Log↘ = 4.43 > 4 at 0.5%
	E.coli	ATCC 10536	Log↘ = 4.27 > 4 at 0.5 %
	Staphylococcus aureus	ATCC 6538	Log↘ = 4.71 > 4 at 1.0 %
	Enterococcus hirae	ATCC 10541	Log↘ = 4.21 > 4 at 0.5%
	Lactobacillus brevis	DSM 6235	Log↘ = 4.26 > 4 at 0.5 %
	Pediococcus damnosus	ATCC 29358	Log↘ = 4.29 > 4 at 0.5 %
	Enterobacter cloacae	DSM 6234	Log↘ = 4.35 > 4 at 0.5 %
	Salmonella typhimurium	ATCC 13311	Log↘ = 4.32 > 4 at 0.5 %
	Listeria monocytogenes	ATCC 19111	Log↘ = 4.08 > 4 at 0.5 %
	Campylobacter jejuni	ATCC 33291	Log↘ = 4.11 > 4 at 0.5 %
Conclusion as reported	According to EN 13697 (2015), the product ***SOPURCLEAN NR***, when diluted at 1.0 % (v/v), in hard water, possesses bactericidal activity in 15 minutes at +4°C under dirty conditions for dairies (10 g/l MILK). With the same use conditions, the product ***SOPURCLEAN NR*** is also active against *Lactobacillus brevis, Pediococcus damnosus, Enterobacter cloacae, Salmonella typhimurium, Listeria monytogenes and Campylobacter jejuni*.		
Remarks	Nothing to mention		
RMS conclusion	**Reliability 1: Key study** According to EN 13697 (2015) relevant for surface disinfection by soaking/dipping procedures, the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni*, *Listeria monocytogenes and Pediococcus damnosus*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Milk).		

d. Fungal surface test EN13697: obligatory and complementary strains

Name of the document	Sopurclean NR-fung-non-porous surface-CH59415_RT_R1_KEY				
EN Standard Used	EN 13697 : 2015				
Test-Product	***SOPURCLEAN NR***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.5 - 1 - 1.5 – 2 %	15 min	+4°C	10 g/l MILK	YES
Target Organisms	**Name**			**Strain**	**Log Reduction**
	Candida albicans			ATCC 10231	Log↘ = 3.32 > 3 at 1.0 %
	Saccharomyces cerevisiae			ATCC 9763	Log↘ = 3.06 > 3 at 0.5 %
	Saccharomyces cerevisiae diastaticus			DSM 70487	Log↘ = 3.13 > 3 at 0.5 %
Conclusion as reported	According to EN 13697 (2015), the product ***SOPURCLEAN NR***, when diluted at 1.0 % (v/v), in hard water, possesses yeasticidal activity in 15 minutes at +4°C under dirty conditions for dairies (10 g/l Milk). With the same use conditions, the product ***SOPURCLEAN NR*** is also active against *Saccharomyces cerevisiae.*				
Remarks	Nothing to mention				
RMS conclusion	**Reliability 1: Key study** According to EN 13697 (2015) relevant for surface disinfection by soaking/dipping procedures, the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses yeasticidal activity (including *Saccharomyces cerevisiae and Saccharomyces cerevisiae diastaticus)* in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Milk).				

According to the results of the 4 efficacy tests provided by the Applicant and summarised above, the product ***SOPURCLEAN NR***:

- Can be used during CIP procedures and possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni* and *Listeria monocytogenes*) and yeasticidal activity (including *Saccharomyces cerevisiae* and *Saccharomyces cerevisiae diastaticus*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Milk) when diluted at 1 % (v/v), in hard water. To be active against *Pediococcus damnosus*, the product *SOPURCLEAN NR* must be used at 1.5%.
- Can be used for surface disinfection by soaking/dipping procedures, spraying (conveyors, external machines, inside of cold storages/freezers, …) or manual cleaning procedures and possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni*, and *Listeria monocytogenes*) and yeasticidal activity (including *Saccharomyces cerevisiae* and *Saccharomyces cerevisiae diastaticus*) in 15 minutes at +4°C under "worst-case" dirty conditions (10 g/l Milk) when diluted at 1 % (v/v), in hard water.
- In case of outbreaks caused by *Pediococcus damnosus*, the product ***SOPURCLEAN NR*** must be used at 1.5% (in 15 min at +4°C under dirty conditions) during CIP and soaking/dipping procedures.

2. Supporting information:

Since the product was developed on the market for use in Belgium, a lot of data were generated in the past by the Applicant for this BP for which an authorisation was sought in Belgium.
As a purpose of clarity, all the data generated in the past are shown below as supportive information.

a. Bacterial suspension test EN 1276 (1997): obligatory strains

<table>
<tr><td>Name of the document</td><td colspan="5">6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276_FOOD</td></tr>
<tr><td>EN Standard Used</td><td colspan="5">EN 1276 : 1997</td></tr>
<tr><td>Test-Product</td><td colspan="5">SOPURCLEAN NR</td></tr>
<tr><td rowspan="2">Test Conditions</td><td>Concentrations</td><td>Contact time</td><td>T°C</td><td>Interfering Substance</td><td>$CaCO_3$ at 300 mg/kg</td></tr>
<tr><td>0.75 – 1 - 1.25 - 1.5 %</td><td>5 min</td><td>+20°C</td><td>3 g/l BSA: Dirty</td><td>YES</td></tr>
<tr><td rowspan="5">Target Organisms</td><td colspan="2">Name</td><td>Strain</td><td colspan="2">Log Reduction</td></tr>
<tr><td colspan="2">Pseudomonas aeruginosa</td><td>ATCC 15442</td><td colspan="2">Log↘ > 5 at 0.75 % - 5 min - +20°C – Dirty</td></tr>
<tr><td colspan="2">E.coli</td><td>ATCC 10536</td><td colspan="2">Log↘ > 5 at 0.75 % - 5 min - +20°C – Dirty</td></tr>
<tr><td colspan="2">Staphylococcus aureus</td><td>ATCC 6538</td><td colspan="2">Log↘ > 5 at 1.25 % - 5 min - +20°C – Dirty</td></tr>
<tr><td colspan="2">Enterococcus hirae</td><td>ATCC 8043</td><td colspan="2">Log↘ > 5 at 1.25 % - 5 min - +20°C – Dirty</td></tr>
<tr><td>Conclusion as reported</td><td colspan="5">According to EN 1276 (1997), the product SOPURCLEAN NR, when diluted at 1.25 % (v/v), in hard water, possesses bactericidal activity in 5 minutes at +20°C under dirty conditions (3 g/L bovine albumin).</td></tr>
<tr><td>Remarks</td><td colspan="5">- The study, from 02/2015, has been performed according to the 1997 version of the EN 1276 standard: in-force standard versions should have been used.
=> Reliability 2</td></tr>
</table>

RMS conclusion	According to EN 1276 (1997), the product ***SOPURCLEAN NR***, when diluted at 1.25 % (v/v), in hard water, possesses bactericidal activity in 5 minutes at +20°C under dirty conditions (3 g/L bovine albumin).

b. Bacterial suspension test EN 1276 (1997) practical conditions & strains

Name of the document	« 6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276-(1997)-IN PRACTICAL USE CONDITIONS-Sopurclean NR -20150120 (FOOD)"				
EN Standard Used	EN 1276 : 1997				
Test-Product	***SOPURCLEAN NR***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.75 - 1 - 1.5 %	15 min	+10°C	3 g/l BSA: Dirty	YES
Target Organisms	**Name**	**Strain**	**Log Reduction**		
	Pseudomonas aeruginosa	ATCC 15442	Log↘ > 5 at 1.0 % - 15 min - +10°C – Dirty		
	E.coli	ATCC 10536	Log↘ > 5 at 0.75 % - 15 min - +10°C – Dirty		
	Staphylococcus aureus	ATCC 6538	Log↘ > 5 at 1.5 % - 15 min - +10°C – Dirty		
	Salmonella typhimurium	ATCC 13311	Log↘ > 5 at 0.75 % - 15 min - +10°C – Dirty		
	Lactobacillus brevis	DSM 6235	Log↘ > 5 at 1.5 % - 15 min - +10°C – Dirty		
Conclusion as reported	According to EN 1276 (1997), the product ***SOPURCLEAN NR***, when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis* and *Salmonella typhimurium*) in 15 minutes at +10°C under dirty conditions (3 g/L bovine albumin).				
Remarks	- The study, from 02/2015, has been performed according to the 1997 version of the EN 1276 standard: in-force standard versions should have been used. **=> Reliability 2**				
RMS conclusion	Supportive information				

c. Fungal suspension test EN 1650 (1997): obligatory strains

Name of the document	"6_7-EVALUATION-OF-THE-FUNGICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1650-(1997)-IN-GENERAL-USE-CONDITIONS-SOPURCLEAN_NR-20150401"				
EN Standard Used	EN 1650 : 1997				
Test-Product	***SOPURCLEAN NR***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.75 - 1.5 - 2%	15 min	+20°C	3 g/l BSA: Dirty	YES
Target Organisms	**Name**	**Strain**	**Log Reduction**		
	Candida albicans	ATCC 10231	Log↘ > 4 at 0.75 % - 15 min - +20°C – Dirty		
Conclusion as reported	According to EN 1650 (1997), the product ***SOPURCLEAN NR***, when diluted at 0.75 % (v/v), in hard water, possesses yeasticidal activity in 15 minutes at 20°C under dirty conditions (3 g/L bovine albumin).				
Remarks	- The study, from 02/2015, has been performed according to the 1997 version of the EN 1650 standard: in-force standard versions should have been used ! **=> Reliability 2**				
RMS conclusion	Supportive information				

d. Bacterial surface test EN 13697 (2001): obligatory strains

Name of the document	"6-7-BACTERICIDAL-ACTIVITY-ON-NON-POROUS-SURFACE-SOPURCLEAN-NR-20150608" Technical Report N°301/2015 Rev.2
EN Standard Used	EN 13697 : 2001

Test-Product	***SOPURCLEAN NR***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.5 - 1 - 2 - 3 %	5 min	+20°C	3 g/l BSA: Dirty	YES
Target Organisms	**Name**	**Strain**	**Log Reduction**		
	Pseudomonas aeruginosa	ATCC 15442	Log↘ = 4.22 > 4 at 0.5 % - 5 min - +20°C – Dirty		
	E.coli	ATCC 10536	Log↘ = 4.01 > 4 at 1 % - 5 min - +20°C – Dirty		
	Staphylococcus aureus	ATCC 6538	Log↘ = 4.12 > 4 at 0.5 % - 5 min - +20°C – Dirty		
	Enterococcus hirae	ATCC 10541	Log↘ = 4.08 > 4 at 1 % - 5 min - +20°C – Dirty		
Conclusion as reported	According to EN 13697 (2001), the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity in 5 minutes at +20°C on surfaces (hard and non-porous) under dirty conditions (3 g/L bovine albumin).				
Remarks	Nothing to mention				
RMS conclusion	**Reliability 1: Key study** According to EN 13697 (2001), the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity in 5 minutes at +20°C on surfaces (hard and non-porous) under dirty conditions (3 g/L bovine albumin).				

e. Fungal surface test EN13697: (2001) obligatory strains

Name of the document	"6-7-FUNGICIDAL-ACTIVITY-ON-NON-POROUS-SURFACE-SOPURCLEAN-NR-20150608" Technical Report N°302/2015 Rev.2				
EN Standard Used	EN 13697 : 2001				
Test-Product	***SOPURCLEAN NR***				
Test Conditions	**Concentrations**	**Contact time**	**T°C**	**Interfering Substance**	**$CaCO_3$ at 300 mg/kg**
	0.5 – 1 - 2 - 3 %	15 min	+20°C	3 g/l BSA: Dirty	YES
Target Organisms	**Name**	**Strain**	**Log Reduction**		
	Candida albicans	ATCC 10231	Log↘ = 3.31 > 3 at 1 % - 15 min - +20°C – Dirty		
Conclusion as reported	According to EN 13697 (2001), the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses yeasticidal activity in 5 minutes at +20°C on surfaces (hard and non-porous) under dirty conditions (3 g/L bovine albumin).				
Remarks	Nothing to mention				
RMS conclusion	**Reliability 1: Key study** According to EN 13697 (2001), the product ***SOPURCLEAN NR***, when diluted at 1 % (v/v), in hard water, possesses yeasticidal activity in 15 minutes at +20°C on surfaces (hard and non-porous) under dirty conditions (3 g/L bovine albumin).				

According to the results of the 5 efficacy tests provided by the Applicant and summarised above:

- The product *SOPURCLEAN NR* is bactericidal (suspension) in the following conditions: 1.25% - +20°C – 5 min - in dirty conditions.
- The product SOPURCLEAN NR is yeasticidal (suspension) in the following conditions: 0.75% - + 20°C – 15 min – in dirty conditions.
- The product *SOPURCLEAN NR* is bactericidal (on surfaces) in the following conditions: 1 % - +20°C – 5 min - in dirty conditions.
- The product *SOPURCLEAN NR* is yeasticidal (on surfaces) in the following conditions: 1 % - +20°C – 15 min - in dirty conditions.

1.2.5.4 Mode of action, including time delay

Octanoic acid is an organic compound whose molecules contain a linear 8-carbon chain with a carboxyl group at the end, in which a carbon atom is bound to an oxygen atom by a double bond and to a hydroxyl group by a single bound.

Decanoic acid is an organic compound whose molecules contain a linear 10-carbon chain with a carboxyl group at the end, in which a carbon atom is bound to an oxygen atom by a double bond and to a hydroxyl group by a single bound.

As such the antifungal activity of fatty acids has been recognized for many years, it has been demonstrated that the fungitoxicity of these compounds is dependent on chain length, concentration and pH of the medium. In 1913 Kiesel from the Pasteur Institute found that the antimicrobial activity of saturated fatty acids increased as the number of carbon in the fatty acid chain increased up to 11 carbons, the branched-chain fatty acids were less active than those with straight chains and an equal number of carbon atoms, and substitution of hydrogen by hydroxyl decreased activity.
Cowles (1941) showed that at low pH values, fatty acids have a bactericidal action and their activity increases with chain length. The data showed that the antimicrobial activity of fatty acids increases with decreasing pH, provided that the low pH values do not make the compound so insoluble that a static concentration for the organism under test cannot be obtained. The change in activity related to the hydrogen ion concentration is much greater for the short-chain acids, suggesting that the ion of the long-chain compound exerts additional action. Many authors have discussed the antibacterial effects of the fatty acids, and the consensus is that their action is due to the undissociated molecule, not the anion. If this were so, their activity would be profoundly affected by pH, since this determines the degree of dissociation of the acid. More rapid killing at lower pH, which by itself was not lethal, supports this conclusion. Also yeasts are affected by fatty acids with short chain lengths (C10-C12). In conclusion, it can be said that below pH 3, neutralization of the short fatty acids is nearly complete and mainly undissociated acid molecules are present in aqueous solutions. The undissociated acid molecule permits a diffusion or penetration of these acid surfactants through the cell membrane, allowing the solubilization of phospholipids present in the cell membrane. This process will destabilize the micro-organisms cells and could become lethal through changes in e.g. osmotic pressure, hydrogen ion pump function etc.

1.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference**
Summary of key information for **Meta SPC1;3 & 4**							
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC***	Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Lactobacillus brevis* *Pediococcus damnosus* *Enterobacter cloacae* *Salmonella typhimurium* *Listeria monocytogenes* *Campylobacter jejuni*	**EN 1276:2009**	**Quantitative suspension test** - Temperature: +4°C - Contact time: 15 min - Concentrations tested: 1 - 1.5 – 2 – 2.5% - Interfering substance: 10g yeasts/L	**Conclusion as reported:** With obligatory test organisms: Bactericidal activity at 1.5% in 15 min at +4°C in presence of yeasts. With additional test organisms: Active against *Lactobacillus brevis*, *Enterobacter cloacae*, *Salmonella typhimurium*, *Listeria monocytogenes* or *Campylobacter jejuni* at 1.5% in 15 min at +4°C in presence of yeasts. Active against *Pediococcus damnosus* at 2% in 15 min at +4°C in presence of yeasts. **RMS conclusion:** Bactericidal activity	Sopurcip EC-bact suspension-CH59115_RT_KEY Technical Report No. CH – 591/2015 Rev.1 **Reliability 1** **Key study**

						(in suspension ⇔ CIP) *1.5%* *15 min* *+4°C* *Dirty conditions*	
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC***	Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis* Additional test organisms: *Saccharomyces cerevisiae* *Saccharomyces cerevisiae diastaticus*	**EN 1650 : 2008+2013**	**Quantitative suspension test** - Temperature: +4°C - Contact time: 15 min - Concentrations tested: 1 - 1.5 – 2 – 2.5% - Interfering substance: 10g yeasts/L (dirty)	**Conclusion as reported:** With obligatory test organisms: Yeasticidal activity at 1.5% in 15 min at +4°C in presence of yeasts. With additional test organisms: Active against *Saccharomyces cerevisiae* and *Saccharomyces cerevisiae diastaticus* at 1.5% in 15 min at +4°C in presence of yeasts. **RMS conclusion:** Bactericidal activity (in suspension ⇔ CIP) *1.5%* *15 min* *+4°C* *Dirty conditions*	Sopurcip EC-fung-suspension-CH59215_RT_KEY Technical Report No. CH – 592/2015 Rev.1 **Reliability 1** **Key study**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC***	Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa*	**EN 13697:2001**	**Quantitative carrier test – hard non-porous surfaces** - Temperature: +4°C	**Conclusion as reported:** With obligatory test organisms: Bactericidal activity at 1.5% in 15 min at	Sopurcip EC-bact-non-porous surface-CH58915_RT_KEY Technical Report No. CH – 589/2015 Rev 1

			Staphylococcus aureus Additional test organisms: *Lactobacillus brevis* *Pediococcus damnosus* *Enterobacter cloacae* *Salmonella typhimurium* *Listeria monocytogenes* *Campylobacter jejuni*		- Contact time: 15 min - Concentrations tested: 1 - 1.5 – 2 – 2.5% - Interfering substance: 10g yeasts/L (dirty)	+4°C in presence of yeasts. With additional test organisms: Active against *Lactobacillus brevis*, *Pediococcus damnosus*, *Enterobacter cloacae*, *Salmonella typhimurium*, *Listeria monocytogenes* or *Campylobacter jejuni* at 1.5% in 15 min at +4°C in presence of yeasts. **RMS conclusion :** Bactericidal activity (on surfaces ⇔ soaking/dipping) *1.5%* *15 min* *+4°C* *Dirty conditions*	**Reliability 1** **Key study**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC***	Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis* Additional test organisms: *Saccharomyces cerevisiae* *Saccharomyces cerevisiae diastaticus*	**EN 13697:2001**	**Quantitative carrier test – hard non-porous surfaces** Test temperature: +4°C Contact time: 15 min Concentrations tested: 1.5 – 2 – 2.5% Interfering substance:	**Conclusion as reported:** With obligatory test organisms: Yeasticidal activity at 1.5% in 15 min at +4°C in presence of yeasts. With additional test organisms: Active against *Saccharomyces cerevisiae* and	Sopurcip EC-fung-non-porous surface-CH59015_RT_KEY Technical Report No. CH – 590/2015 Rev 1 **Reliability 1** **Key study**

					10g yeasts/L (dirty)	*Saccharomyces cerevisiae diastaticus* at 1.5% in 15 min at +4°C in presence of yeasts. **RMS conclusion:** Yeasticidal activity (on surfaces ⇔ soaking/dipping) *1.5%* *15 min* *+4°C* *Dirty conditions*	
Additional supportive information							
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC***	Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276:1997**	**Quantitative suspension test** - Temperature: +20°C - Contact time: 5 min - Concentrations tested: 0.75 – 1 – 1.5% - Interfering substance: BSA 0.3g/L (clean) and 3g/L (dirty)	**Conclusion as reported:** Bactericidal activity at 1% in 5 min at +20°C in dirty conditions. **RMS conclusion:** Bactericidal activity *1%* *5 min* *+20°C* *Dirty conditions*	"6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276-(1997)-IN GENERAL USE CONDITIONS-SOPURCIP_EC-20150120" **Reliability 2**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC* (breweries)**	Obligatory test organisms: *E.coli* *Pseudomonas aeruginosa* Additional test organisms: *Lactobacillus brevis* *Pediococcus damnosus*	**EN 1276:1997**	**Quantitative suspension test** - Temperature: +10°C - Contact time: 15 min - Concentrations tested: 0.75 – 1 – 1.5% - Interfering substance:	**Conclusion as reported:** Bactericidal activity at 1% in 15 min at +10°C in dirty conditions (10 g/L Yeast Extract - breweries) **RMS conclusion:** **Supportive information**	"6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276-(1997)-IN PRACTICAL USE CONDITIONS-SOPURCIP_EC-20150120" **Supportive information**

					BSA 0.3g/L (clean) and 10g yeasts/L (dirty)		
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC***	Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	**EN 1650:1997**	**Quantitative suspension test** - Temperature: +20°C - Contact time: 15 min - Concentrations tested: 7.5 – 10 – 12.5% - Interfering substance: BSA 0.3g/L (clean) and 3g/L (dirty)	**Conclusion as reported:** Yeasticidal activity at 7.5% in 15 min at +20°C in clean & dirty conditions **RMS conclusion: Supportive information**	"6_7-EVALUATION-OF-THE-FUNGICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1650-(1997)-IN GENERAL USE CONDITIONS-SOPURCIP_EC-20150120" **Supportive information**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP and Soaking/dipping procedures	***SOPURCIP EC*** **(breweries)**	Obligatory test organisms: None Additional test organisms: *Saccharomyces cerevisiae* *Saccharomyces cerevisiae diastaticus*	**EN 1650 : 1997**	**Quantitative suspension test** - Temperature: +10°C - Contact time: 15 min - Concentrations tested: 0.75 – 1 – 1.5% - Interfering substance: BSA 0.3g/L (clean) and 10g yeasts/L (dirty)	**Conclusion as reported:** Active against *Saccharomyces cerevisiae* at 1% in 15 min at +10°C in clean & dirty conditions Active against *Saccharomyces cerevisiae diastaticus* at 0.75% in 15 min at +10°C in clean & dirty conditions **RMS conclusion: Supportive information**	"6_7-EVALUATION-OF-THE-FUNGICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1650-(1997)-IN GENERAL USE CONDITIONS-SOPURCIP_EC-20150120" **Reliability 3**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference**
Summary of key information for **Meta SPC2**							
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping; Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Lactobacillus brevis* *Pediococcus damnosus* *Enterobacter cloacae* *Salmonella typhimurium* *Listeria monocytogenes* *Campylobacter jejuni*	**EN 1276:2009**	**Quantitative suspension test** - Temperature: +4°C - Contact time: 15 min - Concentrations tested: 0.5 - 1 – 1.5 - 2 % - Interfering substance: Milk (Dirty conditions)	**Conclusion as reported :** With obligatory test organisms: Bactericidal activity at 1% in 15 min at +4°C in presence of milk. With additional test organisms (excluding *Pediococcus damnosus*): Bactericidal activity at 1% in 15 min at +4°C in presence of milk. With *Pediococcus damnosus* : Bactericidal activity at 1.5% in 15 min at +4°C in presence of milk. **RMS conclusion:** Bactericidal activity (in suspension ⇔ CIP) *1 % 15 min+4°C*	Sopurclean NR-bact-suspension-CH59515_RT_R1_KEY **Reliability 1** **Key study**

						Dirty conditions	
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping and /or Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis* Additional test organisms: *Saccharomyces cerevisiae* *Saccharomyces cerevisiae diastaticus*	**EN 1650: 2008+2013**	**Quantitative suspension test** - Temperature: +4°C - Contact time: 15 min - Concentrations tested: 0.5 - 1 – 1.5 - 2 % - Interfering substance: Milk (Dirty conditions)	**Conclusion as reported:** With obligatory test organisms: Yeasticidal activity at 1% in 15 min at +4°C in presence of milk. With additional test organisms: active against *Saccharomyces cerevisiae* at 1% in 15 min at +4°C in presence of milk. **RMS conclusion:** Yeasticidal activity (in suspension ⇔ CIP) *1 %* *15 min* *+4°C* *Dirty conditions*	Sopurclean NR-fung-suspension- corrected CH59615_RT_R1_KEY **Reliability 1** **Key study**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping and /or Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Lactobacillus brevis*	**EN 13697:2001**	**Quantitative carrier test – hard non-porous surfaces** - Temperature: +4°C - Contact time: 15 min - Concentrations tested: 0.5 - 1 – 1.5 - 2 %	**Conclusion as reported :** With obligatory test organisms: Bactericidal activity at 1% in 15 min at +4°C in presence of milk. With additional test organisms (excluding	Sopurclean NR-bact-non-porous surface-CH59315_RT_R1_KEY **Reliability 1** **Key study**

			Pediococcus damnosus *Enterobacter cloacae* *Salmonella typhimurium* *Listeria monocytogenes* *Campylobacter jejuni*		- Interfering substance: Milk (Dirty conditions)	*Pediococcus damnosus*): Bactericidal activity at 1% in 15 min at +4°C in presence of milk. **RMS conclusion:** Bactericidal activity (on surfaces ⇔ spraying; soaking/dipping; manual cleaning) *1%* *15 min* *+4°C* *Dirty conditions*	
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping and /or Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis* Additional test organisms: *Saccharomyces cerevisiae* *Saccharomyces cerevisiae diastaticus*	**EN 13697:2001**	**Quantitative carrier test – hard non-porous surfaces** - Temperature: +4°C - Contact time: 15 min - Concentrations tested: 0.5 - 1 – 1.5 - 2 % - Interfering substance: Milk (Dirty conditions)	**Conclusion as reported:** With obligatory test organisms: Yeasticidal activity at 1% in 15 min at +4°C in presence of milk. With additional test organisms: active against *Saccharomyces cerevisiae* at 1% in 15 min at +4°C in presence of milk. **RMS conclusion:** Yeasticidal activity (on surfaces ⇔ spraying; soaking/dipping; manual cleaning)	Sopurclean NR-fung-non-porous surface-CH59415_RT_R1_KEY **Reliability 1** **Key study**

						1% *15 min* *+4°C* *Dirty conditions*	
Additional supportive information							
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping; Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276:1997**	**Quantitative suspension test** - Temperature: +20°C - Contact time: 5 min - Concentrations tested: 0.75 – 1 – 1.25 - 1.5% - Interfering substance: BSA 0.3g/L (clean) and 3g/L (dirty)	**Conclusion as reported:** Bactericidal activity at 1.25% in 5 min at +20°C in dirty conditions **RMS conclusion:** Bactericidal activity *1.25%* *5 min* *+20°C* *Dirty conditions*	6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276_FOOD **Reliability 2**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping; Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* Additional test organisms: *Lactobacillus brevis* *Salmonella typhimurium*	**EN 1276:1997**	**Quantitative suspension test** - Temperature: +10°C - Contact time: 15 min - Concentrations tested: 0.75 - 1 – 1.5% - Interfering substance: BSA 0.3g/L (clean) and 3g/L (dirty)	**Conclusion as reported:** Active against *E.coli; Pseudomonas aeruginosa; Staphylococcus aureus; Lactobacillus brevis and Salmonella typhimurium* at 1.5% in 15 min at +10°C in dirty conditions **RMS conclusion: Supportive information**	« 6_7-EVALUATION-OF-THE-BACTERICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1276-(1997)-IN PRACTICAL USE CONDITIONS-SOPURCIP_EC-20150120 (FOOD)" **Reliability 2 Supportive information**

PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping; Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Candida albicans*	**EN 1650:1997**	**Quantitative suspension test** - Temperature: +20°C - Contact time: 15 min - Concentrations tested: 0.75 – 1.5 - 2% - Interfering substance: BSA 0.3g/L (clean) and 3g/L (dirty)	**Conclusion as reported:** Yeasticidal activity at 0.75% in 15 min at +20°C in dirty conditions **RMS conclusion: Supportive information**	"6_7-EVALUATION-OF-THE-FUNGICIDAL-ACTIVITY-ACCORDING-TO-THE-EU-STANDARD-TEST-METHOD-EN-1650-(1997)-IN-GENERAL-USE-CONDITIONS-SOPURCLEAN_NR-20150401" **Reliability 2 Supportive information**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping; Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 13697:2001**	**Quantitative carrier test – hard non-porous surfaces** - Temperature: +20°C - Contact time: 5 min - Concentrations tested: 0.5 - 1 – 2 – 3% - Interfering substance: BSA 0.3g/L (clean) and 3g/L (dirty)	**Conclusion as reported:** Bactericidal activity at 1% in 5 min at +20°C in dirty conditions **RMS conclusion:** Bactericidal activity (on surfaces ⇔ soaking/dipping) *1%* *5 min* *+20°C* *Dirty conditions*	"6-7-BACTERICIDAL-ACTIVITY-ON-NON-POROUS-SURFACE-SOPURCLEAN-NR-20150608" Technical Report N°301/2015 Rev.2 **Reliability 1 Key study**
PT4 **"Food and feed area"**	- Concentrate to dilute in tap water - CIP; Spraying; Soaking/dipping; Manual cleaning	***SOPURCLEAN NR***	Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	**EN 13697:2001**	**Quantitative carrier test – hard non-porous surfaces**	**Conclusion as reported:** Yeasticidal activity at 1% in 15 min at	Doc N° CH-302/2015 **Reliability 1 Key study**

					- Temperature: +20°C - Contact time: 15 min - Concentrations tested: 0.5 - 1 – 2 – 3% - Interfering substance: BSA 0.3g/L (clean) and 3g/L (dirty)	+20°C in dirty conditions **RMS conclusion:** Yeasticidal activity (on surfaces ⇔ soaking/dipping) *1%* *15 min* *+20°C* *Dirty conditions*	

Conclusion on the efficacy of the product

Meta SPC1, 3 and 4: *SOPURCIP EC* (representative product)
(*Please refer to the justification included in the section related to Meta SPC1*).

For disinfection by either CIP (for Meta SPC 1, 3 and 4 products) or soaking/dipping (for Meta SPC 1 products) procedures without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the product ***SOPURCIP EC***, when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity and yeasticidal activity in 15 minutes at +4°C (and above, up to +20-25°C).
In case of outbreaks caused by *Pediococcus damnosus*, the product ***SOPURCIP EC*** must be used at 2%.
Since the efficacy of the representative product ***SOPURCIP EC*** has been proven under a worst-case scenario including the more critical Interfering Substance (i.e. yeast extract), the product could be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.
Please note that, for uses in slaughterhouse-meat industry, a cleaning step is always mandatory.

Meta SPC2: *SOPURCLEAN NR* (representative product)

For disinfection by CIP, soaking/dipping, spraying and manual cleaning procedures without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the product *SOPURCLEAN NR*, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity and yeasticidal activity in 15 minutes at +4°C (and above, up to +20-25°C).
In case of outbreaks caused by *Pediococcus damnosus*, the product ***SOPURCLEAN NR*** must be used at 1.5%.
Since the efficacy of the representative product *SOPURCLEAN NR* has been proven under a worst-case scenario including the more critical Interfering Substance (i.e. skimmed milk), the product could be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.
Please note that, for uses in slaughterhouse-meat industry, a cleaning step is always mandatory.

META SPC 1

General claim:

For disinfection by either CIP or soaking/dipping procedures without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the products of ***META SPC 1*** when diluted at 1.5 % (v/v), in hard water, possesses bactericidal and yeasticidal activity in 15 minutes at +4°C (and above, up to +20-25°C).
The product can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

Specific claim:

For disinfection by either CIP or soaking/dipping procedures without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the product of ***META SPC 1*** when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni, Listeria monocytogenes)* and yeasticidal activity (including *Saccharomyces cerevisiae and Saccharomyces cerevisiae diastaticus)* in 15 minutes at +4°C (and above, up to +20-25°C).
In case of outbreaks caused by *Pediococcus damnosus*, the products ***of Meta SPC1*** must be used at 2%.

The product can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.
Please note that, for uses in slaughterhouse-meat industry, a cleaning step is always mandatory.

META SPC 2

General claim:
For disinfection by CIP, soaking/dipping, spraying and manual cleaning procedures without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the products of ***META SPC 2*** when diluted at 1 % (v/v), in hard water, possesses bactericidal activity and yeasticidal activity in 15 minutes at +4°C (and above, up to +20-25°C).
The products can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.
Specific claim:

For disinfection by CIP, soaking/dipping, spraying and manual cleaning procedures without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the products of ***META SPC 2***, when diluted at 1 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni, Listeria monocytogenes*) and yeasticidal activity (including *Saccharomyces cerevisiae and Saccharomyces cerevisiae diastaticus)* in 15 minutes at +4°C (and above, up to +20-25°C).
In case of outbreaks caused by *Pediococcus damnosus*, the products ***of Meta SPC2*** must be used at 1.5%.

The products can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.
Please note that, for uses in slaughterhouse-meat industry, a cleaning step is always mandatory.

Meta SPC 3

General claim:

For disinfection by CIP without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the products of ***META SPC 3*** when diluted at 1.5 % (v/v), in hard water, possesses bactericidal and yeasticidal activity in 15 minutes at +4°C (and above, up to +20-25°C).
The product can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

Specific claim:

For disinfection by CIP without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the product of ***META SPC 3*** when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni, Listeria monocytogenes*) and yeasticidal activity (including *Saccharomyces cerevisiae and Saccharomyces cerevisiae diastaticus)* in 15 minutes at +4°C (and above, up to +20-25°C).
In case of outbreaks caused by *Pediococcus damnosus*, the products of Meta SPC3 must be used at 2%.

The product can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

Please note that, for uses in slaughterhouse-meat industry, a cleaning step is always mandatory.

Meta SPC 4

General claim:

For disinfection by CIP without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the products of ***META SPC 4*** when diluted at 1.5 % (v/v), in hard water, possesses bactericidal and yeasticidal activity in 15 minutes at +4°C (and above, up to +20-25°C).
The product can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

Specific claim:

For disinfection by CIP without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the product of ***META SPC 4*** when diluted at 1.5 % (v/v), in hard water, possesses bactericidal activity (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni, Listeria monocytogenes*) and yeasticidal activity (including *Saccharomyces cerevisiae and Saccharomyces cerevisiae diastaticus)* in 15 minutes at +4°C (and above, up to +20-25°C).
In case of outbreaks caused by *Pediococcus damnosus*, the products of Meta SPC4 must be used at 2%.

The product can be used in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.
Please note that, for uses in slaughterhouse-meat industry, a cleaning step is always mandatory.

1.2.5.6 Occurrence of resistance and resistance management

Resistance is not expected when used as recommended. Intensive use over several decades did not lead to the development of significant resistance levels among field populations.
Users should be vigilant of resistance development (especially considering the intensive industrial uses of the products) and report suspected outbreaks to the relevant authorities.

1.2.5.7 Known limitations

As stated by the applicant, the products are intended to be used via CIP with recovery of the cleaning-disinfecting solution.
The disinfection step is always preceded by a pre-rinsing and cleaning (caustic shot) to dissolve and remove all organic and inorganic soiling.
After each disinfection cycle, the use solution is recovered (automatically) and stored in a dedicated tank. Before the next disinfection cycle, the active substances content of the use solution is measured and adjusted, when necessary, (automatically or manually) by adding fresh concentrated product (jargon word "topping up"). This will allow to maintain the required active substance level to meet the expected efficacy.
Only practical experience and industry best practices can determine how long the use solution may be re-used before final discard to the WWTP.
As the assessment of efficacy was done based on an overall "worst case" situation, meaning in presence of high organic loads (skimmed milk or yeast) for both meta SPC's, the claim of CIP with re-use could be authorized under the hereabove mentioned operational conditions.

For disinfection procedures in slaughterhouses, a cleaning step (with a cold alkaline solution) before disinfection is always mandatory.

Diluted and undiluted products of **Meta SPC 1, 3 and 4** should have a pH < 2.

1.2.5.8 Evaluation of the label claims

Based on the efficacy tests submitted and validated, the following claims can be supported. Thus, representative product ***SOPURCIP EC*** for **Meta SPC 1, 3 and 4** can be granted with the following claimed use conditions:

- Can be used for disinfection by either CIP or soaking/dipping procedures, in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.
- Is a combined cleaning-disinfectant (even if a pre-rinsing is always recommended and usually performed by the users).

  For disinfection procedures in slaughterhouses, a cleaning step (with a cold alkaline solution) before disinfection is always mandatory.

  Possesses bactericidal (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni, Listeria monocytogenes*) & yeasticidal (including *Saccharomyces cerevisiae and Saccharomyces cerevisiae diastaticus)* activity when diluted at 1.5 % (v/v) in 15 minutes at +4°C (and above, up to +20-25°C).

After dilution, the user should check that the diluted products have a pH ≤ 2. In case of outbreaks caused by *Pediococcus damnosus*, the products of Meta SPC4 must be used at 2%.

- The dipping solution must replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
- In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

Please note that suggested claim is considered applicable to all products present in meta SPC 1, 3 and 4 of the ***SOPURCLEAN BPF***.

Based on the efficacy tests submitted and validated, the following claims can be supported. Thus, representative product ***SOPURCLEAN NR*** for **Meta SPC 2** can be granted with the following claimed use conditions:

- Can be used for disinfection by either CIP, spraying, soaking/dipping or manual wiping/mopping procedures, in various food & feed industries including manufacture of drinks, manufacture of dairy food, slaughterhouse-meat industry, vegetables & fruits preservation, manufacture of dairy oils-fat, bakery & alimentary pasta, storage of grains-flour (malting industry), candy industry and manufacture of feed products.

  About the disinfection by manual wiping/mopping cleaning (for *meta* SPC 2 products), a sentence such as "items to be disinfected have to stay sufficiently wet at least 15 min during mopping to allow optimal disinfection" should be mentioned on the label.

- Is a combined cleaning-disinfectant (even if a pre-rinsing is always recommended and usually performed by the users).

  For disinfection procedures in slaughterhouses, a cleaning step (with a cold alkaline solution) before disinfection is always mandatory.

- Possesses bactericidal (including *Lactobacillus brevis, Enterobacter cloacae, Salmonella typhimurium, Campylobacter jejuni, Listeria monocytogenes*) & yeasticidal (including *Saccharomyces cerevisiae and Saccharomyces cerevisiae diastaticus)* activity when diluted at 1 % (v/v) in 15 minutes at +4°C (and above, up to +20-25°C).

In case of outbreaks caused by *Pediococcus damnosus*, the products of Meta SPC2 must be used at 1.5%.

- The dipping solution must replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
- In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

Please note that suggested claim is considered applicable to all products present in meta SPC 2 of the ***SOPURCLEAN BPF***.

1.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Nothing to mention.

1.2.6 Risk assessment for human health

Two of the meta SPC1 products are identical to the example products in the PT4 CAR octanoic acid and CAR decanoic acid, namely *Septacid BN* and *Septacid BN PS*, application CIP.
The other products under evaluation are very similar to *Septacid BN* and *Septacid BN PS*. Given the high degree of similarity no additional testing has been asked nor submitted for the evaluation of the ***SOPURCLEAN BPF*** with octanoic and decanoic acid, meta SPC1, 2, 3 and 4. Consequently, the risk assessment for human health has been performed relying on data from the octanoic and decanoic CARs and the SDS of the non-active co-formulants.

The data for medium chain triglycerides (MCTs) as well as for the free fatty acids do not indicate any adverse systemic effect and support NOAELs above 1000 mg/kg bw/d. Daily human uptake of fatty acids as food contents is, e.g. according to Henderson et al. 2003 about 900 mg/kg bw day and the metabolic pathways are similar for all fatty acids, that is complete catabolism for energy supply or conversion to fat suitable for storage. Therefore, the derivation of a systemic AEL is considered unnecessary. Risk assessment is focused on risk for local effects.
According to the CARs of octanoic and decanoic acid, the available data for the active substances are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AECs). In any case the data for the active substances would be inadequate for the assessment of the biocidal products that are different with regard to pH, solvents and other ingredients. Therefore, a qualitative risk assessment for local effects of the product was preferred.
This assessment covers all biocidal products in the ***SOPURCLEAN BPF*** which all reveal similar amounts of octanoic and decanoic acid (the percentage of both active ingredients together is at minimum 1.8% for meta SPC1 and 3% for meta SPC 2, 3 and 4 and at maximum 3% for all meta SPC (1, 2, 3 and 4) and similar composition (differing in the kind of applied mineral acid). For practical reasons, ***SOPURCLEAN BPF*** products is used as name within the following text referring to all products contained in the respective meta SPCs.

1.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No studies on skin and eye irritation are available for any member of the ***SOPURCLEAN BPF***. However, the composition of the products indicates that all products of the ***SOPURCLEAN BPF*** have a pH < 2 and cause severe burns. This results in classification of the different products as Corrosive Cat 1A, H314 (total Weight of Evidence evaluation).

Tests on active substances
No specific guideline studies are available for Octanoic or Decanoic acid. However, sufficient publications are available to assess the irritation potential by a total weight of evidence approach (please refer to Annex section #2.2).

Eye irritation

No studies on skin and eye irritation are available for any member of the SOPURCLEAN Biocidal Product Family. However, the composition of the products indicates that all products of the SOPURCLEAN Biocidal Product Family have a pH < 2 and cause severe burns. This results in classification of the different products as Corrosive Cat 1A, H314.

Tests on active substances (please refer to Annex section #2.2).

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Cause severe burns (pH<2 for all concentrated products of the SOPURCLEAN BPF)
Justification for the value/conclusion	No studies on skin and eye irritation are available for any member of the ***SOPURCLEAN BPF***. However, the composition of the products indicates that all products of the ***SOPURCLEAN BPF*** have a pH < 2 and cause severe burns. This results in classification of the different products as Corrosive Cat 1A, H314 (total Weight of Evidence evaluation).
Classification of the product according to CLP	Skin corrosion Cat.1A, H314

Respiratory tract irritation

Considering the strong skin and eye irritation properties of the members of the ***SOPURCLEAN BPF*** also respiratory tract hazard has to be assumed. However, the only available quantitative information for effects via inhalation stems from acute inhalation studies and is summarized in the doc IIA of the active substances. The available data are not sufficient for classification for respiratory irritation (STOT – single exposure, category 3) since the EU CLP regulation 1272/2008 supports respective classification only when largely based on human respiratory data.

The above mentioned explanation is valid for all products of the ***SOPURCLEAN BPF*** with exception of those products which belongs to the Meta-SPC 2 or 4. As mentioned in **Error! Reference source not found.** (overview of SoCs), methane sulfonic acid (GCL of 20%) and propionic acid (SCL of 10%) are classified as STOT SE 3. Methane sulfonic acid is present in Meta-SPC 4 at levels > 20% hence requiring meta-SPC 4 OP to be classified as STOT SE 3 (H335). Propionic acid is present in meta-SPC 2 at levels <20% but >10% hence requiring the meta-SPC 2 to be classified as STOT SE 3 (H335) as well.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The only available quantitative information for effects via inhalation stems from acute inhalation studies and is summarized in the doc IIA of the active substances. The available data are not sufficient for classification for respiratory irritation (STOT – single exposure, category 3) since the EU CLP regulation 1272/2008 supports respective classification only when largely based on human respiratory data. However, two co-formulants which are substances of concern are classified as STOT SE3: methane sulfonic acid (GCL of 20%) and propionic acid (SCL of 10%). Their presence in respectively SOPURCLEAN CIP OP and SOPURCLEAN NR in levels above the concentration limits triggers classification of both products as STOT SE 3 in absence of additional data on the products themselves.
Classification of the product according to CLP	No classification supported for products in meta SPC 1 and meta SPC 3. Classification as STOT SE 3 (H335) warranted for products in meta SPC 2 and meta SPC 4.

Skin sensitization

No data is available in the products of the SOPURCLEAN BPF in relation to skin sensitization. Therefore, this assessment is based on the information available on the ingredients. None of the ingredients of the members of the ***SOPURCLEAN BPF*** under evaluation is classified as skin sensitizer, which would trigger a classification for the formulation. However, evaluation of the other ingredients is only based on information from the SDS and consultation of the ECHA dissemination web page.

Tests on active substances

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle,** **Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
LLNA	Mouse	C8 fatty acid, Vehicle: acetone:olive oil	Dose / SI 10% / 0.7 25% / 1.0 50% / 1.6 Not sensitising		Gerberick et al, 2004; DocIII-A6.1.5/1
LLNA OECD 429	Mouse	C10 fatty acid, Vehicle: acetone:olive oil	Dose / SI 25% / 3.3 50% / 207 70% / 4.9 erythema Control: HCA 25% / 12.2 WoE evaluation: not sensitising		Weber, 2006; DocIII-A6.1.5/2

Summary table of human data on skin sensitisation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Human	C8 fatty acid	25 volunteers, 1% concentration; occlusive application for 5 alternate 48 hour periods. 10-14 day after treatment, challenge was performed.	0/25 volunteers sensitised Not-sensitizing, but low relevance because of low test concentration and since no information about ethical criteria explicit	DocIIA: Cited in BIBRA 1988
Human	C10 fatty acid	Human maximisation test, 28 volunteers, 1% concentration Occlusive application of test material for 5 alternate 48 hour periods. 10-14 day after treatment, challenge was performed.	0/28 volunteers sensitised Not-sensitizing, but low relevance because of low test concentration and since no information about ethical criteria explicit	DocIIA: cited in Opdyke 1979

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Non sensitising
Justification for the value/conclusion	The active substances are found non-sensitising in the LLNA. None of the ingredients of the members of the ***SOPURCLEAN BPF*** under evaluation is classified as skin sensitizer, which would trigger a classification for the formulations. There are no reactions known between the components that would result in a sensitizer.
Classification of the product according to CLP	None

Respiratory sensitization (ADS)

No data are available to estimate the hazard for respiratory sensitization. However it is assumed that the main toxicological mechanism of action is irritation by direct membrane destruction and consequent inflammatory reactions and there are no metabolites of concern.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Non sensitising
Justification for the value/conclusion	It is assumed that the main toxicological mechanism of action is irritation by direct membrane destruction and consequent inflammatory reactions and there are no metabolites of concern.
Classification of the product according to CLP	None

Acute toxicity

There is only limited acute toxicity information available as only oral and dermal toxicity tests are available for *Septacid BN* and *Septacid BN PS*. These tests were limit tests. Details are provided below. No additional acute toxicity tests have been performed or are deemed required on any of the other products of the ***SOPURCLEAN BPF*** (Sopurclean BN, Sopurclean BN PS, Sopurclean OP N, Sopurclean CIP OP, Sopurcip EC and Sopurclean NR). This based on the fact that the Biocidal Products of the SOPURCLEAN Biocidal Product Family all have corrosive properties in undiluted form (requiring classification of the products as Skin Corr 1A (H314). Consequently, additional testing is considered scientifically unjustified.

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 423, GLP Oral limit test	Rat, Crl (WI) WU BR, 3/group	Septacid BN 200 mg/kg bw (because corrosive: pH and composition)	No mortality	n.a.		B6.6.1.1/ 01 (BPD dossier)
OECD 423, GLP Oral limit test	Rat, Crl (WI) WU BR, 3/group	Septacid BN-PS 200 mg/kg bw (because corrosive: pH and composition)	No mortality	n.a.		B6.6.1.1/ 02 (BPD dossier)

There is no human data available.

Data waiving
No additional acute oral toxicity tests have been performed or are deemed required on any of the additional products of the ***SOPURCLEAN BPF*** (Sopurclean BN, Sopurclean BN PS, Sopurclean OP N, SopurcleanCIP OP, Sopurcip EC and Sopurclean NR). This based on the fact that the Biocidal Products of the SOPURCLEAN Biocidal Product Family all have corrosive properties in undiluted form (requiring classification of the products as Skin Corr 1A (H314). Consequently, additional testing is considered scientifically unjustified.

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50: n.a., no mortality
Justification for the selected value	Classification of the corrosive products for acute systemic toxicity is not necessary and acute toxicity testing of corrosives is not allowed according to the EU Testing Methods Regulation. No deaths occurred for the products *Septacid BN* and *Septacid BN-PS*, which indicates that the LD50 is above the need for classification as toxic if swallowed. For all ingredients of the members of the SOPURCLEAN Biocidal Product Family under evaluation the information on acute toxicity is available and the calculation method does not indicate a need for classification. The composition of the products indicates that the products cause severe burns. Respective classification and labelling is considered appropriate and sufficient to address the acute hazard.

Classification of the products according to CLP	None

Acute toxicity by inhalation

There is only limited acute toxicity information available as only oral and dermal toxicity tests are available for *Septacid BN* and *Septacid BN PS*. No additional acute toxicity tests have been performed or are deemed required on any of the other products of the ***SOPURCLEAN BPF*** (Sopurclean BN, Sopurclean BN PS, Sopurclean OP N, Sopurclean CIP OP, Sopurcip EC and Sopurclean NR). This based on the fact that the Biocidal Products of the SOPURCLEAN Biocidal Product Family all have corrosive properties in undiluted form (requiring classification of the products as Skin Corr 1A (H314). Consequently, additional testing is considered scientifically unjustified.

The above mentioned explanation is valid for all products of the ***SOPURCLEAN BPF*** with exception of those products which belongs to meta-SPC 3 and present in concentrations triggering classification of the product. As mentioned in **Error! R eference source not found.** (overview of SoCs), nitric acid is classified acute inhalation toxic category 3. Nitric acid is present in Meta-SPC 3 at levels requiring it to be classified as Acute Inhalation Tox Cat. 4. Please see additional information in the Confidential Annex.

Data waiving
No acute inhalation toxicity tests have been performed or are deemed required on any of the products of the ***SOPURCLEAN BPF*** (Sopurclean BN, Sopurclean BN PS, Sopurclean OP N, Sopurclean CIP OP, Sopurcip EC, Sopurclean NR, Septacid BN and Septacid BN PS). This based on the fact that the Biocidal Products of the SOPURCLEAN Biocidal Product Family all have corrosive properties in undiluted form (requiring classification of the products as Skin Corr 1A (H314). Consequently, additional testing is considered scientifically unjustified.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	n.a.
Justification for the selected value	The composition of the products indicates that the products cause severe burns. Respective classification and labelling is considered appropriate and sufficient to address the acute inhalation hazard for the products of the SOPURCLEAN BPF. However, one co-formulant which is a substances of concern is classified as acute inhalation toxic Cat. 3 (nitric acid). In absence of additional data on the product itself, the presence of nitric acid in SOPURCLEAN OP N triggers classification of the product as Acute Toxic Cat. 4.
Classification of the product according to CLP	No classification applicable for all products in meta SPC 1,2 and 4. Classification of the product of meta SPC 3 as Acute Toxic Cat. 4.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity

Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 402, limit test, GLP	Rat, Crl(WI) WU BR, 5/group	Septacid BN 400 mg/kg bw	No mortality Strong skin irritation when applied for 24 hrs as 8% aqueaous solution	n.a.		B6.1.2/01 (BPD dossier)
OECD 402, limit test, GLP	Rat, Crl(WI) WU BR, 5/group	Septacid BN-PS 400 mg/kg bw	No mortality No skin irritation when applied for 24 hrs as 8% aqueaous solution	n.a.		B6.1.2/02 (BPD dossier)

There is no human data available.

Data waiving
No additional acute dermal toxicity tests have been performed or are deemed required on any of the additional products of the ***SOPURCLEAN BPF*** (Sopurclean BN, Sopurclean BN PS, Sopurclean OP N, SopurcleanCIP OP, Sopurcip EC and Sopurclean NR). This based on the fact that the Biocidal Products of the SOPURCLEAN Biocidal Product Family all have corrosive properties in undiluted form (requiring classification of the products as Skin Corr 1A (H314). Consequently, additional testing is considered scientifically unjustified.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50: n.a., no mortality
Justification for the selected value	Classification of the corrosive products for acute systemic toxicity is not necessary and acute toxicity testing of corrosives is not allowed according to the EU Testing Methods Regulation. No deaths occurred for the products Septacid BN and Septacid BN-PS, which indicates that the LD50 is above the need for classification as toxic when in contact with skin. For all ingredients of the members of the SOPURCLEAN Biocidal Product Family under evaluation the information on acute toxicity is available and the calculation method does not indicate a need for classification. The composition of the products indicates that the products cause severe burns. Respective classification and labelling is considered appropriate and sufficient to address the acute hazard.
Classification of the products according to CLP	None

Acute toxicity data on the active substances

Summary table of animal studies on acute toxicity – active substances						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**

Oral Similar to OECD 401	Rat Wistar, 5 rats/sex	C8 fatty acid Limit test 5 mg/kg bw		> 5 g/kg bw		BPD dossier Kästner 1981 Doc III-A 1.1
Dermal OECD 402; EU B.3 GLP	Rat, HanRcc:WIST (SPF) rats 5m+5f/dose/ group	C10 fatty acid 2000 mg/kg bw (diluted ~25% in PEG) 24 hours	Reversible skin irritation in all animals; on day 2: moderate sedation (4m, 3f), deep respiration (3m, 2f), hunched posture (3m, 1f)	> 2000 mg/kg		BPD dossier Talvioja K. 2006; Doc III-A 6.1.2
Inhalation	C8 and C10 fatty acids: all secondary literature with very limited documentation. Therefore all the available data are considered together in a weight of evidence evaluation without giving special weight to the one or the other reference. Consequently no classification is proposed.					BPD dossier

There is no human data available.

Information on dermal absorption

No information on the dermal absorption of any of the members of the ***SOPURCLEAN BPF*** is available. Therefore, 100% dermal absorption is assumed. All products cause severe burns in undiluted form.

Active substances
No studies on skin absorption are available. Undissociated Octanoic acid with a log Pow of 3.03 as well as undissociated Decanoic acid with a log Pow of 4.09 is expected to easily penetrate and cross cell membranes. As it is found with absorption from the gut, it is appropriate to assume that the permeation through skin is easy. Also, the skin irritating effects of the C8 and C10 fatty acids would support dermal absorption. On the other hand the low water solubility would limit dermal absorption. However, after skin contact, the formation of a reservoir of the active substance in the stratum corneum and desquamation of the stratum corneum in time will result in less than 100% systemic availability. Nevertheless, in the absence of a dermal uptake study for the purpose of risk assessment 100% absorption of C8 and C10 fatty acids through the skin will be assumed.

Substance	C8 fatty acids	C10 fatty acids
Value(s)*	100%	100%
Justification for the selected value(s)	All products cause severe burns in undiluted form. No dermal uptake study available.	All products cause severe burns in undiluted form. No dermal uptake study available.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

All biocidal products in the ***SOPURCLEAN BPF*** reveal similar amounts of octanoic and decanoid acid and similar composition: differing in the kind of applied supporting mineral acid, solvents/emulsifiers, stabilizers, surfactants, dispersing agents.
Sulfuric acid, phosphoric acid, nitric acid, methane-sulfonic acid, glycolic acid, propionic acid, lactic acid and citric acid are all classified as irritants/corrosive. The classification of these non-active substances carry through the classification of the concentrated biocidal products which all have a pH <2. Hence all members of the SOPURCLEAN BPF (meta SPC 1, 2, 3 and 4) are classified as corrosive Cat. 1A (H314). The products containing methane sulfonic acid > 20% or propionic acid > 10% are additionally classified as STOT SE 3 (H335) (respectively meta SPC 4 and 2). The products containing nitric acid are to be classified for acute inhalation toxicity (Cat. 4), which relates to product present in meta SPC 3.

Vapour pressure non-active substances:
Please see additional information in the Confidential Annex.

Available toxicological data relating to a mixture
Not relevant

Endocrine Disruption Assessment for Active & Non-active Substances in the SOPURCLEAN BPF

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the endocrine disrupting properties of the substances in ***SOPURCLEAN BPF***:

First step: Assessment of the ED properties of the active substances in ***SOPURCLEAN BPF***:

According to point 2.1.1 of the final CA document, the assessment of endocrine disrupting properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the BE eCA should not evaluate the endocrine disrupting properties of these substances nor request additional data on the endocrine disrupting properties in the context of product authorisation procedures. The CAR of Octanoic acid and Decanoic acid stated that there is no evidence for endocrine disruption for these substances. Moreover, as Octanoic acid and Decanoic acid are not part of the list[1] of approved active substance identified as possible endocrine disrupting, the evaluation of these active substances is currently not triggered for an early review.
Therefore, the BE eCA considers that there is no concern regarding endocrine disrupting properties of Octanoic acid and Decanoic acid.

Second step: Assessment of the endocrine disrupting properties of non-active substances ('co-formulants') in ***SOPURCLEAN BPF***:
After reviewing the potential endocrine disrupting properties of all co-formulants (please refer to the procedure in the CONFIDENTIAL Annex), none of the co-

[1] Please refer to CA-September18.Doc.7.5.a-final .

formulants are subject to an on-going evaluation or a decision regarding their endocrine disrupting properties. Based on the available information, the BE eCA considers that there is no concern regarding the endocrine disrupting properties of these co-formulants.

Overall conclusion on the biocidal family regarding endocrine disrupting properties of the ***SOPURCLEAN BPF***:
Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the endocrine disrupting properties of the substances used in the formulated product of the ***SOPURCLEAN BPF***.
If one or several components are identified as having endocrine disrupting properties in the future, the conditions for granting the ***SOPURCLEAN BPF*** authorisation will be revised.

1.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	yes	n.a.	n.a.	no	n.a.	n.a.
Dermal	n.a.	yes	n.a.	n.a.	no	n.a.	n.a.
Oral	n.a.	no	n.a.	n.a.	no	n.a.	n.a.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	CIP	Primary Cleaning in place, closed system Only contact under particular circumstances (contamination during maintenance of equipment)	professional
2.	Spraying systems at low pressure	Primary Spraying, automated system, human intervention with actual spraying Professional surface disinfection by spraying liquid Spraying model 1	professional
3.	Soaking baths	Primary Use of an immersion bath for dipping of equipment Dipping model 4	professional
4.	Manual treatment	Primary Professional surface disinfection by wiping Surface disinfection model 1&3	professional

Industrial exposure

Manufacturing of active substance and formulation of products is not covered by BPR, otherwise the product is not used in an industrial way.

Professional exposure

Primary exposure

Scenario 1: CIP (meta SPC1, 2, 3 and 4)

Description of Scenario 1 – Cleaning in place (CIP)		
Meta SPC1 products: Septacid BN, Septacid BN PS, Sopurclean BN, Sopurclean BN PS, Sopurcip EC Meta SPC2 products: Sopurclean NR Meta SPC3 products: Sopurclean OP N Meta SPC4 products: Sopurclean CIP OP Trained professionals only The biocidal will be (semi-) automatically dosed in the CIP vessel either by volume or conductivity measurements. The solution will circulate in the closed equipment, pipes, tanks, etc. for disinfection. Vessels are cleaned by spraying them with a solution. High and low pressure spraying are used. - High pressure spraying: sharply defined jet at up to 60 bar. - Low pressure spraying: higher flow of solution (20 to 75 m3/h) at a low pressure (up to 6 bar overpressure) is sprayed at the vessel wall and flows over the walls allowing the chemical effect of the solution to be obtained. After disinfection the solution will be recovered in an adequate CIP vessel for re-use. Table 3 provides an overview of the best practices for re-use and recovery of the BP as advised by the applicant. Application methods: Drums or IBC containers and jerrycans containing the Biocidal product are connected to the system via installed pipe installation. The whole cleaning process is operated by a valve system in a sequential order. - Wear appropriate protective equipment during all the steps (coverall, gloves, goggles). - Dilute the concentrated product in tap water to reach the required use dilution. - Main steps: pre-rinsing - cleaning and/or disinfecting cycle(s) – final rinsing. - For an effect on bacteria: dilution rate: 1.5%v/v (meta SPC1, 3 and 4), 2%v/v (meta SPC1, 3 and 4 if an effect on *Pediococcus damnosus* is desired – only for outbreaks), 1.0% (meta SPC2), contact time: minimum 15 minutes; temperature + 4°C. - For an effect on yeast: min. 1.5 %v/v (meta SPC1, 3 and 4), 1.0% (meta SPC2), contact time: minimum 15 minutes; temperature +4°C. **For META-SPC1, 3 and 4:** Rinse carefully the treated equipment (vessels) and the pumping pipes used. **For META-SPC2:** The final rinsing may be skipped. Application rate and frequency: The disinfectant solution will be used in a closed CIP system and the solution will be recovered for re-use. If needed, the recovered use concentration is adjusted (see Table 3 for instructions). Frequency (indicative): about 300 runs/year within the CIP circuit will be done. Use concentration: 1 to 1.5%v/v (for meta SPC2 and meta SPC1, 3 and 4 products respectively), at +4°C (exceptionally 2% v/v if an effect on *Pediococcus damnosus* is desired only for outbreaks, meta SPC 1, 3 and 4).		
	Parameters	
Tier 1	As all concentrated meta SPC1, 2, 3 and 4 SOPURCLEAN products are corrosive (pH<2). Where direct contact cannot be not fully excluded by the technology, eventually in case of exceptional maintenance work, full dermal, eye and respiratory protection (for SOPURCLEAN OP-N only) by appropriate personal protective equipment is necessary.	

Calculations Local exposure for Scenario 1 - CIP

No exposure of professionals is expected during the application of the meta SPC1, 2, 3 and 4 products referring to the statement of the applicant as the involved cleaning procedures in food industries are performed in closed equipment preventing any entrance of leakage of materials for hygienic reasons. Drums or IBC containers and jerrycans are connected to the system via the installed pipe installation. The whole cleaning process is operated by a valve system in a sequential order. No other human intervention to operate the process system is in place.

As direct contact with the biocidal product or the application solutions might be conceivable under particular circumstances (e.g. contamination during maintenance of equipment), dermal and inhalation exposure estimates are derived for considering also these scenarios, even if they are expected to be an exception and not to refer to

the typical activities. Human exposure to the application solutions are expected to be covered by the following derived scenario describing contact to the pure biocidal product, as the application solutions reveal significantly lower active substance concentrations than the biocidal products.

Meta SPC1

Dermal exposure
A direct dermal contact to the meta SPC1 SOPURCLEAN products is considered to be negligible for normal work practice. However, in case of potential dermal contact, use of PPE (e.g. chemical resistant gloves) is expected for preventing direct dermal contact, due to the immediate and direct effect of all the meta SPC1 SOPURCLEAN products of being corrosive as they contain mineral acids.
Accidental spillages to the bare skin would be immediately washed off and the contaminated skin rinsed with water, if this happens. Therefore, residues of spillages remaining on bare skin are not expected and the use of chemical resistant gloves is assumed for direct handling of the meta SPC1 SOPURCLEAN products

Inhalation exposure
The meta SPC1 SOPURCLEAN products are intended to be used in closed systems. Therefore, inhalation exposure of the operators is expected to be disregardable. Assuming inhalation of air saturated with the active substances as a very conservative assumption (e.g. due to leakages of BP on floor, residues in open barrels, etc.), this results in following concentration in air (saturation concentration at 25°C).

The concentration of Octanoic acid and Decanoic acid in air is estimated from following equation (ideal gas law):

$W = (1000*P*V*M) / (R*T)$

where

W is the concentration in air (mg/m3)
P is the vapour pressure (Octanoic acid: $1.35x10^{-2}$ Pa; Decanoic acid: $2.17x10^{-4}$ Pa))
V is the volume of air (1 m^3)
M is the molecular weight (144.21 g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature (298 K ~ 25°C)

Using the values listed above, the saturation concentration in air is calculated to be:

- Octanoic acid: 0.7858 mg/m^3
- Decanoic acid: 0.0151 mg/m^3

Meta SPC2

Dermal exposure

A direct dermal contact to the meta SPC2 SOPURCLEAN product is considered to be negligible for normal work practice. However, in case of potential dermal contact, use of PPE (e.g. chemical resistant gloves) is expected for preventing direct dermal contact, due to the immediate and direct effect of the meta SPC2 SOPURCLEAN product of being corrosive containing a mineral acid.
Accidental spillages to the bare skin would be immediately washed off and the contaminated skin rinsed with water, if this happens. Therefore, residues of spillages remaining on bare skin are not expected and the use of chemical resistant gloves is assumed for direct handling of the meta SPC2 SOPURCLEAN product.

Inhalation exposure
The meta SPC2 SOPURCLEAN product is intended to be used in closed systems. Therefore, inhalation exposure of the operators is expected to be disregardable. Assuming inhalation of air saturated with the active substances as a very conservative assumption (e.g. due to leakages of BP on floor, residues in open barrels, etc.), this results in following concentration in air (saturation concentration at 25°C).

The concentration of Octanoic acid and Decanoic acid in air is estimated from following equation (ideal gas law):

$W = (1000*P*V*M) / (R*T)$

where

W is the concentration in air (mg/m3)
P is the vapour pressure (Octanoic acid: $1.35x10^{-2}$ Pa; Decanoic acid: $2.17x10^{-4}$ Pa))
V is the volume of air (1 m^3)
M is the molecular weight (144.21 g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature (298 K ~ 25°C)

Using the values listed above, the saturation concentration in air is calculated to be:

- Octanoic acid: 0.7858 mg/m^3
- Decanoic acid: 0.0151 mg/m^3

Meta SPC3

Dermal exposure
A direct dermal contact to the meta SPC3 SOPURCLEAN products is considered to be negligible for normal work practice. However, in case of potential dermal contact, use of PPE (e.g. chemical resistant gloves) is expected for preventing direct dermal contact, due to the immediate and direct effect of all the meta SPC3 SOPURCLEAN products of being corrosive as they contain mineral acids.
Accidental spillages to the bare skin would be immediately washed off and the contaminated skin rinsed with water, if this happens. Therefore, residues of spillages remaining on bare skin are not expected and the use of chemical resistant gloves is assumed for direct handling of the meta SPC3 SOPURCLEAN products

Inhalation exposure
The meta SPC3 SOPURCLEAN products are intended to be used in closed systems. Therefore, inhalation exposure of the operators is expected to be disregardable. Assuming inhalation of air saturated with the active substances as a very conservative assumption (e.g. due to leakages of BP on floor, residues in open barrels, etc.), this results in following concentration in air (saturation concentration at 25°C).

The concentration of Octanoic acid and Decanoic acid in air is estimated from following equation (ideal gas law):

W = (1000*P*V*M) / (R*T)

where

W is the concentration in air (mg/m3)
P is the vapour pressure (Octanoic acid: $1.35x10^{-2}$ Pa; Decanoic acid: $2.17x10^{-4}$ Pa))
V is the volume of air (1 m^3)
M is the molecular weight (144.21 g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature (298 K ~ 25°C)

Using the values listed above, the saturation concentration in air is calculated to be:

- Octanoic acid: 0.7858 mg/m^3
- Decanoic acid: 0.0151 mg/m^3

Only in the case of ***Sopurclean OP N*** assuming inhalation of air saturated with the ingredients as a very conservative assumption, this results in a situation where immediate safety interventions (evacuation) are necessary to protect workers against inhalation risks: (NO)x vapours which are toxic and the vapour pressure of nitric acid 100% at 20°C = 5600 Pa.

Meta SPC4

Dermal exposure
A direct dermal contact to the meta SPC4 SOPURCLEAN products is considered to be negligible for normal work practice. However, in case of potential dermal contact, use of PPE (e.g. chemical resistant gloves) is expected for preventing direct dermal contact, due to the immediate and direct effect of all the meta SPC4 SOPURCLEAN products of being corrosive as they contain mineral acids.
Accidental spillages to the bare skin would be immediately washed off and the contaminated skin rinsed with water, if this happens. Therefore, residues of spillages remaining on bare skin are not expected and the use of chemical resistant gloves is assumed for direct handling of the meta SPC4 SOPURCLEAN products

Inhalation exposure

The meta SPC4 SOPURCLEAN products are intended to be used in closed systems. Therefore, inhalation exposure of the operators is expected to be disregardable. Assuming inhalation of air saturated with the active substances as a very conservative assumption (e.g. due to leakages of BP on floor, residues in open barrels, etc.), this results in following concentration in air (saturation concentration at 25°C).

The concentration of Octanoic acid and Decanoic acid in air is estimated from following equation (ideal gas law):

$W = (1000*P*V*M) / (R*T)$

where

W is the concentration in air (mg/m3)
P is the vapour pressure (Octanoic acid: $1.35x10^{-2}$ Pa; Decanoic acid: $2.17x10^{-4}$ Pa))
V is the volume of air (1 m^3)
M is the molecular weight (144.21 g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature (298 K ~ 25°C)

Using the values listed above, the saturation concentration in air is calculated to be:

- Octanoic acid: 0.7858 mg/m^3
- Decanoic acid: 0.0151 mg/m^3

Scenario 2 – Spraying systems at low pressure

Description of Scenario 2 – Spraying systems at low pressure		
Meta SPC1 products: - Meta SPC2 products: Sopurclean NR Meta SPC3 products: - Meta SPC4 products: - The biocidal product will be used for the disinfection of hard surfaces in contact with food processing. Based on the type of industry, the surface will be pre-cleaned or pre-rinsed before the disinfecting step. The diluted solution (1%v/v) is sprayed on the surface via a low pressure spraying device. The final rinsing step may be skipped. Spraying of external surfaces of equipment in breweries, milk industry,… Spraying of horizontal or vertical surfaces in industrial installations of the food/feed industry (e.g. on conveyer belts) Spraying of surfaces in professional settings (e.g. in a slaughterhouse). Wear protective equipment (coverall, gloves, goggles). Primary exposure of the professional users of the BP might occur during the cleaning / disinfection of equipment or surfaces via spray application. During the mixing and loading phase from drums, IBC container, jerrycan, exposure to the undiluted biocidal product could be relevant. During the application phase, the biocidal product is used as a 1-2% dilution in water. At this concentration, the BP is not hazardous anymore.		
	Parameters[1]	Value
Tier 1	Please see additional information in the Confidential Annex.	
	Dilution of the applied product	2%
	Inhalation exposure Potential exposure via inhalation	104 mg/m^3

Calculations Local exposure for Scenario 2 – Spraying systems at low pressure

Meta SPC1

Not applicable

Meta SPC2

Dermal:
Direct dermal contact to the product of meta SPC2 is possible for normal work practice. However, in case of potential dermal contact, PPE (chemical resistant gloves, acid-proof protective coverall, safety glasses, face shield in case there is potential for splashes) are expected to be worn for preventing direct dermal contact, due to the immediate and direct effect of these BPs as being corrosive in undiluted form. Accidental spillages to the bare skin would be immediately washed off and the contaminated skin rinsed with water, if this happens. Therefore, residues of spillages remaining on bare skin are not expected and the use of PPE is assumed for direct handling of the biocidal product of meta SPC2.

Inhalation:
As a result of their low concentration in the product, the active substances are not expected to lead to substantial inhalation exposure levels.

With regard to the other ingredients, propionic acid is the ingredient identified with the highest vapor pressure of all ingredients of the meta SPC2 family (vapor pressure of 0.399 kPa at 23°C).

Please see additional information in the Confidential Annex.

Starting point for the qualitative exposure assessment (applicant, agreed by BE):

Default data PT 4	Mixing and Loading phase	Application phase	Post-application phase (Secondary exposure)
Type	Liquid	Liquid	Liquid
Activity	Pour and dilute	Spraying	Activities following disinfection of installations
Total duration per day	10 minutes	120 minutes	360 minutes
Exposure frequency	Daily	Daily	Daily

	Breweries and Milk Industry	Mixing and Loading phase	Application phase	Post-application phase
OCs	Type	Liquid	Liquid	Liquid
	Concentration of BP	100%	1-2%	1-2%
	Activity	Pour and dilute	Spraying	Tasks involving or in the vicinity of disinfected installations
	Process kinetics	Low energy process	Low energy process	Low energy process
	Automated or manual process	Manual or automated	Fully or semi-automated	Manual or automated
	Total duration per day	5 minutes	20 minutes	440 minutes
	Exposure frequency	Daily	Daily	Daily
Technical RMMs	Pressure of spray equipment	Not applicable	Low pressure spraying: up to 6 bar	Not applicable
	Closed system	BP is supplied to the facility in a closed container.	No	No
	Very high level of containment	Connection to the spraying installation via "dry coupling" connector.	Spraying of surfaces is a fully automated process. Workers are not present in the work area during the spraying.	Workers only re-enter the work area after spraying solution has been drained.
	Equipment under negative pressure	Not applicable	Not applicable	Not applicable
	Regular cleaning of equipment and work area	Clean equipment and the work area every day. Drain down and flush system prior to equipment break-in and maintenance.	Clean equipment and the work area every day. Drain down and flush system prior to equipment break-in and maintenance.	Clean equipment and the work area every day.
Organisational RMMs	Control staff entry to work area	Restrict access to work area to trained personnel.	Personnel shall not enter area when spraying is taking place.	No
	Ensure all equipment well maintained	Ensure regular inspection and maintenance of equipment and machines. Monitor the effectiveness of control measures.	Ensure regular inspection and maintenance of equipment and machines. Monitor the effectiveness of control measures.	Not applicable
	Mgmt / supervision in place	Supervision in place to check that the RMMs in place are being used correctly, and that OCs are followed.	Supervision in place to check that the RMMs in place are being used correctly, and that OCs are followed.	Not applicable
	Training of staff on good practice	Provide specific activity training to operators to minimise exposures.	Not applicable	Not applicable
	Procedures and training for emergency decontamination and disposal	Trained cleaning personnel properly equipped with eye protection should handle spills After spillage / leakage spills should be cleaned as soon as possible using absorbent material to collect the spill. Suitable disposal containers should be used.	Trained cleaning personnel properly equipped with eye protection should handle spills After spillage / leakage spills should be cleaned as soon as possible using absorbent material to collect the spill. Suitable disposal containers should be used.	Not applicable
	Good standard of personal hygiene	A good basic standard of occupational hygiene is implemented	A good basic standard of occupational hygiene is implemented	A good basic standard of occupational hygiene is implemented
	Recording of any near-miss situations	Record any near-miss situations. Identify and implement corrective actions.	Record any near-miss situations. Identify and implement corrective actions.	Record any near-miss situations. Identify and implement corrective actions.
PPEs	Face shield	At minimum chemical goggles are to be worn.	At minimum chemical goggles are to be worn.	Not applicable
	Substance / task appropriate gloves	Use neoprene or rubber gloves (EN 374) Take into account the diversity of types, it is necessary to respect the instructions of the manufacturer.	Use neoprene or rubber gloves (EN 374) Take into account the diversity of types, it is necessary to respect the instructions of the manufacturer.	Not applicable
	Protection coverall (EN 13034, 13962, 14605 or 943)	Wear a suitable coverall to prevent skin contamination.	Wear a suitable coverall to prevent skin contamination.	Not applicable
	Chemical goggles	Use eye protection according to EN 166, designed to protect against liquid splashes.	Use eye protection according to EN 166, designed to protect against liquid splashes.	Not applicable

Meta SPC3

Not applicable

Meta SPC4

Not applicable

Scenario 3 – Soaking baths

Description of Scenario 3 – Soaking baths		
Meta SPC1 products: Septacid BN PS, Sopurclean BN PS, Sopurcip EC Meta SPC2 product: Sopurclean NR Meta SPC3 products: / Meta SPC4 products: / The biocidal product will be used for the disinfection of small parts (spare parts, tools, valves, hoses,...) used along the food manufacturing process. Based on the type of industry, the surface will be pre-cleaned or pre-rinsed before the disinfecting step. The small parts are submerged in soaking baths containing a biocide solution of typically 1 to 1.5 %v/v (for respectively meta SPC2 and meta SPC1 products). Application method: - Wear appropriate protective equipment (coverall, gloves, goggles). - Steps: pre-rinsing - cleaning - disinfecting phases, - The concentrated product delivered in drums, IBC container, or jerrycans is pumped in the bath and tap water is added to reach the required use solution. 'Loading' of liquid in a soaking bath means that the solution is pumped in its concentrated form directly into the soaking bath in order to minimize the splashing of the solution (via flux pump or similar). - The equipment to be disinfected is soaked in the bath.The items are placed and removed manually from the baths. The baths are only open during the loading and unloading of the baths, and closed during the application phase. The cleaning solution is already present in the bath before the items are placed in it. **For META-SPC1:** Rinse carefully the treated equipment (vessels) and the pumping pipes used. **For META-SPC2:** The final rinsing may be skipped. The following potential exposure routes are identified: - Skin: contact due to dipping of the equipment and contact with use solution during dipping. - Eye: potential eye exposure if equipment added in a violent way into the bath. - Respiratory tract: bath is normally open, so potential exposure. - Oral: not relevant in an industrial setting. In addition, not considered as relevant due to emptying and rinsing of equipment before use.		
	Parameters[1]	Value
Tier 1	Content of active substance Octanoic acid Decanoic acid	 Septacid BN PS: 1.5% Sopurclean BN PS: 1.8% SopurCIP EC: 1.1% Sopurclean NR: 2.7% Septacid BN PS: 1.5% Sopurclean BN PS: 1.2% SopurCIP EC: 0.75% Sopurclean NR: 0.3%
	Content of non-active substance of concern Sulphuric acid Propionic acid	 SopurCIP EC: 7.8% Sopurclean NR: 19.5%
	Dilution of the applied product	2%
	Inhalation exposure Potential exposure via inhalation	0.2 mg/m^3
	Exposure duration	30 minutes

Calculations Local exposure for Scenario 3 – Soaking baths

Meta SPC1

Dermal and eye:

All those products are manipulated during the filling of the soaking bath with the necessary skin and eye protection (acid-proof protective clothing/coveralls, chemical resistant gloves, safety goggles, face shield in case there is potential for splashes). Also after the dipping (at the moment of use of the equipment), skin and eye protecting PPE's should be used.

Inhalation:
There is no inhalation exposure risk because of the low use concentrations and the very low vapor pressure of the active ingredients.
With regard to the other ingredients, sulfuric acid was the ingredient identified with the highest vapor pressure of all ingredients of the meta SPC1 family (vapor pressure of approx. 49 Pa at 20°C).

Please refer to Risk Assessment for Substances of Concern.

Meta SPC2

Dermal and eye:
The product should be manipulated during the filling of the soaking bath with the necessary skin and eye protections (acid-proof protective clothing/coverall, chemical resistant gloves, safety goggles, face shield in case there is potential for splashes) and also after the dipping (at the moment of use of the equipment), skin and eye protecting PPE's should be used.

Inhalation:
There is no inhalation exposure risk because of the low use concentrations and the very low vapor pressure of the active ingredients.
With regard to the other ingredients, propionic acid was the ingredient identified with the highest vapor pressure of all ingredients of the meta SPC1 family (vapor pressure of approx. 0.399 Pa at 23°C).

Please see additional information in the Confidential Annex.

Scenario 4 – manual disinfection

Description of Scenario 4 – Manual disinfection		
Meta SPC1 products: - Meta SPC2 products: Sopurclean NR Meta SPC3 products: - Meta SPC4 products: - The biocidal product will be used for the manual disinfection of small parts used along the food manufacturing process. Based on the type of industry, the surface will be pre-cleaned or pre-rinsed before the disinfecting step. The small parts will be manually cleaned using a biocide solution of typically 1%v/v. Application method: - Wear appropriate protective equipment (coverall, gloves, goggles). - Steps: pre-rinsing / cleaning / disinfecting phase. - Dilute the concentrated product (delivered in drums, IBC container or jerrycan) in tap water before use. - Apply the use solution with the appropriate tool, e.g. mops, cloths, brushes, on hard surfaces. - After the treatment, the surfaces are ready to be re-used. The following potential exposure routes are identified: – Skin – Eye – Respiratory tract Model used as starting point for the qualitative exposure assessment: professional surface disinfection by wiping, liquid: Recomm. 6 No. 20 (Inhalation exposure: Surface Disinfection Model 1&3, TNsG part 2, 2002, User Guidance version 1, p28, duration 79 min/d for inhalation). Guidance for Human Health Risk Assessment, volume III, Part B (version 1.0, December 2013); Biocidal Health Exposure Methology, version 1 , October 2015; Recommendation No. 6, Methods and models to assess exposure to biocidal products, version 1, January 2015.		
	Parameters[1]	Value
Tier 1	Content of active substance Octanoic acid Decanoic acid	 2.7% 0.3%
	Content of non-active substance of concern Propionic acid	 19.5%
	Dilution of the applied product	2%
	Inhalation exposure Potential exposure via inhalation	 22.9 mg/m^3
	Exposure duration	79 minutes

Calculations local exposure for Scenario 4 – Manual disinfection

Meta SPC1

Not relevant

Meta SPC2

Dermal and eye:

This product should be manipulated during the dilution of the product to its use concentration with the necessary skin and eye protections (acid-proof protective clothing, chemical resistant gloves, safety goggles, face shield in case there is potential for splashes) and also during the actual manual cleaning step, skin and eye protecting PPE's should be used even though the product is no longer considered hazardous in concentrations of 1 or 2% (use concentrations).

Inhalation:
There is no inhalation exposure risk because of the low use concentrations and the very low vapor pressure of the active ingredients.
With regard to the other ingredients, propionic acid was the ingredient identified with the highest vapor pressure of all ingredients of the SPC2 family (vapour pressure of 0.399 kPa at 23°C).

Please see additional information in the Confidential Annex.

Meta SPC3
Not relevant

Meta SPC4
Not relevant

Secondary exposure

CIP– closed system
Meta SPC1, 2, 3 and 4: No secondary exposure potential for professional users.
(For META-SPC1, 3 and 4: Rinse carefully the treated equipment (vessels) and the pumping pipes used with drinking water. For META-SPC2: The final rinsing may be skipped.)

Soaking baths
Meta SPC1: Secondary exposure of the professionals is not relevant as the quantity of residual disinfectant is negligible as rinsing is mandatory before the equipment may be used.
Meta SPC2: Secondary exposure of the professionals might occur during the post-application phase, i.e. during activities following the disinfection step, such as using the treated surfaces or equipment. At that stage however the operator is exposed to limited residues of a non-hazardous product as the use concentration of 1 to 2% BP is not hazardous anymore.

Spraying systems at low pressure
Meta SPC2: Secondary exposure of the professionals might occur during the post-application phase, i.e. during activities following the disinfection step, such as manual processing of meat that is transported on a disinfected conveyer belt. At that stage the operator is exposed to a non-hazardous product as the use concentration of 1 to 2% BP is not hazardous anymore.

Manual disinfection
Meta SPC2: Secondary exposure of the professionals might occur during the post-application phase, i.e. during activities following the disinfection step, such as using the treated surfaces or equipment. At that stage however the operator is exposed to

limited residues of a non-hazardous product as the use concentration of 1 to 2% BP is not hazardous anymore.

Non-professional exposure

The biocidal products of the SOPURCLEAN BPF are for professional use only.
No non-professional exposure is foreseen.

Exposure of the general public

The biocidal products of the SOPURCLEAN BPF are not sold to non-professionals and possible residues in food and beverages are very low and of no concern (see also DocIV-A2.10/03; original BPF dossiers). See also 'Dietary exposure'.
Human exposure of the general public is considered not relevant.

Dietary exposure

Meta SPC1, 3 and 4
The only possibility of secondary exposure as a result of use of BPs from meta SPC 1, 3 and 4 is when a consumer drinks beer (or another beverage) which was processed in a plant where the processing installations were disinfected with these BPs. The contribution of these residues originating from the CIP process or from parts cleaned in soaking baths is considered to be not relevant regarding the low concentrations possible in drinks e.g. beer. The possible residues are only a small fraction compared to the natural presence. Verschaeve 2006 (A2.10/03) describes as an example the unavoidable residues in a brewery showing a residue of 2.6 – 150 ppb octanoic + decanoic acid from CIP processing compared to 100 – 4000 ppb naturally present in beer.
In conclusion, possible residues in food and beverages are very low and of no concern (see also DocIV-A2.10/03; original BPF dossiers).

Meta SPC2
The meta SPC2 product Sopurclean NR does not need to be rinsed according to the applicant as in the diluted form the product and active substances are not hazardous anymore (systemic and local).
Additionally, the non-rinsing of the meta SPC2 product is further discussed in the context of the recent guidance on Maximum Residue Limits (MRLs) – interim approach (CA-March 27-Doc.7.6.c-final).
Sopurclean NR is diluted for all 4 scenario's to a 1 to 2% solution, which contains in this final solution (assumed 2%) 0.054% octanoic acid and 0.006% decanoic acid. For the C8 and C10 acids the derivation of systemic AELs were considered unnecessary. Risk assessment is focused on risk for local effects. At the diluted concentration, there is no local hazard anymore. That is the trigger why no rinsing is required for the meta SPC product Sopurclean NR.

For octanoic and decanoic acid no ADI or ARfD are set, and no specific MRL's are set or required yet according to Leg (EU) 2015/1608 (Annex IV).
As no specific MRL exists for octanoic and decanoic acid, a default MRL value of 0.01 mg/kg food could be applied. However, as no specific reference values can be derived due to the lack of systemic adverse effects (no systemic AELs, ADI, ARfD) no assessment is deemed needed. In addition, according to the CARs the daily human uptake of fatty acids as natural food contents is, e.g. according to Henderson et al 2003 already about 900 mg/kg bw day. The consumer exposure to the active substances (without systemic hazards identified, without derived reference values) linked to use as a biocidal product is considered as negligible compared to other uses in the food chain.
In conclusion, possible residues in food and beverages are of no concern.

1.2.6.3 Risk characterisation for human health

The derivation of a systemic AEL is considered inappropriate. Risk assessment is focused on risk for local effects. However, the available data for the active substances are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AEC)s.
In conclusion, a qualitative risk assessment of the potential local effects is made.

This, according to the CAR's of the active substances octanoic acid and decanoic acid PT4:
As summarized in Doc IIA.5 the publications from Webb 1993, Harkins 1968, Traul et al. 2000 for medium chain triglycerides (MCTs) as well as the publications from Mori 1953 and WHO/IPCS 1998 for the free fatty acids do not indicate any adverse systemic effect and support NOAELs above 1000 mg/kg bw/d. Daily human uptake of fatty acids as food contents is, e.g. according to Henderson et al 2003 about 900 mg/kg bw day and the metabolic pathways are similar for all fatty acids, that is complete catabolism for energy supply or conversion to fat suitable for storage (see also Doc II-A 3.1). Therefore, the derivation of a systemic AEL is considered unnecessary. Risk assessment is focused on risk for local effects. The available data for the active substances is insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AECs). In any case the data for the active substances would be inadequate for the assessment of the biocidal products that are different with regard to pH, solvents and other ingredients.

Absorption of the active substance and other non-active ingredients:

- Oral absorption: 100%
- Dermal absorption: 100%
- Inhalation absorption: 100%

As there are no dermal absorption studies available for any of the biocidal products under the BPF and the concentrated products have a pH < 2, 100% absorption is assumed to be a conservative estimate.

The following steps were taken during this qualitative risk assessment:

- Step 1: Description of the local hazards
- Step 2: Assignment of hazard categories
- Step 3: Identification of the exposure scenarios
- Step 4: Acceptability or non-acceptability of the risks
- Step 5: Concluding qualitatively on the acceptability of risk

Similar amounts of total decanoic and octanoic acid are present in the other SOPURCLEAN BPF family members with except for Sopurclean NR and SopurCIP EC. For Sopurclean NR the total quantity of octanoic and decanoic is equal to the other products but with a different ratio (2.7% octanoic acid and 0.3% decanoic acid), for SopurCIP EC the total concentration active substance is lower in comparison to all the other products in the SOPURCLEAN BPF (1.1% octanoic, 0.75% decanoic acid). Therefore, similar rules across the BP are considered to be applicable.

Risk From Substances of concern:

Scenario 1: CIP (meta SPC1, 2, 3 and 4)

Meta SPC 3 – inhalation exposure
Relevant to ***Sopurclean OP-N*** : contains 18% nitric acid (CAS 7697-37-2)

Nitric acid

Route/Duration	DNEL	Remarks
Inhalation Long term - systemic	Low hazard, no threshold defined	Source: REACH registration dossier
Inhalation Short term - systemic	Low hazard, no threshold defined	Source: REACH registration dossier
Inhalation Long term - local	2.6 mg/m^3	Source: REACH registration dossier
Inhalation Short term - local	2.6 mg/m^3	Source: REACH registration dossier

The vapour pressure referenced in the background document to the RAC opinion on nitric acid is 64 hPa at 20°C. This value has been used for this assessment as well.

Scenarios were prepared in ART (Advanced Reach Tool), simulating connecting of vessels containing the biocidal products to the CIP process. Medium containment was selected.
Exposure estimations performed with ART (Advanced Reach Tool) indicate that the connecting activity (transfer of liquid) with undiluted Sopurclean OP N product in a small room (100 m^3)(selected as conservative input parameter) leads to an exposure estimate of 0.034 mg/m^3 (full shift, 90th percentile).
The **long-term local** DNEL of nitric acid is 2.6 mg/m^3 leading to a risk characterization ratio for long-term systemic exposure to nitric acid in the undiluted biocidal product mixture of 0.013. These are considered acceptable levels.

If we evaluate the potential peak exposure that could be the result of the Sopurclean OP N, in the same scenario as presented above (same scenario with no non-exposure duration) this leads to an exposure estimate of 8.2 mg/m^3 (full shift, 90th percentile). This is an absolute worst-case situation which is considered to be unrealistic. Upon comparison with the short-term/long-term local DNEL of nitric acid of 2.6 mg/m^3 this results in an RCR of 3.15.
The ART calculation have been added in the Annex

Meta SPC 4 – inhalation exposure
Relevant to ***Sopurclean CIP OP*** : contains 20.3% methane sulfonic acid (CAS 75-75-2)

Methane sulfonic acid

Route/Duration	DNEL	Remarks
Inhalation Long term - systemic	6.76 mg/m^3	Source: REACH registration dossier

Inhalation Long term - local	0.7 mg/m^3	Source: REACH registration dossier

Physico-chemistry data used for the ART scenario: 0.000475 hPa at 21°C (REACH Registration dossier)

Scenarios were prepared in ART (Advanced Reach Tool), simulating connecting of vessels containing the biocidal products to the CIP process. Medium containment was selected.
Exposure estimations performed with ART (Advanced Reach Tool) indicate that the connecting activity (transfer of liquid) with undiluted Sopurclean CIP OP product in a small room (100 m^3)(selected as conservative input parameter) leads to an exposure estimate of 0.000017 mg/m^3 (full shift, 90th percentile).
The **long-term systemic** DNEL of methane sulfonic acid is 6.76 mg/m^3 leading to a risk characterization ratio for long-term systemic exposure to methane sulfonic acid in the undiluted biocidal product mixture of 2.5 x 10^{-6}. These are considered very acceptable levels.
The **long-term local** DNEL of methane sulfonic acid is 0.7 mg/m^3 leading to a risk characterization ratio for long-term systemic exposure to methane sulfonic acid in the undiluted biocidal product mixture of 2.4 x 10^{-5}. These are considered very acceptable levels.

If we additionally evaluate the potential peak exposure that could be the result of the Sopurclean CIP OP, in the same scenario as presented above (same scenario with no non-exposure duration) this leads to an exposure estimate of 0.004 mg/m^3 (full shift, 90th percentile). This is an absolute worst-case situation which is considered to be unrealistic. Upon comparison with the long-term local DNEL of methane sulfonic acid of 0.7 mg/m^3 this results in an RCR of 0.00571.
The ART calculation have been added in the Annex

Scenario 2 - Spraying:

Meta-SPC 2:
The ART calculation have been added in the Annex

Scenario 3 – Soaking Bath

Meta-SPC 1:

Applicant: Exposure estimations performed with ART (Advanced REACH Tool) indicate that 15 minutes in the proximity of soaking bath (2% solution of the BP) in a small room (100 m^3) leads to an exposure estimate of 0.0056 mg/m^3 (full shift, 90th percentile). This when taking into account a biocidal product with a concentration of 7.8% sulfuric acid. The long-term local DNEL of sulfuric acid is 0.05 mg/m^3 leading to a risk characterization ratio for long-term local exposure to sulfuric acid in the diluted bp mixture of 0.112. These are considered acceptable levels.

The ART calculation have been added in the Annex

Meta-SPC 2:

The ART calculation have been added in the Annex

Scenario 4 – Manual Cleaning

Meta-SPC 2

The ART calculation have been added in the Annex

Risk for industrial users

Manufacturing of active substance and formulation of products is not covered by BPR, otherwise the product is not used in an industrial way.

Risk for professional users

Systemic effects
Not relevant

Local effects

Qualitative assessment of the different uses Meta SPC1
Scenario 1 - CIP: Septacid BN, Septacid BN PS, Sopurclean BN, Sopurclean BN PS, Sopurclean OP N, Sopurclean CIP OP, Sopurcip EC

Scenario 3 – Soaking baths: Septacid BN PS, Sopurclean BN PS, Sopurclean CIP OP, Sopurcip EC

Step 1: Description of the local hazards
Undiluted biocidal products:
Skin corrosive Cat. 1A, H314 (Causes severe burns and eye damage)
Based on the composition of the meta SPC1 BPF products

Diluted biocidal products (2%):
Skin corrosive Cat. 1A, H314 (Causes severe burns and eye damage)
Based on the pH of the 2% solutions: pH < 2

Local endpoints: Local skin and eye effects = skin corrosion

Step 2: Assignment of hazard categories
The classification of the Biocidal products in meta SPC1 is as starting point.

Classification	Hazard Category
Skin Corr. Cat. 1A	Very high

Step 3: Identification of the exposure scenarios
See 2.2.6.2. Exposure assessment

Professionals only
Scenario 1: CIP
Scenario 3: Soaking baths

Step 4: Acceptability or non-acceptability of the risks

Scenario 1: CIP

Septacid BN, Septacid BN PS, Sopurclean BN, Sopurclean BN PS, Sopurclean OP N, Sopurclean CIP OP, Sopurcip EC

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314	-	4	Professionals	containers containing the product are connected to CIP via installed pipes	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling Treated equipment (vessels) and dosing equipment has to be rinsed) Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable

Primary exposure: use of the diluted application solution – application phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk

Very high	Skin corr. Cat 1A, H314	-	4	Professionals	CIP use takes place in a closed system Treated equipment (vessels) and dosing equipment has to be rinsed) Exceptional maintenance work with max. 2% dilutions	Skin Eye Respiratory tract	Low frequency Few minutes per day (closed system) Exceptional maintenance: more than few minutes Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling Treated equipment (vessels) and dosing equipment has to be rinsed) Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable + Trained workers + use of appropriate PPE

Primary exposure: post-application phase / Secondary exposure
Not considered relevant as rinsing takes place

Scenario 3: Soaking bath

Septacid BN PS, Sopurclean BN PS, Sopurcip EC

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk

Very high	Skin corr. Cat 1A, H314	-	4	Professionals	Filling soaking bath: The concentrated product is pumped in the bath and tap water is added to reach the required use solution Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Use of appropriate PPE: coverall, gloves, eye protection, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable + Trained workers + use of appropriate PPE

Primary exposure: use of the diluted application solution - application phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314	-	4	Professionals	The equipment to be disinfected is soaked in the bath Volume bath: small Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Use of appropriate PPE: coverall, gloves, eye protection, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard

									category are achievable + Trained workers + use of appropriate PPE

Primary exposure: post-application phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314	-	4	Professionals	After application and before use, equipment is rinsed Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Equipment is rinsed. Use of appropriate coverall, gloves, eye protection, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable + Trained workers + use of appropriate PPE

Secondary exposure:
Not relevant as rinsing takes place

Qualitative assessment of the different uses Meta SPC2

Product: *Sopurclean NR*

Scenario 1: CIP
Scenario 2: Spraying systems at low pressure
Scenario 3: Soaking bath
Scenario 4: Manual cleaning
With or without final rinsing

Step 1: Description of the local hazards
Undiluted biocidal products:
Skin corrosive Cat. 1A, H314 (Causes severe burns and eye damage)
STOT SE 3, H335 (May cause respiratory irritation)
Based on the composition of the meta SPC2 BPF product

Diluted biocidal products (2%):
No classification warranted
Based on the addition rules for mixture classification, pH > 2

Local endpoints: Local skin and eye effects = skin corrosion

Step 2: Assignment of hazard categories
The classification of the Biocidal products in meta SPC2 is as starting point.

Classification	Hazard Category
Skin Corr. Cat. 1A	Very high
STOT SE 3	Low

However, the diluted product at the typical use concentration of 2% no longer requires classification. Consequently, only the parts of the exposure scenarios related to the undiluted product are to be considered relevant.

Step 3: Identification of the exposure scenarios
See 2.2.6.2. Exposure assessment

Professionals only
Scenario 1: CIP
Scenario 2: Spraying systems at low pressure
Scenario 3: Soaking bath
Scenario 4: Manual cleaning
With or without final rinsing

Step 4: Acceptability or non-acceptability of the risks

Scenario 1: CIP

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314 STOT SE 3, H335	-	4	Professionals	containers containing the product are connected to CIP via installed pipes, installed valve installation, connections with dry coupling	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling Treated equipment (vessels) and dosing equipment has to be rinsed) Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable

Primary exposure: use of the diluted application solution – application phase

At this stage the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore. Nevertheless, the use of appropriate PPE is required: coverall, gloves, goggles, face shield in case there is potential for splashes.

Primary exposure: use of the diluted application solution – post-application phase

At this stage the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore.

Secondary exposure
Not relevant

Scenario 2: Spraying systems low pressure

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314 STOT SE 3 H335	-	4	Professionals	BP is supplied in closed container. Connection to the spraying installation via dry coupling valves connector. Drain down and flush system prior to equipment break-in and maintenance. Strict access to work area to trained operator and cleaning personnel; Management supervision in place; Monitoring the effectiveness of control measures; near-miss situations are recorded and corrective actions are taken, Use of appropriate coverall, gloves, goggles, face shield in case there is potential for splashes.	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Use of appropriate coverall, gloves, goggles, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable

Primary exposure: use of the diluted application solution – application phase

Situation 1: Spraying is a fully automated process.

Workers are not present in the work area during spraying. Workers only re-enter the work area after spraying solution has been drained. Workers are not required to wear PPE in this case.

Organisational RMM: tasks are restricted to trained personnel, management supervision is in place, effectiveness of control measures is monitored, near-miss situations are recorded and corrective actions are taken.

Situation 2: In circumstances that manual spraying has to be done (manual handling with a hand-held spraying nozzle), the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore. In this case, appropriate PPE is required: coverall, gloves, goggles, face shield in case there is potential for splashes.

Supervision is in place to check that the risk management measures are in place and that operational conditions are followed. Procedures are in place in case of spillage and cleaning personnel is properly trained and equipped.

Primary exposure: use of the diluted application solution – post-application phase

At this stage the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore.
Workers only re-enter the work area after spraying solution has been drained.
Organisational RMM: Good basic standard of occupational hygiene is implemented, near-miss situations are recorded and corrective actions are taken.
PPE: no specific measures required.

Secondary exposure
Not relevant

Scenario 3: Soaking bath

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314 STOT SE 3 H335	-	4	Professionals	Filling soaking bath: The concentrated product is pumped in the bath and tap water is added to reach the required use solution Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Use of appropriate coverall, gloves, goggles, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable + Trained workers + use of appropriate PPE

Primary exposure: use of the concentrated product - Application phase

At this stage the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore. There is a very low potential for inhalation exposure as the concentrations are low and the small volume of soaking baths. Nevertheless, it is required that the trained professionals use appropriate PPE: Coverall, gloves, goggles, face shield in case there is potential for splashes.

Primary exposure: use of the concentrated product – Post-application phase

At this stage the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore. There is a very low potential for inhalation exposure as the concentrations are low and the small volume of soaking baths. Nevertheless, it is required that the trained professionals use appropriate PPE: Coverall, gloves, goggles, face shield in case there is potential for splashes.

Secondary exposure
Not relevant

Scenario 4: Manual cleaning

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314 STOT SE 3 H335	-	4	Professionals	Manual dilution of the product in tap water Trained professional operators Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Use of appropriate coverall, gloves, goggles, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable + Trained workers + use of appropriate PPE

Primary exposure: use of the concentrated product - Application phase

At this stage the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore. There is a very low potential for inhalation exposure as the concentrations are low and the small volumes used for manual cleaning. Nevertheless, it is required that the trained professionals use appropriate PPE: Coverall, gloves, goggles, face shield in case there is potential for splashes.

Primary exposure: use of the concentrated product – Post-application phase
At this stage the operator is exposed to a non-hazardous product as the use concentration of the diluted 2% biocidal product is not hazardous anymore. There is a very low potential for inhalation exposure as the concentrations are low and the small volume of soaking baths. Nevertheless, it is required that the trained professionals use appropriate PPE: Coverall, gloves, goggles, face shield in case there is potential for splashes.

Secondary exposure
Not relevant

Qualitative assessment of the different uses Meta SPC3
Scenario 1 - CIP: Sopurclean OP N

Step 1: Description of the local hazards
Undiluted biocidal products:
Skin corrosive Cat. 1A, H314 (Causes severe burns and eye damage)
Acute inhalation toxicity Cat. 4, H332 (Harmful if inhaled)

Based on the composition of the meta SPC3 BPF products

Diluted biocidal products (2%):
Skin corrosive Cat. 1A, H314 (Causes severe burns and eye damage)
Based on the pH of the 2% solutions: pH < 2

Local endpoints: Local skin and eye effects = skin corrosion

Step 2: Assignment of hazard categories
The classification of the Biocidal products in meta SPC3 is as starting point.

Classification	Hazard Category
Skin Corr. Cat. 1A	Very high
Acute Tox. Cat. 4	No hazard category assigned

Step 3: Identification of the exposure scenarios
See 2.2.6.2. Exposure assessment

Professionals only
Scenario 1: CIP

Step 4: Acceptability or non-acceptability of the risks

Scenario 1: CIP
Sopurclean OP N

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314 Acute Tox. Cat. 4, H332	-	4	Professionals	containers containing the product are connected to CIP via installed pipes	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin, eye and inhalation exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling Treated equipment (vessels) and dosing equipment has to be rinsed) Use of appropriate PPE: coverall, gloves, goggles, mask/filter.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable

Primary exposure: use of the diluted application solution – application phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk

Very high	Skin corr. Cat 1A, H314	-	4	Professionals	CIP use takes place in a closed system Treated equipment (vessels) and dosing equipment has to be rinsed) Exceptional maintenance work with max. 2% dilutions	Skin Eye Respiratory tract	Low frequency Few minutes per day (closed system) Exceptional maintenance: more than few minutes Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling Treated equipment (vessels) and dosing equipment has to be rinsed) Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable + Trained workers + use of appropriate PPE

Primary exposure: post-application phase / Secondary exposure
Not considered relevant as rinsing takes place

Secondary exposure:
Not relevant as rinsing takes place

Qualitative assessment of the different uses Meta SPC4
Scenario 1 - CIP: Sopurclean CIP OP

Step 1: Description of the local hazards
Undiluted biocidal products:
Skin corrosive Cat. 1A, H314 (Causes severe burns and eye damage)
STOT SE 3, H335 (May cause respiratory irritation)
Based on the composition of the meta SPC1 BPF products

Diluted biocidal products (2%):
Skin corrosive Cat. 1A, H314 (Causes severe burns and eye damage)
Based on the pH of the 2% solutions: pH < 2

Local endpoints: Local skin and eye effects = skin corrosion

Step 2: Assignment of hazard categories
The classification of the Biocidal products in meta SPC4 is as starting point.

Classification	Hazard Category
Skin Corr. Cat. 1A	Very high
STOT SE 3	Low

Step 3: Identification of the exposure scenarios
See 2.2.6.2. Exposure assessment

Professionals only
Scenario 1: CIP

Step 4: Acceptability or non-acceptability of the risks

Scenario 1: CIP
Sopurclean CIP OP

Primary exposure: use of the concentrated product - M&L phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk
Very high	Skin corr. Cat 1A, H314 STOT SE 3 H335	-	4	Professionals	IBC containers containing the product are connected to CIP via installed pipes	Skin Eye Respiratory tract	Low frequency Few minutes per day or less Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin, eye and respiratory exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling Treated equipment (vessels) and dosing equipment has to be rinsed) Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable

Primary exposure: use of the diluted application solution – application phase

Hazard			Exposure						Risk
Hazard category	Effects in term of C&L	Additional relevant hazard information	PT	Who is exposed	Task, uses, processes	Potential exposure route	Likelihood, frequency, duration potential exposure	Relevant RMM	Conclusion on risk

Very high	Skin corr. Cat 1A, H314	-	4	Professionals	CIP use takes place in a closed system Treated equipment (vessels) and dosing equipment has to be rinsed) Exceptional maintenance work with max. 2% dilutions	Skin Eye Respiratory tract	Low frequency Few minutes per day (closed system) Exceptional maintenance: more than few minutes Very low potential for exposure	Technical and organisational RMM adequate for the very high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure (IBC containers containing the product are connected to CIP via installed pipes; connections with dry coupling Treated equipment (vessels) and dosing equipment has to be rinsed) Use of appropriate PPE: coverall, gloves, goggles, face shield in case there is potential for splashes.	Acceptable: No exposure expected since + Technical and organisational RMM adequate for the very high hazard category are achievable + Trained workers + use of appropriate PPE

Primary exposure: post-application phase / Secondary exposure
Not considered relevant as rinsing takes place

Secondary exposure:
Not relevant as rinsing takes place

Conclusion

Qualitative assessment of the different uses Meta SPC1
Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, the M&L, the application, and the post-application phases, the risk is considered acceptable for:

Scenario 1 – CIP
(products: Septacid BN, Septacid BN PS, Sopurclean BN, Sopurclean BN PS, Sopurcip EC)

Scenario 3 – Soaking baths
(products: Septacid BN PS, Sopurclean BN PS, Sopurcip EC)
Secondary exposure is not relevant

Qualitative assessment of the different uses Meta SPC2
Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, the M&L, the application, and the post-application phases, the risk is considered acceptable for:

Scenario 1 – CIP
Scenario 2 – Spraying systems low pressure
Scenario 3 – Soaking baths
Scenario 4 – Manual cleaning

(all related to the Sopurclean NR product)
Secondary exposure is not relevant

Qualitative assessment of the different uses Meta SPC3
Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, the M&L, the application, and the post-application phases, the risk is considered acceptable for:

Scenario 1 – CIP
(products: Sopurclean OP N)
Secondary exposure is not relevant

Qualitative assessment of the different uses Meta SPC4
Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, the M&L, the application, and the post-application phases, the risk is considered acceptable for:

Scenario 1 – CIP
(products: Sopurclean CIP OP)
Secondary exposure is not relevant

Risk for non-professional users

The biocidal products of the SOPURCLEAN BPF are for professional use only.
No non-professional exposure is foreseen.

Risk for the general public

The biocidal products of the SOPURCLEAN BPF are not sold to non-professionals and possible residues in food and beverages are very low and of no concern (see also DocIV-A2.10/03; original BPF dossiers). See also 'Dietary exposure'.
Human exposure of the general public is considered not relevant.

Risk for consumers via residues in food

Meta SPC1, 3 and 4
The only possibility of secondary exposure as a result of use of BPs from meta SPC 1, 3 and 4 is when a consumer drinks a beverage e.g. beer or eats food which was processed in a plant where the processing installations were disinfected with these BPs. The contribution of these residues originating from the CIP process is considered to be not relevant regarding the low concentrations possible in drinks and food e.g. beer. The possible residues are only a small fraction compared to the natural presence. Verschaeve 2006 (A2.10/03) describes as, an example, the unavoidable residues in a brewery showing a residue of 2.6 – 150 ppb octanoic + decanoic acid from CIP processing compared to 100 – 4000 ppb naturally present in beer.
In conclusion, possible residues in food and beverages are very low and of no concern (see also DocIV-A2.10/03; original BPF dossiers).

Meta SPC2
The meta SPC2 product Sopurclean NR does need not to be rinsed according to the applicant because in the diluted form the product and active substances are not hazardous anymore (systemic and local).
Additionally, the non-rinsing of the meta SPC2 product is further discussed in the context of the recent guidance on Maximum Residue Limits (MRLs) – interim approach (CA-March 27-Doc.7.6.c-final).
Sopurclean NR is diluted for all 4 scenario's to a 1 to 2% solution, which contains in this final solution (based on 2%) 0.054% octanoic acid and 0.006% decanoic acid. For the C8 and C10 acids the derivation of systemic AELs were considered unnecessary. Risk assessment is focused on risk for local effects. At the diluted concentration, there is no local hazard anymore. That is the trigger why no rinsing is required for the meta SPC product Sopurclean NR.
For octanoic and decanoic acid no ADI or ARfD are set, and no specific MRL's are set or required yet according to Leg (EU) 2015/1608 (Annex IV).
As no specific MRL exists for octanoic and decanoic acid, a default MRL value of 0.01 mg/kg food could be applied. However, as no specific reference values can be derived due to the lack of systemic adverse effects (no systemic AELs, ADI, ARfD) no assessment is deemed needed. In addition, according to the CARs the daily human uptake of fatty acids as natural food contents is, e.g. according to Henderson et al 2003 already about 900 mg/kg bw day. The consumer exposure to the active substances (without systemic hazards identified, without derived reference values) linked to use as a biocidal product is considered as negligible compared to other uses in the food chain.
In conclusion, possible residues in food and beverages are of no concern.

1.2.7 Risk assessment for animal health

Not relevant.

1.2.8 Risk assessment for the environment

The following assessment covers the ***SOPURCLEAN BPF*** grouping a range of products used as disinfectants in food and feed areas (PT4).
The BPF Sopurclean is divided in four Meta SPC:

- Meta SPC1 grouping Septacid BN, Sopurclean BN, Septacid BN-PS, Sopurclean BN-PS and Sopurcip EC
- Meta SPC2 with Sopurclean NR
- Meta SPC 3 with Sopurclean OP N
- Meta SPC 4 with Sopurclean CIP OP

The products of the ***SOPURCLEAN BPF*** contain a mixture of two active substances: Octanoic acid, with a concentration ranging from 1.1% to 2.7%, and Decanoic acid, with a concentration ranging from 0.3% to 1.5% (Please refer to Table 2.2.8–1 in the Confidential Annex for additional information).
The concentration in the formulated products is 3% maximum for both active substances.

Two formulated products containing the highest concentration of active substances - i.e. **Septacid BN** and **Sopurclean NR** – are used in the risk assessment as worst-case representatives of the ***SOPURCLEAN BPF***. **Septacid BN** is used as representative for meta SPC1, 3 and 4 products while **Sopurclean NR** is representative for meta SPC2 products.

1.2.8.1 Effects assessment on the environment

All data used for the effect assessment of *Septacid BN* and *Sopurclean NR* are based on the available information on the active substances Octanoic acid and Decanoic acid, such as they are presented in their respective CAR.
In addition two new tests on the products *SOPURCLEAN CIP OP* (1.8% of Octanoic acid and 1.2% Decanoic acid) and *SOPURCLEAN CIP LF* (Octanoic acid 5%) have been submitted by the applicant in order to prove that increasing the Octanoic acid concentration from 1.5% to 2.7% should not impair the sewage treatment plant functioning (Please refer to monitoring data paragraph in part III "Emission estimation" and to Document III-B).

An overview of the physico-chemical characteristics and ecotoxicity data of the active substances, taken from their respective EU CAR, is summarized below.

Environmental fate and behaviour

Octanoic and Decanoic acids are readily biodegradable (with a mean degradation rate of 84% and 92% respectively, at the end of the 28 days exposure period), both passing the 10-days window criteria. The adsorption/desorption screening tests showed that both active substances rapidly degrade in soil despite soil sterilization, so that no equilibrium could be reached (K_{oc} calculated via EUSES was 83.9 L/kg for Octanoic acid and 264 L/kg for Decanoic acid), leading to negligible likelihood for leakage of these substances to groundwater. Neither hydrolysis, nor photolysis are

expected in water for both fatty acids due to the lack of functional group or reactive center able to react within the aquatic environment.

The vapour pressure of Octanoic and Decanoic acids is low ($1.35x10^{-2}$ and $2.17x10^{-4}$ Pa at 25 °C, respectively), resulting in low exposure to the atmosphere. The half-life of the substances was calculated to be 46.1h (Octanoic acid) and 34.5h (Decanoic acid) respectively, leading to an accumulation in air and a long-range transport unlikely.

Octanoic acid is liquid at room temperature (melting point:16.6°C) while Decanoic acid is solid to 29.8-31.6°C. Both substances have a good solubility in water (2.97 g/L for Octanoic acid and 43 mg/L for Decanoic acid). Octanoic and Decanoic acids are also completely miscible in octanol (the calculated log Pow was 3.03 and 4.09, respectively), indicating a high potential for bioaccumulation.

Ecotoxicity data

Ecotoxicity data for Octanoic and Decanoic acids are summarized in Table 2.2.8–2. All data are available in their respective CAR (Document II-A.4 Environmental effects assessment).

Table 2.2.8–2 Summary of the ecotoxicological studies used to derive the Predicted No Effect Concentrations for Octanoic acid and Decanoic acid

Species	Study	Endpoint	Octanoic acid	Decanoic acid
Fish	Acute	LC_{50} (96h)	68 mg/L	81.2 mg/L[1]
Aquatic invertebrate	Acute	EC_{50} (48h)	13.4 mg/L[2]	16 mg/L
Algae growth	Chronic	NOE_rC	**0.47 mg/L[2]**	**0.57 mg/L**
Respiration inhibition, Aerobic activated sludge	Chronic	NOEC	**≥ 837 mg/L[2]**	**≥ 1,000 mg/L**
Mammal, oral dietary	Short-term	NOEL	≥ 7000 mg/kg bw/day[2]	≥ 7000 mg/kg bw/day[3]
Bird, oral dietary	Short-term	EC_{50}	**> 993 mg/kg diet[4]**	**> 993 mg/kg diet[4]**

In bold, endpoints used to calculate the Predicted No Effect Concentrations (PNEC).
[1]No test was submitted for this endpoint for Octanoic acid, so Decanoic acid results presented here rely on read-across to Octanoic acid.
[2]No test was submitted for this endpoint for Decanoic acid, so Octanoic acid results presented here rely on read-across to Decanoic acid.
[3]NO(A)EL for Decanoic and Octanoic acid is ≥ 7300 mg/kg bw day based on the assumption that both acid doses may be summed up for a common NO(A)EL.
[4]No toxicity tests were performed on birds for Octanoic and Decanoic acid. However, data of tests conducted with Nonanoic acid are available for read across.

Both active substances showed a relatively low acute toxicity for fish and daphnid but a high chronic toxicity to algae (NOEC = 0.57 mg/L for Decanoic acid and 0.47 mg/L for Octanoic acid). No other long-term studies were required because the substance is primarily emitted to the sewage treatment plant (STP) before reaching the aquatic environment. No marine species were tested based on studies performed on freshwater species and because no major emissions to the marine environment are expected. As lowest endpoint for the aquatic compartment was provided by the algae growth test for both fatty acids, the NOEC measured in these studies was used to derive the Predicted No Effect Concentrations (PNEC) for the water compartment. Table 2.2.8–3 summarizes the PNEC for the different compartment according to the active substance.

The effect on biological sewage treatment processes was assessed by determining inhibition of respiration of the micro-organisms present in aerobic activated sludge following 3 hours contact. No inhibitory effect on aquatic microbial activity was registered for Decanoic acid (NOEC ≥1000 mg/L) while no data was submitted for Octanoic acid. The effect assessment for this substance rely on data provided for Decanoic acid. The PNEC for STP micro-organisms was derived from the endpoint of the respiration inhibition test.

There are no toxicity data available for sediment-dwelling organisms, neither for Octanoic acid, nor for Decanoic acid. The PNEC for benthic organisms was therefore calculated based on equilibrium partitioning method and PNECwater.

For the soil compartment, there are also no toxicity data available. Since for the relevant products no direct exposure to the terrestrial compartment is expected, further testing was not considered necessary. The PNEC for soil organisms was thus calculated based on the equilibrium partitioning method.

The log Pow value of Octanoic and Decanoic acid were both over the trigger value of 3, suggesting a risk of bioaccumulation and secondary poisoning via ingestion of contaminated food (eg. earthworms or fish) by birds or mammals. The BCF for fish, calculated from the log Pow of the substance, was 75 L/kg for Octanoic acid and 597.72 L/kg for Decanoic acid. The calculated BCF for earthworm was 14 L/kg for Octanoic acid and 148 L/kg for Decanoic acid. However, bioaccumulation should not be an issue as both active substances are rapidly biodegradable. Moreover, they are fatty acids, metabolized by ß-oxidation, which is quantitatively the most significant pathway for catabolism of fatty acids and results in the final products CO_2 and water.

To estimate the secondary poisoning via the aquatic and the terrestrial food chain, chronic oral toxicity data have to be submitted for birds and mammals. For dietary toxicity tests on mammals, rats received for 91 days a diet consisting to 26.6% of Decanoic acid, 23.2% Octanoic acid and triglycerides. The NOEL was calculated to be 7000 mg/kg bw/day, giving a long-term $PNEC_{oral}$ for mammals of 1555 mg a.s./kg diet for both substances.
No toxicity data were submitted for birds, neither for Decanoic acid, nor for Octanoic acid. However, data of tests conducted with Nonanoic acid are available for read across (Please refer to the Assessment Report for Nonanoic acid, 2010). As no mortality or other effect was observed during the dietary tests on birds, the EC_{50} of dietary toxicity tests in Japanese quail and Mallard duck was > 993 mg/kg diet, giving a long-term $PNEC_{oral}$ for birds of 0.331 mg a.s./kg diet for both substances. As the long-term PNEC for mammals is higher than those for birds, only the PNEC for birds is considered for the risk assessment.

The physico-chemical properties of the active substances do not suggest that they may pose a risk to the atmospheric environment. Therefore, no PNECs where calculated for the air compartments.

Table 2.2.8–3 Predicted No Effect Concentrations for Octanoic acid and Decanoic acid according to the environmental compartment

PNEC by compartment	Unit	Octanoic acid	Decanoic acid
$PNEC_{water}$	mg/L	0.0047	0.0057
$PNEC_{STP\ micro\text{-}organisms}$	mg/L	83.71	100.0
$PNEC_{sediment}$*	mg/kg wwt	0.0123	0.0372
$PNEC_{soil}$*	mg/kg wwt	0.0075	0.0272
$PNEC_{oral,chronic}$	mg/kg diet	0.3310	0.3310

** PNEC for soil and sediment were calculated via the equilibrium partitioning method.*

No further information is available on the active substances or on the products.

(I) Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

According to the CAR of the active substances, Octanoic acid is classified as "Aquatic chronic 2– H411" (Toxic to aquatic life with long lasting effects) and Decanoic acid is classified as "Aquatic Chronic 3 – H412" (Harmful to aquatic life with long-lasting effects). However a more recent harmonised classification is available. In such case, according to the Guidance on the Application of the CLP Criteria[4], the harmonised classification must be used.

According to the Classification & Labelling Inventory of ECHA, Octanoic acid[5] and Decanoic acid[6] have both a harmonized classification for ecotoxicology and are classified as "Aquatic Chronic 3 – H412" (Harmful to aquatic life with long-lasting effects).
The active substances contained in the BPF are the same as evaluated in their respective CAR and therefore no new data or information on these active substances is required.

Please see Confidential Annex for additional information.

Therefore, it can be concluded that the formulated products do not contain any substances at such a concentration that it has an effect on the environmental classification of the ***SOPURCLEAN BPF***. No additional information is then required.

Conclusion on the environmental classification and labelling of the product
None of the products contained in the ***SOPURCLEAN BPF*** require an environmental classification or labelling.

(II) Further Ecotoxicological studies

No further data is available.

Regarding the endocrine disruption assessment of active and non-active substances in the ***SOPURCLEAN BPF***, a stepwise approach based on CA-March18.Doc.7.b-final was followed:

First step: Assessment of the ED properties of the active substances in ***SOPURCLEAN BPF***:

4 ECHA (2017), Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 5.0

5 https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/92567

6 https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/34031

According to point 2.1.1 of the CA document, the assessment of endocrine disrupting properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the RMS should not evaluate the endocrine disrupting properties of these substances nor request additional data on the endocrine disrupting properties in the context of product authorisation procedures. The CAR of Octanoic acid and Decanoic acid stated that there is no evidence for endocrine disruption for these substances. Moreover, as Octanoic acid and Decanoic acid are not part of the list[7] of approved active substance identified as possible endocrine disrupting, it is for the moment not triggered for an early review.
Therefore, BE eCA considers that there is no concern regarding endocrine disrupting properties of Octanoic acid and Decanoic acid

Second step: Assessment of the endocrine disrupting properties of non-active substances ('co-formulants') in ***SOPURCLEAN BPF***:

After reviewing the potential endocrine disrupting properties of co-formulants (please refer to the procedure in Annex), none of the co-formulants are subject to an on-going evaluation or a decision regarding their endocrine disrupting properties. Based on the available information, BE eCA considers that there is no concern regarding the endocrine disrupting properties of these co-formulants.

Overall conclusion on the biocidal family regarding endocrine disrupting properties of the Biocidal Family Product ***SOPURCLEAN***:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the endocrine disrupting properties of the substances used in the formulated product of the ***SOPURCLEAN BPF***.
If one or several components are identified as having endocrine disrupting properties in the future, the conditions for granting the Biocidal Family Product authorisation will be revised.

(III) Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

The two respiration inhibition tests, using SOPURCLEAN CIP OP[8] (1.8% of Octanoic acid and 1.2% Decanoic acid) and SOPURCLEAN CIP LF[9] (5% Octanoic acid), have been performed to measure the inhibition of aerobic nitrification, aerobic carbon oxidation and anaerobic carbon reduction (Please refer to Document III-B). They are summarized in the table below.

Summary table - Further ecotoxicological studies

Summary table of further ecotoxicological studies							
Method, Guideline, GLP status, Reliability	Species/ Inoculum	End point	Exposure	Results		Remark	Reference
			Duration	NOAEL (ppm)	IC_{50} (ppm)		
-	Activated sludge	COD removal	15 h	>700	>700		Houtmeyers M., Appels L. (2017)

7 Please refer to CA-September18.Doc.7.5.a-final .

8 Houtmeyers M., Appels L. (2017), "Sopura report: Inhibition assessment of aerobic/anaerobicwastewater treatment processes by SOPURCLEAN CIP OP", KULeuven, Leuven, Belgium.

9 Van den Broeck R. *et al.* (2014), "Sopura report: Inhibition assessment of aerobic/anaerobic wastewater treatment processes by SOPURCLEAN CIP LF", KULeuven, Leuven, Belgium.

		NH_4N removal	-	>700	>700		
		Biogas yield	27 d	>600	>700		
-	Activated sludge	COD removal	15h	900 <X< 1800	900 <X< 1800		Van den Broeck R. *et al.* (2014)
		NH_4N removal	-	<900	900 <X< 1800		
		Biogas yield	14 d	<900	1800 <X< 4600		

The reports are quite succinct[10]: material and method are brief and incomplete, raw data were not reported and no reference substance was used in these tests. Moreover, it was not stated if a guideline (e.g. OECD 209) has been followed or if the tests were performed under GLP. These reports were therefore only considered as supporting information.

SOPURCLEAN CIP OP was tested at concentration of 0, 300, 400, 500, 600 and 700 ppm, which corresponds to an Octanoic acid concentration of 0, 5.4, 7.2, 9.0, 10.8 and 12.6 mg/L, respectively.
Regarding aerobic processes assessment, the activated sludge was taken from a large-scale municipal wastewater treatment plant, which is designed and operated for carbon oxidation and nitrification/denitrification. Inhibition of biological carbon oxidation was assessed by respirometry, i.e. by measuring the activated sludge oxygen uptake rate (OUR). The specific OUR (SOUR) is the OUR divided by the biomass concentration. The tested concentrations did not induce any visible inhibitory effects towards the microorganisms responsible for carbon oxidation: all corrected COD removal rates ranged between 105 and 110% and the highest values for relative SOUR decrease (-25.6% at 500 pm) indicated that the product is aerobically biodegradable, indicating that carbon oxidation was unaffected by the addition of SOPURCLEAN CIP OP at concentrations up to 700ppm.
Moreover as the OUR is proportional to the nitrification rate, nitrification rate can also be monitored by respirometry. The ammonia removal rate ranged between 101 and 102% at all test concentrations and the relative SOUR-decrease was below the 10% threshold for all test concentrations, indicating no inhibitory effect of SOPURCLEAN CIP OP at concentrations up to 700ppm.
Inhibition of the anaerobic degradability was determined via a Biochemical Methane Potential test, in laboratory scale mesophilic single stage batch reactors of 1L content. The batch reactors were inoculated with digested wastewater sludge (5g organic dry solids) originated from the digester of a full-scale WWTP (Antwerpen-Zuid, Belgium), then filled with synthetic wastewater (composition based on those described by Ersahin et al.,2014[11]) in a 1:1 DS:COD ratio. Finally, tap water was added to reach a total volume of 850mL in each reactor. Reactors were subsequently incubated at 37°C

10 The Applicant wishes to further clarify that these reports were not initiated with the current use/application in mind. This explains the incompleteness of the report.

11 Ersahin M.E., Ozgun H., Tao Y., van Lier J.B. (2014). Applicability of dynamic membrane technology in anaerobic membrane bioreactors, Water Research (48:1), 420-429

in a temperature controlled water bath. The batch experiments are monitored until the digestion process is completed (at least 14 days). All tests were carried out in triplicate. The produced biogas was collected in displacement bottles filled with acidified water (0.05M H_2SO_4) to prevent the dissolution of CO_2. During the test period, the volume of biogas was monitored by the displacement of the liquid. Next to the biogas production, COD and concentration of organic acids were measured before and after digestion. After 27 days, there was a decrease of biogas yield at all tested concentrations, except at 400 ppm where biogas yield increased. However, none of these variations were significant, except at 600 ppm (- 27% of biogas yield compared to the blank control). The COD concentrations (481-543 mO_2/L) were comparable to the control and organic acid concentrations (80.5-101 mg/L) were well below the inhibitory threshold of 5000 mg/L. There was no reduced COD removal or build-up of volatile fatty acids during the digestion process.
Based on these results, NOAEL for SOPURCLEAN CIP OP was set at 700 ppm for carbon oxidation and nitrification. However, as the anaerobic carbon reduction test showed a detectable decrease in biogas yield at 600 ppm, the NOAEL for SOPURCLEAN CIP OP was set at 500 ppm for carbon reduction, which corresponds to an Octanoic acid concentration of 9.0 mg/L.

In the second study, SOPURCLEAN CIP LF was tested at concentrations of 0, 900, 1800, 4600 and 9200 ppm, corresponding to an Octanoic acid concentration of 45, 90, 230 and to 460 mg/L.
Regarding aerobic processes assessment, the activated sludge was taken from a large-scale municipal wastewater treatment plant, which is designed and operated for carbon oxidation and nitrification/denitrification. Inhibition of biological carbon oxidation was assessed by respirometry (please see above). Only at lowest tested concentration i.e., 900ppm, no inhibitory effect was recorded. For all other concentrations, carbon oxidation was completely inhibited: respiration ceased completely (100% of relative SOUR decrease) and no COD was removed (from -7.9% at 1800 ppm to 2.1% at 9200 ppm). It was suspected that the strongly acidic pH of the test product, due to lactic, propionic and sulphuric acids, was partly responsible of the inhibition of the biological carbon oxidation.
Nitrification rate was also monitored by respirometry. The ammonia removal rate significantly decreased from 1800 ppm (27.3%) while the nitrification rate significantly decreased from 900 ppm (47.99% of relative SOUR decrease, increasing to 100% from 1800 ppm). It was suspected to be partly due to the high acids concentration in the formulated product, which strongly acidified the medium.
Inhibition of the anaerobic degradability was determined via a Biochemical Methane Potential test, in laboratory scale mesophilic single stage batch reactors of 1L content. The batch reactors were inoculated with digested wastewater sludge (150 mL) originated from the digester of a full-scale WWTP (Antwerpen-Zuid, Belgium), then filled with 660 mL of synthetic wastewater (starch solution diluted with with tap water to reach a COD concentration equal to 50000 mg/L). Reactors were subsequently incubated at 37°C in a temperature controlled water bath. The batch experiments are monitored until the digestion process is completed (14 days). All tests were carried out in triplicate. The produced biogas was collected in displacement bottles filled with acidified water (0.05M H_2SO_4) to prevent the dissolution of CO_2. During the test

period, the volume of biogas was monitored by the displacement of the liquid. Next to the biogas production, COD and concentration of organic acids were measured before and after digestion. After 14 days, there was a significant decrease of biogas yield from 18000 ppm (- 44% compared to the blank control). The COD concentrations (1384-1884 mO_2/L) were comparable to the control and organic acid concentrations (104-1272 mg/L) were below the inhibitory threshold of 5000 mg/L.
Based on these results, the NOAEL for SOPURCLEAN CIP LF was set at 900 ppm for carbon oxidation and carbon reduction while NOAEL was <900ppm for nitrification. This correspond to an Octanoic acid concentration of 45 mg/L.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	Supporting information
Justification for the value/conclusion	No method, guideline and GLP status mentioned, no reference substance, material and method incomplete, raw data not reported.

(IV) Supervised trials to assess risks to non-target organisms under field conditions

No further data is available.

(V) Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

The product is not in the form of bait or granules, so no such data is required.

(VI) Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant.

(VII) Foreseeable routes of entry into the environment on the basis of the use envisaged

According to the intended uses of the ***SOPURCLEAN BPF***, the main emission pathway to the environment is assumed to be the waste water. It is assumed that waste water is emitted to the surface water after treatment in a local waste water treatment plant. Fresh water and fresh water sediments could thus be exposed to the active substances. The soil can be then exposed through sludge application, leading to an emission to groundwater. Emissions to air are considered to be negligible. More information is available below in Section 2.2.3 Fate and distribution in exposed environmental compartments.

(VIII) Further studies on fate and behaviour in the environment (ADS)

No further data is available. It was stated in the CAR of both actives substances that additional information is required for product authorisation, concerning the degradation rates of the active substances during pre-treatment and/or in a waste water treatment plant (e.g. preferably monitoring of STP influent and effluent concentrations, or by means of simulations tests). Indeed, both Octanoic and Decanoic acids exceeded the trigger concentration of 0.1 µg/L in groundwater after emission

from an off-site STP following the use in CIP, which is equivalent to the Scenario 1 assessed below (Please refer to Doc II-C of CAR of Octanoic and Decanoic acid).

However a monitoring study, measuring the concentration of both Octanoic and Decanoic acids in STP effluent, was already submitted with the CARs of the active substances (please refer to "Monitoring data" in the section "Emission estimation" below). This study was performed with **SEPTACID BN**, which is used as representative for meta SPC1, 3 and 4 products. Two reports were provided to demonstrate that this monitoring study can also cover meta SPC 2 product (for further details, please refer to "Monitoring data" in the section "Emission estimation" below). Given that this montoring study was already performed with a representative product of the ***SOPURCLEAN BPF*** and given that the risk assessment performed below (based on all available data) showed that no unacceptable risk to the groundwater is expected from the ***SOPURCLEAN BPF*** and that the requirements of Directive 98/83/EC and 2006/118/EC[12] are complied with, no further data were deemed necessary and no new monitoring data was requested.

(IX) Leaching behaviour (ADS)

Not relevant.

(X) Testing for distribution and dissipation in soil (ADS)

For details, please refer to the respective CAR of Octanoic and Decanoic acid (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –Distribution and dissipation in soil	
Value/conclusion	Octanoic and Decanoic acid can be both considered to be "readily biodegradable", passing the 10-day window (79-80% biodegradation for Decanoic acid and 66-73% of degradation for Octanoic acid after 10 days). The DT_{50} soil value of both substances was estimated to be 2.1 days at 12°C (based on data from Nonanoic acid). A default Koc value of 264 L/kg for Decanoic acid and 83.9 L/kg for Octanoic acid has been calculated via EUSES.

(XI) Testing for distribution and dissipation in water and sediment (ADS)

For details, please refer to the respective CAR of Octanoic and Decanoic acid (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –distribution and dissipation in water and sediment	
Value/conclusion	Neither Decanoic acid, nor Octanoic acid can be hydrolysed or photolysed in water. As both active substances are readily biodegradable and no Koc value could be determined due to their fast degradation in soil, Octanoic and Decanoic acid are not expected to be persistent in sediment.

(XII) Testing for distribution and dissipation in air (ADS)

12 Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, OJL372, 27.12.2006.

For details, please refer to the respective CAR of Octanoic and Decanoic acid (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –distribution and dissipation in air	
Value/conclusion	The DT_{50} air value has been estimated to be 46.1h for Octanoic acid and 34.5h for Decanoic acid. No accumulation in air is to be expected.

(XIII) If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant.

(XIV) If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant

1.2.8.2 Exposure assessment

The environmental exposure assessment has been performed in accordance with the Emission Scenario Document for Product Type 4 (Disinfectants used in food and feed areas)[13] as well as the Guidance on the Biocidal Product Regulation (ECHA, 2015)[14] and the EUSES Background report (EC 2004)[15] and is based on information relating to the Intended Use (Chapter 3 of this document) and confidential information available in the respective CAR of the active substances (Doc. II-B confidential). The environmental exposure assessment was conducted for the local scale only. The emission estimations have been calculated for the whole ***SOPURCLEAN BPF***, i.e. for an Octanoic acid concentration of 2.7% and a Decanoic acid concentration of 1.5% as a worst-case situation.

In the Emission Scenario Document for Product Type 4 (ESD for PT 4) the environmental release pathway for substances used as disinfectants in food, drink and milk industries is described. The main emission pathway to the environment is assumed to be the **waste water**. Based on the physico-chemical properties of the active substances, it is expected that the emissions will primarily affect the aquatic compartment

(I) General information on Septacid BN (representative product for meta SPC 1,meta SPC 3 and meta SPC 4)

Assessed PT	**PT 4 – Food and Feed Area**

13 JRC scientific and technical reports (2011). Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas.

14 ECHA (2015) Guidance on Biocidal Products Regulation: Volume IV Environment Part B Risk Assessment (active substances), Version 1.0. European Chemicals Agency, Helsinki, Finland. Available via https://echa.europa.eu/

15 EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via http://ecb.jrc.ec.europa.eu/euses/.

Use of the product	*Cleaning In Place (CIP):* The biocide is (semi-) automatically dosed in the CIP vessel either by volume or conductivity measurements. The solution circulates in the closed equipment (pipes, tanks, etc.) for disinfection. Vessels are cleaned by spraying them with the biocide solution. High and low pressure spraying are used. After disinfection the solution will be recovered in an adequate CIP vessel for re-use. Rinse carefully the treated equipment (vessels) and the used pumping pipes. Frequency (indicative): about 300 runs/year within the CIP circuit. Use concentration: 1.5% v/v max., +4°C Contact time: 15 minutes Industrial / Trained professional
	Dipping/soaking: The biocidal product is used for the disinfection of small parts (spare parts, tools, valves, hoses, etc.) used along the food manufacturing process. Based on the type of industry, the surface is typically pre-cleaned or pre-rinsed before the disinfecting step, but is not mandatory. The small parts are submerged in soaking baths containing a biocide solution. Rinse carefully the treated equipment (vessels) and the used pumping pipes. Use concentration: 1.5% v/v max., +4°C Contact time: 15 minutes Industrial / Trained professional
Assessed scenarios	Scenario 1: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) IHO (2006) Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries Scenario 3: Disinfection of milking parlour systems
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (EUR 25117 EN – 2011)
Approach	Scenario 1: Tonnage based Scenario 2: Average daily consumption Scenario 3: Average daily consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation - Volume IV Environment - Part B Risk Assessment (active substances) – Version 1.0, April 2015
Groundwater simulation	EUSES & FOCUS Pearl.
Confidential Annexes	YES
Life cycle steps assessed	Scenario: 1,2 and 3 Production: No Formulation: No Use: Yes Service life: No
Remarks	-

(II) General information on Sopurclean NR (representative product for meta SPC 2)

Assessed PT	PT 4
Use of the product	*Cleaning In Place (CIP):*

	The biocidal is (semi-) automatically dosed in the CIP vessel either by volume or conductivity measurements. The solution circulates in the closed equipment (pipes, tanks, etc.) for disinfection. Vessels are cleaned by spraying them with the biocide solution. High and low pressure spraying are used. After disinfection the solution will be recovered in an adequate CIP vessel for re-use. Rinse carefully the treated equipment (vessels) and the used pumping pipes. Frequency (indicative): about 300 runs/year within the CIP circuit. Use concentration: 1% v/v max., +4°C Contact time: 15 minutes Industrial / Trained professional
	Spraying The biocidal product is used for the disinfection of hard surfaces in contact with food processing. Based on the type of industry, the surface is pre-cleaned or pre-rinsed before the disinfecting step, although this is not a mandatory step. The diluted solution (typically 1%v/v) is sprayed on the surface via a low pressure spraying device. The final rinsing step may be skipped. Use concentration: 1% v/v max., +4°C Contact time: 15 minutes Industrial / Trained professional
	Dipping/soaking: The biocidal product is used for the disinfection of small parts (spare parts, tools, valves, hoses, etc.) used along the food manufacturing process. Based on the type of industry, the surface is pre-cleaned or pre-rinsed before the disinfecting step, although this is not a mandatory step. The small parts are submerged in soaking baths containing a biocide solution of typically 1%v/v. Rinse carefully the treated equipment (vessels) and the used pumping pipes. Use concentration: 1% v/v max., +4°C Contact time: 15 minutes Industrial / Trained professional
	Manual cleaning: The biocidal product is used for the manual disinfection of small parts used along the food manufacturing process. Based on the type of industry, the surface is pre-cleaned or pre-rinsed before the disinfecting step, although this is not a mandatory step. The small parts are manually cleaned using a biocide solution. Use concentration: 1% v/v max., +4°C Contact time: 15 minutes Industrial / Trained professional
Assessed scenarios	Scenario 1: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) IHO (2006) Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries Scenario 3: Disinfection of milking parlour systems
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (EUR 25117 EN – 2011)
Approach	Scenario 1: Tonnage based Scenario 2: Average daily consumption Scenario 3: Average daily consumption

Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation - Volume IV Environment - Part B Risk Assessment (active substances) – Version 1.0, April 2015
Groundwater simulation	EUSES & FOCUS Pearl.
Confidential Annexes	YES
Life cycle steps assessed	Scenario: 1,2 and 3 Production: No Formulation No Use: Yes Service life: No
Remarks	-

(III) Emission estimation

Scenario 1: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants), IHO (2006)

Tonnage based scenario

The emission estimation is based on the annual tonnage of the active substances used and on the annual waste water amount discharged by a processing plant as local point source. The tonnage-based data can be consulted in the confidential annex of the CAR of the respective active substances.

Concerning the STP to which the waste water is released, two cases have been distinguished:

- The waste water is released to an **on-site STP**. It was further assumed that the on-site treated waste water is directly released to surface water.
- The waste water is released to an **off-site STP** (municipal STP without on-site treatment) with the standard default values according to the Guidance on the Biocidal Product Regulation (BPR, 2015).

Calculations for Scenario 1

The concentration of active substance in influent (on-site STP) and effluent (off-site STP) are calculated according to the following equations:

Concentration of the active substance in the effluent of an on-site STP:

$$C_{effluent} = (Qa.i. / T_{emission}) \bullet 1{,}000 \bullet (1 - F_{dis}) \bullet (1 - F_{elim}) \bullet F_{water} / (CAP_{STP\_on\text{-}site} \bullet DIL)$$

Concentration of the active substance in the influent of an off-site STP:

$$C_{influent} = (Qa.i. / T_{emission}) \bullet 1{,}000 \bullet (1 - F_{dis}) \bullet (1 - F_{elim}) \bullet F_{water} / CAP_{STP\_off\text{-}site}$$

The parameters used for calculations are available in Table 2.2.8–4.Please note that the average annual amount of active substances (Qai) was calculated from the daily use of active substances as provided by the monitoring study, i.e. 5.9 kg for both Octanoic and Decanoic acid (Please see below "Monitoring data").

Table 2.2.8–4 Input parameter for calculating the local emission to the entire plant (scenario 1 – IHO, 2006)

Input parameters for calculating the local emission				
Scenario 1: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) - IHO (2006)				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Amount of biocidal active substance used per year in the local plant	$Q_{a.i\ octa\ \&\ deca}$	Confidential Data	kg/year	Calculated from monitoring study[1]
Number of emission days per year	$T_{emission}$	231	d/year	Default
Fraction released to wastewater	F_{water}	1	/	Default
Fraction of substance eliminated due to onsite pre-treatment of the plant waste water	F_{elim}	0	/	Default
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	/	Default
Capacity of the on-site STP	$CAP_{STP\_on\text{-}site}$	112.7	m³/d	Default
Capacity of the off-site STP	$CAP_{STP\_off\text{-}site}$	2,000	m³/d	Default
Dilution factor in surface water	DIL	160	/	Default

Results are available in Table 2.2.8–5.

Monitoring data

As a risk was identified for surface water and sediment with the standard scenario, the applicant has also submitted monitoring data (please refer to the CAR of the active substances).

Please refer to Confidential annex for more information.

As both active substances are readily biodegradable, other industrial sewage treatment plants using a product from the BPF Sopurclean might show equivalent performances. Therefore, the eCA proposes to consider the monitoring data adequate for refinement purposes (TIER 2) for both the on-site and off-site scenario:

- ON-SITE: the monitoring data will replace the calculated on-site effluent concentrations ($C_{effluent}$), taking into consideration the ESD default dilution factor of 160, since the monitoring data were measured just before release to the river (Please refer to Table 2.2.8–5).
- OFF-SITE: the monitoring data will be considered as a worst-case replacement for the influent concentration for the off-site STP ($Clocal_{influent}$). Worst-case, because no consideration will be given to other wastewater streams entering the off-site STP and thus diluting the wastewater stream from the brewery. The measured monitoring data will be considered as the actual STP influent concentration.

Please note that SEPTACID BN is considered to be only representative of Meta SPC 1, 3 & 4 (as it only contains 1.5% of Octanoic acid) and not of the whole BPF Sopurclean.

Therefore the applicant has submitted two new studies to show that increasing the concentration of Octanoic acid should not impair STP functioning and efficacy.

The two respiration inhibition tests, using SOPURCLEAN CIP OP (1.8% of Octanoic acid and 1.2% Decanoic acid) and SOPURCLEAN CIP LF (5% Octanoic acid), have been performed to measure the inhibition of aerobic nitrification, aerobic carbon oxidation and anaerobic carbon reduction (Please refer to Document III-B). The reports are quite succinct[16]: material and method are brief and incomplete, raw data were not reported and no reference substance was used in these tests. Moreover, it was not stated if a guideline (e.g. OECD 209) has been followed or if the tests were performed under GLP. These reports were therefore only considered as supporting information.

SOPURCLEAN CIP OP was tested at concentration ranging from 300 to 700 ppm which is the typical STP influent concentration and corresponds to an Octanoic acid concentration of 5.4 to 12.6 mg/L. No significant inhibition of the aerobic carbon oxidation (all corrected COD removal rates being over 100%) or of the aerobic nitrification (all ammonia removal rates being over 100%) were recorded at all tested concentration. The NOAEL for carbon oxidation and nitrification was thus set at 700 ppm for the product. However, the anaerobic carbon reduction test showed a detectable decrease in biogas yield at the concentration of 600 ppm (27% decrease compared to the blank control). So although there is no reduction of the COD and of the concentration of organic acids at all tested concentrations at the end of the test, the NOAEL for carbon reduction was set at 500 ppm, corresponding to an Octanoic acid concentration of 9 mg/L.

In the second study, SOPURCLEAN CIP LF was tested at concentrations ranging from 900 to 9200 ppm, corresponding to an Octanoic acid concentration of 45 to 460 mg/L. A significant inhibition of the aerobic carbon oxidation was measured from 1800 ppm (-7.9 % of corrected COD removal rate) while nitrification was inhibited at all tested concentrations (nitrification rate decreased by 48% at 900 ppm). It was suspected to be due to the high acid[17] concentration in the formulated product, which strongly acidified the medium. Anyway, in the absence of further data, the NOAEL was set at 900 ppm for carbon oxidation and <900ppm for nitrification. Regarding the anaerobic carbon reduction test, a significant decrease was measured in biogas yield from a concentration of 1800 ppm (44% reduction compared to the blank control). So although there is once again no reduction of the COD and of the concentration of organic acids at all tested concentrations, the NOAEL or carbon reduction was set at 900 ppm, corresponding to an Octanoic acid concentration of 45 to 460 mg/L.

The lowest endpoint provided by these tests corresponds to an Octanoic acid concentration of 9 mg/L in the STP. Above this concentration, the STP is suspected to be affected by the formulated product. However, according to the ESD calculations for emissions to wastewater due to the intended use of Sopurclean BPF, this inhibitory

16 The Applicant wishes to further clarify that these reports were not initiated with the current use/application in mind. This explains the incompleteness of the report.

17 According to the applicant, the formulated product contains lactic, propionic and sulphuric acids (and not formic acid as mentioned in the report).

concentration is well above the calculated influent concentration of Octanoic acid in the off-site STP (1.69 mg/L, please refer to Table 2.2.8–5). Although this concentration was calculated considering the total amount of Octanoic acid used per year in the local plant and not only the amount of Meta SPC 2 used per year, it was considered to be realistic as the calculated influent concentration of Octanoic acid in the on-site STP was 1.55 mg/L according to the monitoring study (please see above).

Therefore, both on-site and off-site STP should not be impaired by an increase of Octanoic acid concentration from 1.5% (Meta SPC1, 3 and 4) to 2.7% (Meta SPC 2) and monitoring data were considered to be suitable to refine the calculations for the whole BPF Sopurclean (i.e. for an Octanoic acid concentration of 2.7% and a Decanoic acid concentration of 1.5%).

Table 2.2.8–5 Resulting local waste water emission to the entire plant (scenario 1 – IHO, 2006)

Resulting local emission to relevant environmental compartments				
Compartment	**Nomenclature**	**On site**	**Off site**	**Remarks**
Octanoic acid [mg/L]				
On-site waste water effluent	$C_{effluent}$	$1.87x10^{-1}$	-	Standard scenario using confidential tonnage information
On-site waste water effluent	$C_{effluent}$	$2.81\ x10^{-5}$	-	Refinement with monitoring data*
Off-site waste water influent	$C_{influent}$	-	1.69	Standard scenario using confidential tonnage information
Decanoic acid [mg/L]				
On-site waste water effluent	$C_{effluent}$	$1.87x10^{-1}$	-	Standard scenario using confidential tonnage information
On-site waste water effluent	$C_{effluent}$	$8.13\ x10^{-5}$	-	Refinement with monitoring data*
Off-site waste water influent	$C_{influent}$	-	1.69	Standard scenario using confidential tonnage information

* In the report, it is stated that samples have been sampled in the effluent water of the STP just before diluting to the river water. To account the dilution of the STP effluent by the river, as calculated by Ceffluent, monitoring data were divided by 160 (default value for the dilution factor in surface water).

Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries, IHO (2006)

Please note that this scenario covers disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries by spraying as well as disinfection by dipping and soaking. Therefore, the Intended Uses "Dipping/soaking" and "Manual cleaning" are covered by this scenario.

Average consumption based scenario

The local emission is based on the number of applications, the application rate of disinfectant per m² and the area of the treated surface. The main fraction of the residues is released to the sewer system.

Intermediate calculation for Scenario 2 : Application rate of the active substance

To determine the application rates of active substances according to the characteristics and the intended uses of the product, the following equation was applied (parameters used for calculations and results are available in Table 2.2.8–6):

$$Q_{a.i\ appl} = Q_{prod\ appl} \bullet DIL \bullet f_{ai} \bullet \rho_{prod} / 1000$$

In the ESD for PT2[18], it is stated that "*Typical application rates for biocidal products found in the Internet (www.hygies.de) were 0.02-0.06 L/m², up to maximum 0.1L in the pharmaceutical industry"*. In the absence of more specific information, the application rate of use concentration of product ($Q_{prod\ appl}$) was set at 100 mL/m² as a worst-case default value.
The relative density of SOPRUCLEAN BN (1.29 g/cm³) was used in the calculation of the application rate of the active substances, as this formulated product showed the highest relative density (P_{prod}) in the **SOPURCLEAN BPF**.

Table 2.2.8–6 Input parameter for calculating the application rate of the for large scale catering kitchens, canteens, slaughterhouses and butcheries (scenario 2 – IHO, 2006)

Calculation of the application rate of the active substances and co-formulants					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		
Application rate of use concentration of product	$Q_{prod\ appl}$	100		mL/m²	Default
Dilution of the pure product	DIL	2		%	
Fraction of substance in product	f_{ai}	27	15	mL/L	
Relative density of formulated product	P_{prod}	1,290		g/L	
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		
Application rate of the substance	$Q_{a.i\ appl}$	$6.96x10^{-2}$	$3.86x10^{-2}$	g/m²	Output

Final calculation for Scenario 2

The local release to wastewater was calculated according to the following equation:

$$Elocal_{water} = Q_{a.i.appl} \bullet AREA_{surface} \bullet Nappl \bullet (1 - F_{dis}) \bullet (1 - F_{elim}) \bullet F_{water} / 1000$$

By default, one application per day is considered as a reasonable worst-case value. The parameters used for calculations are available in Table 2.2.8–7 and results are available in Table 2.2.8–8.

Table 2.2.8–7 Input parameter for calculating the local emission to large scale catering kitchens, canteens, slaughterhouses and butcheries (scenario 2 – IHO, 2006)

Input parameters for calculating the local emission					
Scenario 2: Releases for in large scale catering kitchens, canteens, slaughterhouses and butcheries - IHO (2006)					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		

18 JRC scientific and technical reports (2011). Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products

Application rate of the active substance	$Q_{a.i.appl}$	$6.96x10^{-2}$	$3.86x10^{-2}$	g/m^2	See above
Surface area to be disinfected for slaughterhouses & butcheries	$AREA_{surface}$	10,000		m^2	Default
Surface area to be disinfected for kitchens & canteens	$AREA_{surface}$	2,000		m^2	Default
Number of applications per day	Nappl	1		d^{-1}	
Fraction of substance disintegrated during or after application, before release to the sewer system	F_{dis}	0		-	Default
Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0		-	Default
Fraction released to wastewater	F_{water}	1		-	Default

Table 2.2.8–8 Resulting local waste water emission to the plant for large scale catering kitchens, canteens, slaughterhouses and butcheries (scenario 2 – IHO, 2006)

Resulting local emission to relevant environmental compartments				
Compartment	**Nomenclature**	**Local emission [kg/d]**		**Remarks**
		Slaughterhouses	**Catering kitchens**	
Waste water – Octanoic acid	$Elocal_{water}$	$6.96x10^{-1}$	$1.39x10^{-1}$	
Waste water – Decanoic acid	$Elocal_{water}$	$3.86x10^{-1}$	$7.73x10^{-2}$	

Scenario 3: Disinfection of milking parlour systems (Baumann, 2000)

Average consumption based scenario

Disinfection of milking parlours is performed by CIP after each milking event. It is assumed that the waste water from the milking parlour system is mainly released to the sewer system.

Intermediate calculation for Scenario 3: Concentration of substance

To determine concentration of substances according to the characteristics and the intended uses of the product, the following equation was applied (parameters used for calculations and results are available in Table 2.2.8–9):

$$C_{form} = DIL \bullet f_{ai} \bullet \rho_{a.i.} / 1000$$

Please note that the relative density of SOPRUCLEAN BN (1.29 g/cm³) was used in the calculation of the application rate of the active substances, as this formulated product showed the highest relative density (P_{prod}) in the **SOPURCLEAN BPF**.

Table 2.2.8–9 Input parameter for calculating the application rate of the substances for milking parlour systems (scenario 3 – Baumann, 2000)

Calculation of the application rate of the active substance					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		
Dilution of the pure product	DIL	2		%	
Fraction of active substance in product	f_{ai}	27	15	mL/L	
Relative density of formulated product	P_{prod}	1,290		g/L	
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		
Concentration of active substance	C_{form}	$6.96x10^{-1}$	$3.86x10^{-1}$	g/L	Output

Intermediate calculation for Scenario 3: Quantity of active ingredient

The quantity of active ingredient was calculated according to the following equation (parameters used for calculations and results are available in Table 2.2.8–10):

$$Q_{a.i.} = C_{form.} \bullet (V_{form\ inst} + V_{form\ tank})$$

Table 2.2.8–10 Input parameter for calculating the application rate of the active substances for milking parlour systems (scenario 3 – Baumann, 2000)

Calculation of the quantity of active ingredient					
Scenario 3: Disinfection of milking parlour systems (Baumann, 2000)					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		
Concentration of active substance	C_{form}	$6.96x10^{-1}$	$3.86x10^{-1}$	g/L	See above
Amount of disinfectant used for cleaning of the milking installation	$V_{form\ inst}$	130		L/d	Default
Amount of disinfectant used for cleaning of the milking storage tank	$V_{form\ tank}$	45		L/d	Default
Output	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		
Quantity of active ingredient used	$Q_{a.i}$	$1.22x10^{+2}$	$6.76x10^{+1}$	g/d	Output

Final calculation for Scenario 3

The local release to wastewater was calculated according to the following equation (parameters used for calculations are available in Table 2.2.8–11):

$$Elocal_{water} = Q_{a.i.} \bullet (1 - F_{dis}) \bullet F_{water} / 1000$$

2.2.8–11 Input parameter for calculating the local emission to milking parlour systems (scenario 3 – Baumann, 2000)

Input parameters for calculating the local emission					
Scenario 3: Disinfection of milking parlour systems (Baumann, 2000)					
Input	**Nomenclature**	**Value**		**Unit**	**Remarks**
		Octanoic	**Decanoic**		
Quantity of active ingredient used	$Q_{a.i}$	$1.22x10^{+2}$	$6.76x10^{+1}$	g/d	See above
Fraction of substance disintegrated during or after application, before release to the sewer system	F_{dis}	0		-	Default
Fraction released to wastewater	F_{water}	1		-	Default

Results are available in Table 2.2.8–12 below.

Table 2.2.8–12 Resulting local waste water emission to the plant for milking parlour systems (scenario 3 – Baumann, 2000)

Resulting local emission to relevant environmental compartments			
Compartment	**Nomenclature**	**Local emission [kg/d]**	**Remarks**
Waste water – Octanoic acid	$Elocal_{water}$	$1.22x10^{-1}$	
Waste water – Decanoic acid	$Elocal_{water}$	$6.76x10^{-2}$	

(IV) Fate and distribution in exposed environmental compartments

Scenario 1: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants)

Disinfection processes are highly automated. The waste water from the different plant units is collected in a collecting tank and the pH is adapted before release either to the public sewer system or to an on-site STP.

When the waste water is released to an **on-site STP**, it was assumed that the treated waste water is directly released to surface water where it can expose both fresh water and fresh water sediments. Exposure to other compartments, such as soil and groundwater (through sludge application), is not considered relevant. Emissions to air are considered to be negligible.

When the waste water is released to an **off-site STP** (i.e. municipal waste water treatment plant), it was assumed that waste water is emitted to the surface water after treatment. Fresh water and fresh water sediments could thus be exposed to the product. The soil can be exposed through sludge application, leading to an emission to groundwater. Emissions to air are considered to be negligible.

Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries

The main fraction of the residues is released to the sewer system. Waste water from slaughterhouses and butcheries, having a high organic load, is usually pre-treated before release to the sewer system while waste water from large scale catering kitchens and canteens is usually not treated before release to the waste water system. After treatment in a municipal STP, the effluent is emitted to the surface water where it can expose both fresh water and fresh water sediments. Application of sludge from the STP can result to an exposure of soil and groundwater. Emissions to air are considered to be negligible.

Scenario 3: Disinfection of milking parlour systems

Disinfection of milking parlours is performed by CIP after each milking event, then the system is flushed with clean water after disinfection to remove any residues of the product. It is assumed that the waste water from the milking parlour system is mainly released to the sewer system. However, in old farms, not connected to the sewer system, emission to manure can still occur, leading to an exposure of soil and groundwater.
After being collected by the sewer system, waste water is treated in a municipal STP, then the effluent is emitted to the surface water where it can expose both fresh water and fresh water sediments. The soil can be exposed through the application of sludge from the STP. Emissions to air are considered negligible.

Table 2.2.8–13 Identification of relevant receiving environmental compartments based on the exposure scenarios

Identification of relevant receiving compartments based on exposure pathway								
Scenario	**Freshwater**	**Freshwater sediment**	**Seawater**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Groundwater**
Scenario 1 – STP on site	Yes	Yes	No	No	No	(No)	No	No
Scenario 1 – STP off site	Yes	Yes	No	No	Yes	(No)	Yes	Yes
Scenario 2	Yes	Yes	No	No	Yes	(No)	Yes	Yes
Scenario 3	Yes	Yes	No	No	Yes	(No)	Yes	Yes

Table 2.2.8–14 Input parameters for calculating the fate and distribution in the environment

Input parameters for calculating the fate and distribution in the environment through EUSES				
Parameter	**Octanoic acid**	**Decanoic acid**	**Unit**	**Remarks**
Molecular weight	144.21	172.27	g/mol	
Melting point	16.6	29.8	°C	
Boiling point	237.0	146.8	°C	
Vapour pressure (at 25°C)	1.35×10^{-2}	2.17×10^{-4}	Pa	
Water solubility (at 20°C)	2,970	43.0	mg/l	Unbuffered

Log octanol-water partition coefficient (Kow)	3.03	4.02	Log 10	
Organic carbon-water partition coefficient (Koc)	83.9	264	L/kg	EUSES calculation
Henry's Law Constant	0.237	0.472	$Pa \bullet m^3/mol$	Calculated with HENRYWIN
Biodegradability	Readily biodegradable	Readily biodegradable		10 days windows passed
Rate constant for STP	-	-	h^{-1}	No data available
DT_{50} for biodegradation in surface water	-	-	d or hr	No data available
DT_{50} for hydrolysis in surface water	Not applicable	Not applicable	d or hr	
DT_{50} for photolysis in surface water	Not applicable	Not applicable	d or hr	
DT_{50} for degradation in soil (at 12ºC)	2.1	2.1	d	Read-across from Nonanoic acid
DT_{50} for degradation in air	46.1	34.5	hr	Calculated with AOPWIN
Accumulation BCF_{fish}	75	597.7	L/kg_{ww}	Calculated from log P_{ow}
Accumulation $BCF_{earthworm}$	14	148	L/kg_{ww}	Calculated from log P_{ow}

The calculations performed through Simple Treat with EUSES provide the following distribution in the STP, which in this case is only relevant for scenario 1 (Please refer to Table 2.2.8–15).

Table 2.2.8–15 Fate and distribution in the sewage treatment plant

Calculated fate and distribution in the STP			
Compartment	**Octanoic acid Percentage [%]**	**Decanoic acid Percentage [%]**	**Remarks**
Air	4.88×10^{-2}	9.48×10^{-2}	
Water	$1.26 \times 10^{+1}$	$1.24 \times 10^{+1}$	
Sludge	7.48×10^{-1}	2.41	
Degraded in STP	$8.66 \times 10^{+1}$	$8.51 \times 10^{+1}$	

(V) Calculated PEC values

PEC in air

In the ESD for PT 4 it is stated that depending on the substance characteristics and the method of application, there will be some potential for direct emissions to the air. Based on the physico-chemical properties of the active substances and co-formulants (low values for both vapour pressure and Henry's Law Constant) and on the Intended Use, the emission to air during the application of the product and finally the emissions via the STP can be considered as negligible for all scenarios. Therefore no significant amounts of Octanoic acid or Decanoic acid are expected in air.

PEC in STP

Predicted environmental concentration in the STP is determined after the elimination processes took place, i.e. degradation, volatilization and sedimentation of the active substances. The fraction remaining in water phase after elimination processes in STP (F_{water}) used for PEC_{STP} calculation are available in Table 2.2.8–15 (compartment : water)

Predicted environmental concentration in the STP is determined after the elimination processes took place, i.e. degradation, volatilization and sedimentation of the active substances.

The predicted environmental concentrations in the STP equal the concentrations in STP effluent and are calculated according to the following the equation:

$$PEC_{STP} = Clocal_{effluent} = Clocal_{influent} \bullet F_{water}$$

For scenario 2 and 3, the concentration in waste water influent is derived from the local release to wastewater ($Elocal_{water}$) multiplied by the amount of effluent/influent per day in the STP the STP ($2 \times 10^{+6}$ L/d per default):

$$Clocal_{influent} = Elocal_{water} \bullet EFFLUENT$$

Please remember that monitoring data were used to refine the concentrations of the off-site STP effluent in scenario 1 (see above "Monitoring data" in Section III Emission estimation). As no further dilution by other wastewater influents was taken into account in the off-site STP, it was considered to be a worst-case scenario.

The results of the calculation are available in Table 2.2.8–20 and Table 2.2.8–21. Please note that for clarity reason, only refined PECs data will be presented for scenario 1.

PEC in surface water

According to the Intended Use, no direct exposure to surface water is expected. Only indirect exposure via STP is possible. For scenario 1, when the treatment of the waste water is performed through an on-site STP, PEC in surface water is equal to on-site waste water effluent (please refer to Table 2.2.8–5). For all others scenarios, PEC in surface water was calculated according to the following equation (parameters used for calculations are available in Table 2.2.8–16):

$$PECwater = \frac{Clocaleffluent}{[1 + (Kp, susp \bullet SS \bullet 10^{-6})] \bullet DF} = \frac{PEC_{STP}}{[1 + (Kp, susp \bullet SS \bullet 10^{-6})] \bullet DF}$$

Please note that the concentrations in STP effluent ($Clocal_{effluent}$) are equal to PEC_{STP} (please refer to PEC in STP above), which are available in Table 2.2.8–20 and Table 2.2.8–21.

Table 2.2.8–16 Input parameters for calculating the predicted environmental concentrations in the surface water.

Input parameters for calculating the PECwater					
Input	**Nomenclature**	**Octanoic acid**	**Decanoic acid**	**Unit**	**Remarks**
Concentration in STP effluent	$Clocal_{effluent}$	Table 2.2.8–5 (scenario 1, on-site) Table 2.2.8–20 & 21 (others scenarios)		mg/L	See comments above.
Solid-water partitioning coefficient in suspended matter	$K_{p, susp}$	8.39	26.4	L/kg	Calculated, see below
Amount of suspended solid in receiving water	SS	10		mg/L	Default
Dilution factor after discharge	DF	15			Default

The Partitioning coefficient between solid and water in suspended matter is calculated by multiplying Koc by the weight fraction of organic carbon in suspended solids (Foc_{susp} = 0.1 by default).

Please note that in scenario 1, elimination processes are not taken into account for on-site STP due to the short distance between the point of effluent discharge and the exposure location (ESD for PT 4), so the PEC_{water} on-site is equal to the concentration of the active substance in effluent of the on-site STP. The results of the calculation are available in Table 2.2.8–20 and Table 2.2.8–21. Please note that for clarity reason, only refined PECs data will be presented for scenario 1.

PEC in sediment

The concentration in the solid phase of the sediment is derived from the concentrations in surface water according to equilibrium partition method. PEC in sediment was thus calculated according to the following equation (parameters used for calculations are available in Table 2.2.8–17):

$$\mathrm{PECsed} = \frac{\mathrm{Ksusp - water}}{\mathrm{RHOsusp}} \bullet \mathrm{PECwater} \bullet 1000$$

Table 2.2.8–17 Input parameters for calculating the predicted environmental concentrations in the sediment of freshwater.

Input parameters for calculating the PECsed					
Input	**Nomenclature**	**Octanoic acid**	**Decanoic acid**	**Unit**	**Remarks**
Suspended matter-water partitioning coefficient	$K_{susp\text{-}water}$	3	7.5	m^3/m^3	EUSES calculation
Density of suspended solid	RHO_{susp}	1,150		kg/m^3	Default
PEC in surface water	PEC_{water}	Table 2.2.8–20 and 21		mg/L	

The results of the calculation are available in Table 2.2.8–20 and Table 2.2.8–21.

PEC in soil

PEC_{local} in soil is normally determined by direct and indirect exposure. According to the Indented Use, direct emissions to the soil compartment is considered as not relevant. The indirect exposure is due to sludge application and described as follows in the BPR (ECHA, 2015): the concentrations in soil is calculated as the average concentration in agricultural soil over a certain time-period after 10 yearly applications of sludge and receiving continuous aerial deposition from a nearby point source over the same period. For terrestrial ecosystem, the concentration is averaged over 30 days while for human indirect exposure, a period of 180 days is used for a worst case approach. Two different soil types are distinguished in this last scenario: arable land and grassland.

Aerial deposition are not assumed to be relevant due to the physico-chemical characteristics of the substances (please refer to PEC in air above). It is assumed that removal is due to leaching, degradation and volatilization.

Please note that for scenario 1, no PEC was determined for on-site STP as the sludge of this kind of STP is not supposed to be released in the environment. Calculations have been performed with EUSES. Results available in Table 2.2.8–22 and Table 2.2.8–23.

PEC in groundwater

Predicted environmental concentrations in groundwater are derived from concentrations in pore water of an agricultural area where sludge has been applied yearly during the last 10 years (BPR, 2015). As biodegradation of the active substances during storage of sludge as well as transformation and dilution in deeper soil layers are not taken into account, it can be considered as a worst-case scenario. Direct emissions to groundwater are not considered as relevant according to the Intended Use but indirect emissions resulting from the soil compartment have been calculated with EUSES and are available in Table 2.2.8–22 and Table 2.2.8–23.

However as the calculated groundwater concentrations of all assessed substances exceed the threshold value of 0.1 µg/L provided by the the BPR (Annex VI, point 68)[19] and the Directive 98/83/EC[20] for off-site STP in scenario 1, additional estimations have been performed using FOCUS Pearl version 4.4.4.

All assessed substances could potentially enter the soil compartment through sludge application on arable land or grassland. According to the Environment Working Groups of the Biocidal Products Committee (WG-II-2014), the default crop for arable land should be "maize" with one application in spring, 20 days before crop emergence. Please note that maize is not considered in the Scandinavian scenario Jokioinen. Regarding grassland, the default crop was "grass/alfalfa" with one spring application by incorporation on March 1st. Application type and depth follow the WG-II-2014 recommendations for sewage sludge, i.e. 20 cm incorporation depth for arable land and 10 cm incorporation depth for application on grassland.

The application rate was based on the maximum rate of sewage sludge application ($Appl_{sludge}$), which is 5000 kg/ha for arable land and 1000 kg/ha for grassland:

$$Appl_{rate} = Appl_{sludge} \bullet C_{sludge} \bullet 10^{-6}$$

Please note that the concentration of active substance in dry sludge (C_{sludge}) has been calculated through EUSES. The calculated application rates are available in Table 2.2.8–18.

Table 2.2.8–18 Application rate of Octanoic acid and Decanoic acid on arable land and grassland through sewage sludge application.

Application rate on crops through sewage sludge application

19 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, Annex VI, point 68, OJ L167, 27.6.2012, p. 166.

20 Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, OJ L330, 5.12.1998, p. 32

Scenario		Concentration in dry sludge (mg/kg)	Application rate on arable land (kg/ha)	Application rate on grassland (kg/ha)
Octanoic acid				
Scenario 1 – STP off site	Tier 1	33.5	**1.675**	**0.335**
	Monitoring data	28.4	1.42	0.284
Decanoic acid				
Scenario 1 – STP off site	Tier 1	103	5.15	1.03
	Monitoring data	113	**5.65**	**1.13**

Bold values were used for FOCUS Pearl modelling.

The input parameters for calculating PEC_{gw} of Octanoic and Decanoic acid through FOCUS Pearl are available in Table 2.2.8–19 According to the Environment Working Groups of the Biocidal Products Committee (WG-V-2016), the default value for the Freundlich adsorption coefficient is 0.9 when the applicant has performed a OECD 106 batch sorption study at multiple concentrations but it was impossible to derive reliable n values.

Table 2.2.8–19 Input parameter for calculating the predicted environmental concentrations of Octanoic acid and Decanoic acid in groundwater with FOCUS Pearl

Input parameters for calculating the groundwater concentration with FOCUS Pearl				
Parameter	**Octanoic acid**	**Decanoic acid**	**Unit**	**Remarks**
Molar mass	144.21	127.27	g/mol	
Vapour pressure (at 25°C)	$1.35x10^{-2}$	$2.17x10^{-4}$	Pa	
Molar enthalpy of vaporization	95		kJ/mol	Default value
Water solubility (at 20°C)	2,970	43.0	mg/L	
Molar enthalpy of dissolution	27		kJ/mol	Default value
Coefficient of sorption on organic matter[1]	48.67	153.13	L/kg	Kom is pH independent by default
Molar enthalpy of sorption	0		kJ/mol	Default value
Reference concentration in liquid phase	0		mg/L	Default value
Freundlich sorption exponent	0.9		-	See comment above
Desorption rate coefficient	0		kJ/mol	Default value
Half-life in soil (12°C)	2.1		d	Read-across from Nonanoic acid
Exponent for the effect of liquid	0.7		-	Default value
Molar activation energy	54		kJ/mol	TAB²
Reference temperature for diffusion	20		°C	Default value
Reference diffusion coefficient in water	$4.3x10^{-5}$		m^2/d	Default value
Reference diffusion coefficient in air	0.43		m^2/d	Default value
Wash-off factor	0.0001		m^{-1}	Default value
Canopy process option	Lumped		-	Default option
Half-life at crop surface	10^6		Day	Default value
Coefficient uptake by plant	0		-	TAB²

1 Coefficient of sorption on organic matter (Kom) is calculated from the organic carbon-water partition coefficient (Koc): Kom = Koc / 1.724

² ECHA (2017). What parameter setting should be applied to FOCUS groundwater scenarios (PEARL) when they are used in biocide exposure assessments (TM II 2010, WG-II-2014, WG-V-2015), Technical Agreements for Biocides, p.13, Augustus 2017.

The model estimate the closest value to the 80th percentile of the substance concentration in groundwater at a 1 m depth as an annual average in µg/L. Please note that calculated values are the concentration in pore water at 1m depth, so they represent the potential concentration in groundwater. According to the minutes of WG-I-2017 and BPC-21 , for a Union Authorisation all nine FOCUS scenarios have to show a safe use for both arable land and for grassland.
Please note that FOCUS Pearl calculations were only performed with Tier 1 values for Octanoic acid and monitoring values for Decanoic acid as they show the highest concentrations in the applied sewage sludge (Please refer to Table 2.2.8–20).
Indeed it was assumed that these higher value will cover the risk for the other scenarios where lower concentrations have been calculated. Results are available in Table 2.2.8–28.

Table 2.2.8–20 Summary table on the predicted environmental concentrations of Octanoic acid for the aquatic compartment

Summary table on PEC values of OCTANOIC ACID for aquatic compartment			
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**
	[mg/m^3]	[mg/l]	[mg/kg$_{wwt}$]
Scenario 1 – STP on site (Monitoring data)	2.81 x10^{-4}	2.81 x10^{-5}	7.33 x10^{-5}
Scenario 1 – STP off site (Monitoring data)	4.50 x10^{-3}	4.50 x10^{-4}	1.17 x10^{-3}
Scenario 2 – Slaughterhouse	4.38 x10^{-2}	4.38 x10^{-3}	1.14 x10^{-2}
Scenario 2 – Catering kitchen	8.76 x10^{-3}	8.76 x10^{-4}	2.28 x10^{-3}
Scenario 3	7.67 x10^{-3}	7.67 x10^{-4}	2.00 x10^{-3}

Table 2.2.8–21 Summary table on the predicted environmental concentrations of Decanoic acid for the aquatic compartment

Summary table on PEC values of DECANOIC ACID for aquatic compartment			
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**
	[mg/m^3]	[mg/l]	[mg/kg$_{wwt}$]
Scenario 1 – STP on site (Monitoring data)	8.13 x10^{-4}	8.13 x10^{-5}	5.30 x10^{-4}
Scenario 1 – STP on site (Monitoring data)	1.30 x10^{-2}	1.30 x10^{-3}	8.47 x10^{-3}
Scenario 2 – Slaughterhouse	2.40 x10^{-2}	2.39 x10^{-3}	1.56 x10^{-2}
Scenario 2 – Catering kitchen	4.79 x10^{-3}	4.79 x10^{-4}	3.12 x10^{-3}
Scenario 3	4.19 x10^{-3}	4.19 x10^{-4}	2.73 x10^{-3}

Table 2.2.8–22 Summary table on the predicted environmental concentrations of Octanoic acid for the terrestrial compartment

Summary table on PEC values of OCTANOIC ACID for terrestrial compartment				
Scenario	**PEC_{soil}** 30 days	**PEC_{soil}** 180 days agriculture	**PEC_{soil}** 180 days grassland	**PEC_{GW}**

	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/l]
Scenario 1 – STP on site	Not relevant	Not relevant	Not relevant	Not relevant
Scenario 1 – STP off site (Monitoring)	4.91 x10^{-3}	8.18 x10^{-4}	3.23 x10^{-4}	5.12 x10^{-4}
Scenario 2 – Slaughterhouse	1.01 x10^{-3}	1.69 x10^{-4}	6.66 x10^{-5}	1.06 x10^{-4}
Scenario 2 – Catering kitchen	2.02 x10^{-4}	3.37 x10^{-5}	1.33 x10^{-5}	2.11 x10^{-5}
Scenario 3	1.77 x10^{-4}	2.95 x10^{-5}	1.17 x10^{-5}	1.85 x10^{-5}

Table 2.2.8–23 Summary table on the predicted environmental concentrations of Decanoic acid for the terrestrial compartment

Summary table on PEC values of DECANOIC ACID for terrestrial compartment				
Scenario	**PEC$_{soil}$** 30 days	**PEC$_{soil}$** 180 days agriculture	**PEC$_{soil}$** 180 days grassland	**PEC$_{GW}$**
	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]
Scenario 1 – STP on site	Not relevant	Not relevant	Not relevant	Not relevant
Scenario 1 – STP off site (Monitoring)	1.52 x10^{-2}	2.35 x10^{-3}	9.34 x10^{-4}	5.30 x10^{-4}
Scenario 2 – Slaughterhouse	1.74 x10^{-3}	2.90 x10^{-4}	1.15 x10^{-4}	6.06 x10^{-4}
Scenario 2 – Catering kitchen	3.48 x10^{-4}	5.79 x10^{-5}	2.30 x10^{-5}	1.21 x10^{-5}
Scenario 3	3.04 x10^{-4}	5.07 x10^{-5}	2.01 x10^{-5}	1.06 x10^{-5}

Table 2.2.8–24 Summary table on average groundwater concentrations of substances of concern closest to the 80th percentile according to FOCUS Pearl 4.4.4 calculations

Summary table on PEC$_{gw}$ values (FOCUS Pearl 4.4.4)		
Scenario	**Octanoic acid & Decanoic acid (µg/L)**	
	Maize	**Grassland**
Chateaudun	0.000000	0.000000
Hamburg	0.000000	0.000000
Jokioinen	-	0.000000
Kremsmünster	0.000000	0.000000
Okehampton	0.000000	0.000000
Piacenza	0.000000	0.000000
Porto	0.000000	0.000000
Sevilla	0.000000	0.000000
Thiva	0.000000	0.000000

(VI) Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Chemicals showing bioaccumulation or biomagnification potential may pose a threat due to exposure of organisms higher in the food chain, e.g. top predators, because of secondary poisoning. The oral intake via fish and worms is therefore assessed for mammals and birds for each substance showing a log Pow value over the trigger value of 3.

As the calculated octanol-water partition coefficient of Octanoic and Decanoic acids indicates a potential for bioaccumulation (log P_{ow}=3.03 and 4.02, respectively), the Predicted Environmental Concentration in food was estimated for fish- and worm-eating animals.

Secondary poisoning via the aquatic food chain

Assessment of secondary poisoning via the aquatic food chain was performed according to the following equation (parameters used for calculations are available in Table 2.2.8–25 and results are available in Table 2.2.8–26):

$$PEC_{oral,predator} = \frac{PEC_{water}}{2} \bullet BCF_{fish} \bullet BMF$$

Please note that an appropriate PEC_{water} reflecting the foraging area of fish-eating mammals and birds should be used for the estimate. Using PEC_{local} only may lead to an overestimation of the risk as predators do also forage on fish from other sites than the area around the point of discharge (moreover biodegradation in surface water is not taken into account in PEC_{local}). It has therefore been decided that a scenario where 50 % of the diet comes from a local area (represented by the PEC_{local}) and 50 % of the diet comes from a regional area (represented by the $PEC_{regional}$) is the most appropriate for the assessment (BPR, 2015). PEC_{water} was therefore divided by 2 in order to perform a more realistic risk assessment.

Table 2.2.8–25 Input parameters for calculating the predicted environmental concentrations of Octanoic acid and Decanoic acid for fish-eating animals

Input parameters for calculating the $PEC_{oral,\ predator}$ for fish-eating animals					
Input	**Nomenclature**	**Octanoic acid**	**Decanoic acid**	**Unit**	**Remarks**
PEC_{water}		Table 2.2.8–20 and 21		mg/L	
Bioconcentration factor for fish	BCF_{fish}	75	597.7	L/kg_{ww}	
Biomagnification factor	BMF	1			Default as log Pow<4.5

Table 2.2.8–26 Summary table of the predicted environmental concentrations of Octanoic acid and Decanoic acid for fish-eating animals

Summary table on calculated $PEC_{oral,\ predator}$ for fish-eating animals		
Scenario	**$PEC_{oral,\ predator}$ for Octanoic acid**	**$PEC_{oral,\ predator}$ for Decanoic acid**
	[mg/kg wet fish]	[mg/kg wet fish]
Scenario 1 – STP on site (Monitoring)	$5.27x10^{-4}$	$1.21x10^{-2}$
Scenario 1 – STP off site (Monitoring)	$8.44x10^{-3}$	$1.94x10^{-1}$
Scenario 2 – Slaughterhouse	$1.64x10^{-1}$	$7.15x10^{-1}$
Scenario 2 – Catering kitchen	$3.29x10^{-2}$	$1.43x10^{-1}$
Scenario 3	$2.88x10^{-2}$	$1.25x10^{-1}$

Secondary poisoning via the terrestrial food chain

Assessment of secondary poisoning via the terrestrial food chain was performed according to the following equation (parameters used for calculations are available in Table 2.2.8–27 and results are available in Table 2.2.8–28):

$$PECoral, predator = \frac{BCFearthworm \bullet Cpore\ water + Csoil \bullet Fgut \bullet CONVsoil}{1 + Fgut \bullet CONVsoil}$$

The concentration in pore water ($C_{porewater}$) was considered to be equal to predicted environmental concentration in pore water of an agricultural area where sludge has been applied yearly during the last 10 years ($PEC_{agr.\ soil\ porewater}$). According to the BPR (ECHA, 2015), this concentration is equal to PEC in groundwater (PEC_{gw}). PEC_{gw} value was thus used to determine $C_{porewater}$.
In the same way, the concentration in soil (C_{soil}) was considered to be equal to predicted environmental concentration in soil of an agricultural area where sludge has been applied during the last 10 years (PEC_{soil}).
Please note that using PEC_{local} only may lead to an overestimation of the risk as predators do also forage on worms from other sites than the area around the point of discharge (i.e. where sludge is applicated). It has therefore been decided that a scenario where 50 % of the diet comes from a local area and 50 % of the diet comes from a regional area is the most appropriate for the assessment (BPR, 2015). PEC_{soil} and PEC_{gw} were therefore divided by 2 in order to perform a more realistic risk assessment.

Table 2.2.8–27 Input parameters for calculating the predicted environmental concentrations of Octanoic acid and Decanoic acid for earthworm-eating animals

Input parameters for calculating the $PEC_{oral,\ predator}$ for worm-eating animals					
Input	**Nomenclature**	**Octanoic acid**	**Decanoic acid**	**Unit**	**Remarks**
Bioconcentration factor for worm	$BCF_{earthworm}$	14	148	L/kg_{ww}	Calculated from log P_{ow}
Concentration in pore water	$C_{pore\ water}$	Refer to PEC_{gw} Table 2.2.8–22 and 23		mg/L	EUSES calculations
Concentration in soil	C_{soil}	Refer to PEC_{soil} Table 2.2.8–22 and 23		mg/kg_{wwt}	EUSES calculations
Fraction of gut loading in worm	F_{gut}	0.1		kg_{dw}/kg_{wwt}	Default

Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	1.13		Default

Please not that no $PEC_{oral,\ predator}$ has been calculated for on-site STP of scenario 1 given that contamination of earthworms take place through application of sludge in agricultural area and no sludge application is expected in this scenario.

Table 2.2.8–28 Summary table of the predicted environmental concentrations of Octanoic acid and Decanoic acid for earthworm-eating animals

Summary table on calculated $PEC_{oral,\ predator}$ for worm-eating animals		
Scenario	**$PEC_{oral,\ predator}$ for Octanoic acid**	**$PEC_{oral,\ predator}$ for Decanoic acid**
	[mg/kg wet worm]	[mg/kg wet worm]
Scenario 1 – STP on site (Monitoring)	Not relevant	Not relevant
Scenario 1 – STP off site (Monitoring)	$1.17x10^{-1}$	$1.53x10^{-1}$
Scenario 2 – Slaughterhouse	$1.14x10^{-1}$	$1.18x10^{-1}$
Scenario 2 – Catering kitchen	$1.13x10^{-1}$	$1.14x10^{-1}$
Scenario 3	$1.13x10^{-1}$	$1.14x10^{-1}$

1.2.8.3 Risk characterisation

The ***SOPURCLEAN BPF*** is used by professional workers as disinfectant of food processing installations, e.g. breweries, slaughterhouses or milking parlours (PT 4), to prevent contamination with micro-organisms. In the ESD for PT 4 it is assumed that most of the disinfectant applied ends up in a sewage treatment plant.

Please note that PNEC values of Octanoic and Decanoic acids are available in Table 2.2.8–3 of this document.

All PEC values are available in Table 2.2.8–20 to 23.

(I) Atmosphere

Based on the physico-chemical properties of the active substances and on the Intended Use, the emission to air during and after the application of the product can be considered as negligible (see above, "PEC in air").
Moreover on the basis of the physico-chemical properties of the active substances (absence of absorption bands in the atmospheric window, short atmospheric lifetimes, absence of Cl, F, N or S substituents in the molecules), neither Octanoic acid, nor Decanoic acid are expected to display adverse abiotic effects on the atmospheric environment (please refer to the respective CAR of the active substances).

Please see additional information in the Confidential Annex.

Conclusion:

Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

(II) Sewage treatment plant (STP)

The sewage treatment plants are considered as the main receiving compartments according to ESD for PT4.

The risk assessment for STP is determined by dividing the PEC_{STP} by the $PNEC_{STP\ micro-organisms}$ (please, refer to Table 2.2.8–30). If the result of this ratio is below 1, an acceptable risk to micro-organisms of sewage treatment plants can be concluded. Please note that no PEC_{STP} has been calculated for on-site STP of scenario 1 as the sludge of this kind of STP is not supposed to be released in the environment.

Table 2.2.8–30 Summary table of the PEC/PNEC values for the sewage treatment plant

Summary table on calculated PEC/PNEC values for sewage treatment plant		
Scenario	**$PEC/PNEC_{STP}$ for Octanoic acid**	**$PEC/PNEC_{STP}$ for Decanoic acid**
Scenario 1 – STP on site (monitoring)	3.36×10^{-6}	8.13×10^{-6}
Scenario 1 – STP off site (monitoring)	5.38×10^{-5}	1.30×10^{-4}

Scenario 2 – Slaughterhouse	5.23 $x10^{-4}$	2.40 $x10^{-4}$
Scenario 2 – Catering kitchen	1.05 $x10^{-4}$	4.79 $x10^{-5}$
Scenario 3	9.16 $x10^{-5}$	4.19 $x10^{-5}$

Please see additional information in the Confidential Annex.

Conclusion:

No unacceptable effect to the aquatic micro-organisms of the STP is expected.

(III) Aquatic compartment

The risk assessment is performed for fresh water and sediment-dwelling organisms and is determined by dividing the PEC_{water} (or PEC_{sed}) by the $PNEC_{water}$ (or the $PNEC_{sed}$). Where the result of this ratio is below the trigger of 1, an acceptable risk to aquatic organisms can be concluded (please, refer to Table 2.2.8–31).

Table 2.2.8–31 Summary table of the PEC/PNEC values for the aquatic compartment. Value in bold are over the trigger of 1.

Summary table on calculated PEC/PNEC values for aquatic compartment		
Scenario	**Octanoic acid**	**Decanoic acid**
	$PEC/PNEC_{water}$ $PEC/PNEC_{sed}$	**$PEC/PNEC_{water}$ $PEC/PNEC_{sed}$**
Scenario 1 – STP on site (monitoring)	5.98x10^{-3}	1.43 $x10^{-2}$
Scenario 1 – STP off site (monitoring)	9.57x10^{-2}	2.28x10^{-1}
Scenario 2 – Slaughterhouse	9.32x10^{-1}	4.20x10^{-1}
Scenario 2 – Catering kitchen	1.86x10^{-1}	8.40x10^{-2}
Scenario 3	1.63x10^{-1}	7.35x10^{-2}

The results for sediment-dwelling organisms is equal to the results for pelagic organisms since both PEC_{sed} and $PNEC_{sed}$ were calculated from the PEC_{water} and $PNEC_{water}$, respectively, by using equilibrium partitioning method and not measured data.

Please see additional information in the Confidential Annex.

Conclusion:

Unacceptable effect to the aquatic compartment is not expected, neither for sediment-dwelling organisms, nor for pelagic organisms.

(IV) Terrestrial compartment

The risk to terrestrial compartment is assessed by dividing the PEC_{soil} (averaged over 30 days) by the $PNEC_{soil}$ calculated via the equilibrium partitioning method. If the result of this ratio is below 1, an acceptable risk to aquatic organisms can be concluded (please, refer to Table 2.2.8–32). Please note that as soil contamination takes place through application of sludge in agricultural area and no sludge application is expected for on-site STP of scenario 1, no PEC_{soil} has been derived for this scenario.

Table 2.2.8–32 Summary table of the PEC/PNEC values for the soil compartment

Summary table on calculated PEC/PNEC values for terrestrial compartment		
Scenario	**$PEC/PNEC_{soil}$ for Octanoic acid**	**$PEC/PNEC_{soil}$ for Decanoic acid**
Scenario 1 – STP on site (monitoring)	Not relevant	Not relevant
Scenario 1 – STP off site (monitoring)	$6.55x10^{-1}$	$5.18x10^{-1}$
Scenario 2 – Slaughterhouse	$1.35x10^{-1}$	$6.40x10^{-2}$
Scenario 2 – Catering kitchen	$2.69x10^{-2}$	$1.28x10^{-2}$
Scenario 3	$2.36x10^{-2}$	$1.12x10^{-2}$

Please see additional information in the Confidential Annex.

Conclusion:

No unacceptable effect to the soil compartment is expected.

(V) Groundwater

The adsorption/desorption tests showed that Octanoic and Decanoic acids rapidly degrade in soil despite soil sterilization, leading to negligible likelihood for leakage of these substances to groundwater. Moreover both substances are readily biodegradable and are therefore not expected to persist in soil.

In addition FOCUS Pearl calculations showed that the potential groundwater concentrations of all assessed substances did never exceed the threshold value of 0.1 µg/L provided by the BPR (Annex VI, point 68) and the Directive 98/83/EC for any scenario (Please refer to Table 2.2.8–24), leading to an acceptable risk for drinking water and groundwater compartment.

Conclusion:

No unacceptable risk to the groundwater is expected and the requirements of Directive 98/83/EC and 2006/118/EC[21] are complied with.

(VI) Primary and secondary poisoning

Primary poisoning

21 Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, OJL372, 27.12.2006.

Not relevant.

Secondary poisoning

The log Pow value of Octanoic and Decanoic acid were both over the trigger value of 3, suggesting a risk of bioaccumulation and secondary poisoning via ingestion of contaminated food by predators. The risk of secondary poisoning for aquatic and terrestrial food chain was thus assessed by dividing the $PEC_{oral,predator}$ by the $PNEC_{oral,predator}$ for both fish-eating and earthworm-eating animals. Where the result of this ratio is below 1, an acceptable risk can be concluded (please, refer to Table 2.2.8–33). Please note that no $PEC/PNEC_{oral,predator}$ value for earthworm-eating animals has been calculated for on-site STP of scenario 1 given that contamination of earthworms take place through application of sludge in agricultural area and no sludge application is expected in this scenario.

Table 2.2.8–33 Summary table on secondary poisoning due to Octanoic acid and Decanoic acid.

Summary table on secondary poisoning				
Scenario	$PEC/PNEC_{oral,\ predator}$ for fish-eating organisms		$PEC/PNEC_{oral,\ predator}$ for worm-eating organisms	
	Octanoic acid	Decanoic acid	Octanoic acid	Decanoic acid
	[mg/kg wet fish]	[mg/kg wet fish]	[mg/kg wet worm]	[mg/kg wet worm]
Scenario 1 – STP on site (Monitoring)	$1.59x10^{-3}$	$3.67x10^{-2}$	Not relevant	Not relevant
Scenario 1 – STP off site (Monitoring)	$2.55x10^{-2}$	$5.86x10^{-1}$	$3.53x10^{-1}$	$4.62x10^{-1}$
Scenario 2 – Slaughterhouse	$1.32x10^{-2}$	$7.23x10^{-3}$	$3.44x10^{-1}$	$3.55x10^{-1}$
Scenario 2 – Catering kitchen	$2.65x10^{-3}$	$1.45x10^{-3}$	$3.42x10^{-1}$	$3.44x10^{-1}$
Scenario 3	$8.69x10^{-2}$	$3.78x10^{-1}$	$3.42x10^{-1}$	$3.44x10^{-1}$

PEC/PNEC values for earthworm-eating animals are all below the trigger value of 1 for both active substances, showing no unacceptable risks to the terrestrial food chain.

Regarding the aquatic food chain, PEC/PNEC values for fish-eating organisms are below the trigger value of 1 for both active substances after refinement with monitoring data for scenario 1, while all values are below the trigger for the other scenarios.

Conclusion:
No unacceptable risk of secondary poisoning trough the ingestion of contaminated terrestrial or aquatic animals is expected.

(VII) Mixture toxicity

Given that the ***SOPURCLEAN BPF*** contains a mixture of two active substances, i.e. Octanoic acid and Decanoic acid, and two co-formulants needing an assessment, a risk assessment regarding the mixture toxicity has been performed according to the Transitional Guidance on mixture toxicity assessment[22].

Please see additional information in the Confidential Annex.

Conclusion:
Mixture toxicity assessment showed that no unacceptable risk is expected from the product of the ***SOPURCLEAN BPF***.

(VIII) Aggregated exposure (combined for relevant emission sources)

According to the BPR (Article 19, point 2)[23], the evaluation shall take into account the cumulative effects as well as the synergistic effects of the biocidal product or of its components. This refers to the environmental risk assessment of the substances which are contained in different products of the same Product Type (PT) or of different PTs. A decision tree on the need for estimation of aggregated exposure (Figure 1 below) was available in the BPR to determine when such exposure is needed.

According to the registered substance database of ECHA, Octanoic[24] and Decanoic[25] acids have both been registered under REACH with an annual tonnage band of 10,000−100,000 tonnes. This is far over the use of Octanoic and Decanoic acid as biocide (PT 4, 18 and 19) that represent less than 10% of the annual tonnage of these substance (Please refer to Document II.A "Appendix Confidential Data and Information" of their respective CAR). Therefore it has been checked if the emission pattern of the active substances was specific to biocides.

Both active substances are notified for inclusion in the EU list of approved active substances for use in biocidal products: Octanoic is notified for use in PT 18 and Decanoic is notified for use in PT 18 and PT 19. In their respective CAR (2013), the following uses are considered: insecticide liquid spray to be used indoors in private households (PT18) and repellent lotion for skin use (PT 19). Intended uses specify that these products have been assessed for a non-professional public only.

According to their respective CAR (2013), insecticides used indoor (PT 18) as well as repellent lotion (PT 19) do generally not directly reach the environmental compartments. However the cleaning step after application can lead the releases to waste water through cleaning/washing methods, which is the same entry path as PT 4. However according to the registered substance database of ECHA, several other

22 ECHA (2014), Transitional Guidance on the Biocidal Products Regulation - Transitional Guidance on mixture toxicity assessment for biocidal products for the environment, European Chemicals Agency, Helsinki, Finland. Available via https://echa.europa.eu/

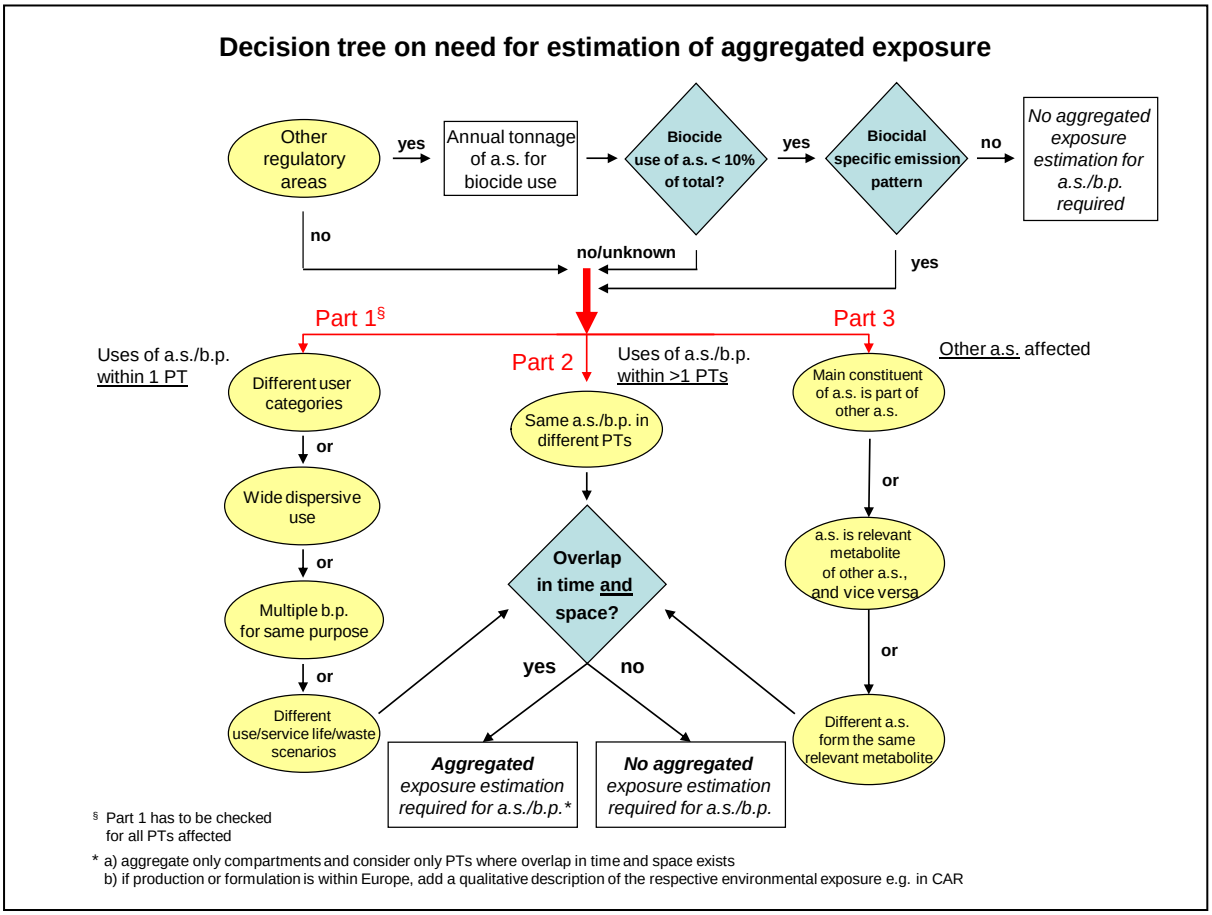
23 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L167, 27.6.2012, p. 166.

24 https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/15370

25 https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/18512

registered uses have a similar emission pattern (washing and cleaning products, cosmetic products, etc.), which is not specific to biocides. Therefore, no aggregated exposure estimation is required for the biocidal products as the main emissions to the environment are considered to be already covered by REACH.

Figure 1: Decision tree on the need for estimation of aggregated exposure



Conclusion:
As less than 10% of the total tonnage of the active substances is used for biocide products and as the emission pattern is not specific to biocides, the aggregated exposure is not considered to be relevant.

Overall conclusion on the risk assessment for the environment of the product
No unacceptable effect to the environment is expected from the ***SOPURCLEAN BPF***, neither for the aquatic compartment, nor for the terrestrial compartment. No unacceptable risk of secondary poisoning trough the aquatic or the terrestrial food chain is to be expected from the products of the ***SOPURCLEAN BPF***. No unacceptable risk to the groundwater is expected from the ***SOPURCLEAN BPF*** and the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

1.2.9 Measures to protect man, animals and the environment

[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]

1.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products. None of the ***SOPURCLEAN BPF*** products are intended to be used in combination with other biocidal products.

1.2.11 Comparative assessment

Not relevant.

2 Annexes

2.1 List of studies for the *SOPURCLEAN BPF*

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
A.Loghmanian	2015	Physico-chemical characteristics of the SOPURCLEAN BN	Sopura Laboratory	VAL 084 A	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
A.Loghmanian	2015	Stability at 0°C of the SOPURCLEAN BN	Sopura Laboratory	VAL 084 S	No	No	Yes	SOPURA	3.4
D. Servais	2015	Stability study in accelerate conditions (40°C) SOPURCLEAN BN	Sopura Laboratory	-	No	No	Yes	SOPURA	3.4
D. Servais	2016	Stability study in normal conditions (20°C) SOPURCLEAN BN	Sopura Laboratory	-	No	No	Yes	SOPURA	3.4
S. Verschaeve	2015	Waiver effect on the light on products of the BPF	-	-	-	No	Yes	SOPURA	3.4
S. Verschaeve	2017	Non-emulsion statement and stability	-	-	-	No	Yes	SOPURA	3.8
A.Loghmanian	2015	Dilution stability of a Sopurclean BN solution	Sopura Laboratory	VAL 084 X	No	No	Yes	SOPURA	3.7
A.Loghmanian	2015	Physico-chemical characteristics of the SOPURCIP EC.	Sopura Laboratory	VAL 084 J	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
A.Loghmanian	2015	Stability at 0°C of the SOPURCIP EC	Sopura Laboratory	VAL 084 V	No	No	Yes	SOPURA	3.4
D. Servais	2015	Stability study in accelerate conditions (40°C) SOPURCIP EC	Sopura Laboratory	-	No	No	Yes	SOPURA	3.4
D. Servais	2016	Stability study in normal conditions (20°C) SOPURCIP EC	Sopura Laboratory	-	No	No	Yes	SOPURA	3.4
A.Loghmanian	2015	Dilution stability of a Sopurclean BN solution	Sopura Laboratory	VAL 084 Y	No	No	Yes	SOPURA	3.7
A.Loghmanian	2015	Physico-chemical characteristics of the SOPURCLEAN NR.	Sopura Laboratory	VAL CLDI068A	No	No	Yes	SOPURA	3.1, 3.2, 3.3, 3.5, 3.8, 3.9
A.Loghmanian	2015	Stability at 0°C of the SOPURCLEAN BN	Sopura Laboratory	VAL CLDI068C	No	No	Yes	SOPURA	3.4
D. Servais	2015	Stability study in accelerate conditions (40°C) SOPURCLEAN NR	Sopura Laboratory	-	No	No	Yes	SOPURA	3.4

D. Servais	2016	Stability study in normal conditions (20°C) SOPURCLEAN NR	Sopura Laboratory	-	No	No	Yes	SOPURA	3.4
A.Loghmanian	2015	Dilution stability of a Sopurclean NR solution	Sopura Laboratory	CLDI068B	No	No	Yes	SOPURA	3.7
M. Brioschi	2015	SOPURCLEAN BN: Determination of the flash point.	CHEMSERVICE	CH-295/2015	Yes	No	Yes	SOPURA	4
A.Loghmanian	2015	Corrosion test for SOPURCLEAN BN	Sopura Laboratory	VAL 084N	No	No	Yes	SOPURA	4.16
S. Verschaeve	2015	Waiver auto-ignition test	-	-	No	No	Yes	SOPURA	4.11
M. Brioschi	2015	SOPURCIP EC: Determination of the flashpoint.	CHEMSERVICE	CH-298/2015	Yes	No	Yes	SOPURA	4
A.Loghmanian	2015	Corrosion test for SOPURCIP EC	Sopura Laboratory	VAL 084P	No	No	Yes	SOPURA	4.16
M. Brioschi	2015	SOPURCLEAN NR: Determination of the flash point.	CHEMSERVICE	CH-300/2015	Yes	No	Yes	SOPURA	4
A.Loghmanian	2015	Corrosion test for SOPURCLEAN NR	Sopura Laboratory	CLDI068D	No	No	Yes	SOPURA	4.16
D. Servais	2015	Validation report of the method of fatty acids content determination in SOPURCIP EC	Sopura Laboratory	-	No	No	Yes	SOPURA	5
Böhler Analytik	2006	Methodenvalidierung 0.1 µg/L for decanoic acid and octanoic acid	Böhler analytic	A4.2/01b	-	No	Yes	Fatty acids Consortium	5
P. Maurer	2015	Evaluation of the bactericidal activity according to the European standard test method EN 1276-(1997) in general use conditions Sopurclean NR + addendum	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	20150401	No	No	Yes	SOPURA	6.7

P. Maurer	2015	Evaluation of the bactericidal activity according to the European standard test method EN 1276-(1997) in general use conditions Sopurclean NR (no decanoic acid) + addendum	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	20150401	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the fungicidal activity according to the European standard test method EN 1650 (1997) in general use conditions -Sopurclean NR	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	20150401	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the fungicidal activity according to the European standard test method EN 1650 (1997) in general use conditions Sopurclean NR- (no decanoic acid).	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	20150401	No	No	Yes	SOPURA	6.7
S. Colombo	2015	Sopurcip EC: Quantitative suspension test for the evaluation of bactericidal activity	CHEMSERVICE	591/2015	No	No	Yes	SOPURA	6.7
S. Colombo	2015	Sopurcip EC: Quantitative suspension test for the evaluation of fungicidal activity	CHEMSERVICE	592/2015	No	No	Yes	SOPURA	6.7
S. Colombo	2015	Sopurcip EC: Bactericidal activity on non-porous surface	CHEMSERVICE	589/2015	No	No	Yes	SOPURA	6.7
S. Colombo	2015	Sopurcip EC: Fungicidal activity on non-porous surface	CHEMSERVICE	590/2015	No	No	Yes	SOPURA	6.7

P. Maurer	2015	Evaluation of the bactericidal activity according to the European standard test method EN 1276 (1997) in general use conditions SOPURCIP EC	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	-	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the bactericidal activity according to the European standard test method EN 1276 (1997) in practical conditions SOPURCIP EC	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	-	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the fungicidal activity according to the European standard test method EN 1650 (1997) in general use conditions SOPURCIP EC	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	-	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the fungicidal activity according to the European standard test method EN 1650 (1997) in practical conditions SOPURCIP EC	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	-	No	No	Yes	SOPURA	6.7
S. Colombo	2017	SOPURCLEAN NR: Quantitative suspension test for the evaluation of bactericidal activity	CHEMSERVICE	CH-595/2015	No	No	Yes	SOPURA	6.7
S. Colombo	2017	SOPURCLEAN NR: Quantitative suspension test for the evaluation of fungicidal activity	CHEMSERVICE	CH-596/2015	No	No	Yes	SOPURA	6.7
S. Colombo	2017	SOPURCLEAN NR: Bactericidal activity on non-porous surface	CHEMSERVICE	CH-593/2015	No	No	Yes	SOPURA	6.7
S. Colombo	2017	SOPURCLEAN NR: Fungicidal activity on non-porous surface	CHEMSERVICE	CH-594/2015	No	No	Yes	SOPURA	6.7

S. Colombo	2015	Sopurclean Nr: Bactericidal activity on non-Porous Surface	CHEMSERVICE	CH – 301/2015	No	No	Yes	SOPURA	6.7
S. Colombo	2015	SOPURCLEAN NR: Fungicidal activity on non-porous surface	CHEMSERVICE	CH – 302/2015 Rev.2	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the bactericidal activity according to the European standard test method EN 1276 (1997) In general use conditions Sopurclean Nr	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	20150401	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the bactericidal activity according to the European standard test method EN 1276-(1997) In general use conditions-**placebo**-Sopurclean Nr	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	20150401	No	No	Yes	SOPURA	6.7
P. Maurer	2015	Evaluation of the fungicidal activity according to the European standard test method -EN 1650-(1997) In general use conditions **placebo** Sopurclean Nr	Microbiology Department Meurice Institute – Haute Ecole Lucia de Brouckère	20140401	No	Yes	SOPURA	SOPURA	6.7
Houtmeyers M., Appels L.	2017	Inhibition assessment of aerobic/anaerobic wastewater treatment processes by SOPURCLEAN CIP OP	KULeuven, Leuven, Belgium	-	No	Yes	SOPURA	SOPURA	9.3
Van den Broeck R. *et al.*	2014	Inhibition assessment of aerobic/anaerobic wastewater treatment processes by SOPURCLEAN CIP LF	KULeuven, Leuven, Belgium	-	No	Yes	SOPURA	SOPURA	9.3

2.2 Assessment of effects on Human Health

Tests on Active Substances

Skin corrosion and Eye irritation

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 430; Transcutaneous electrical resistence test (TER)	C10 fatty acid, 100%	Human skin ex vivo, 24h exposure	29.9 ± 5.4 kΩ/disc (a value of ≤11 kΩ/disc indicates that a substance could produce a corrosive effect on human skin in vivo) Not-corrosive to skin		York et al., 1996
In vitro skin irritation test (Spirlmann et al, 2007)	C9 and melted C10 fatty acids 100%	EpiDerm (reconstructed human epidermis model), 15 and 60 minutes exposure time	irritant Prediction model: Tissue viability <50% or >50% and IL1α release 3x increased. At least irritating to skin		Jirova et al, 2008
QSAR - Toxtree	C8, C9, C10 fatty acid		Irritating or corrosive to skin		http:/ecb.jrc.it/qsar/1

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
Primary skin irritation	Albino Rabbit 5/group	C8 and C10 fatty acid 100%, 0.01ml/animal	24h: Severely irritating (no standard test, score 5 from 10) Severely irritating to skin		Smyth et al, 1962 DocIII-A6.1.4s/01
Acute dermal toxicity test	Rat 5/sex	C10 fatty acid, 25% in PEG Ca 30 (m) and 27 (f) mg/cm2	24h: Skin reactions during daily observation for 15		Talvioja K, 2006 Doc III-A 6.1.2

OECD 402			days post exposure: All animals erythema grade 1 to 2 after application, developed into scaling and scabs (grade 1 to 2), completely reversible after 14 days of observation. Irritating to skin		
LLNA OECD 427	Mouse 4/dose	C10 fatty acid, 70, 50, 25%, in aceton:olive oil 4:1 25 µl/ear, 3 times o, 3 consecutive days	70%: slight irritation50 and 25%: no irritation Reversibility: not within 6 days Mildly irritant		Weber 2006 Doc-III A6.1.5

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
BCOP, TG437, GLP	C10	In vitro score = 16.83	No support for Cat., H318		Wolfinger 2012, DocIII-A6.1.4.e/2

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Non-GLP publication	Rabbit 5/group	C8 and C10 (separately, identical results)	Grade 9, indicating risk for serious damage to eye (H318)	Scoring system: Grade 1: very small area of necrosis Grade 5: burn Grade 10: severe burn	Smyth et al, 1962; DocIII-A6.1.4.e/1
Non-GLP publication	Rabbit	C8 and C10 (separately, identical results)	Corneal opacity and moderate conjunctivitis No reversibility up to 72 hours		Briggs et al, 1976

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Human volunteer Human patch test	Melted C10 fatty acid C9 fatty acid 100%	200 ml/chamber, 4h exposure time 200 ml/chamber, 4h exposure time	Irritant with 18/29 volunteers Irritant with 19/29 volunteers Irritating to skin	Jirova et al, 2008
Human volunteer (n=72) Human patch test	C10 fatty acid C8 fatty acid 100%	Human patch test Patches applied with graded duration of exposure. Assessment after 24/48/72h 200 mg/chamber	Participants showing at least mild irritation: 50 to 56% after 1 hour 78 to 82% after up to 2 hours 90 to 94 after up to 3 hours 92 to 97% after up to 4 hours 14 to 38% after 1 hour 50 to 62% after up to 2 hours 81 to 84% after up to 3 hours 85 to 89% after up to 4 hours At least mildly irritating to skin	Robinson et al, 1999 DocIII A6.1.4s/02
Human volunteer Human patch test	C9 fatty acid, 100ù, 60%, 40%, 20%, 10%, 5% in propanol	0.1 ml, repeated for 15 days	Increased skin thickness for concentrations ≥ 40% Irritating to skin	Wahlberg, 1983
Human volunteer (n=8)	C9 fatty acid 2.5%, 5%, 10%, 20% in propanol	Human 24hrs exposure, measurements 20 minutes after patch removal	2.5% or 5%: None of the measured endpoints indicated skin irritation: visual irritation score, skin reflectance spectrophotometer, transepidermal water loss and laser Doppler flowmetry At least irritating to skin	Anderson et al, 1995

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Cause severe burns (pH<2 for all concentrated products of the ***SOPURCLEAN BPF***)
Justification for the value/conclusion	No studies on skin and eye irritation are available for any member of the SOPURCLEAN Biocidal Product Family. However, several publications involving the active ingredients exist and provide the information added in the summary table of human information on skin corrosion and irritation.

	The composition of the products indicate that all products of the ***SOPURCLEAN BPF*** have a pH < 2 and cause severe burns. This results in classification of the different products as Corrosive Cat 1A, H314 (total Weight of Evidence evaluation).
Classification of the product according to CLP	Skin corrosion Cat.1A, H314

2.3 Assessment of effects on Human Health : ART scenarios

Scenario 1:

Meta-SPC 3


Nitric acid - peak - transfer.pdf


Nitric acid - long-term - transfer.p

Meta-SPC 4


Methane sulfonic acid - peak - transfer.


Methane sulfonic acid - long-term - trai

Scenario 2:

Meta-SPC 2


Propionic acid - spraying.pdf

Scenario 3:

Meta-SPC 1


Sulphuric acid - soaking.pdf

Meta-SPC 2


Propionic acid - soaking.pdf

Scenario 4:

Meta-SPC 2


Propionic acid - manual treatment.pdf

2.4 Output tables from exposure assessment tools

NOT RELEVANT

FOCUS PEARL OUTPUT FILES

Meta SPC2

Scenario 2 – Spraying systems at low pressure

Description of Scenario 2 – Spraying systems at low pressure		
	Parameters[1]	Value
Tier 1	Content of active substance Octanoic acid Decanoic acid	 2.7% 0.3%
	Content of non-active substance of concern Propionic acid	 19.5%
	Dilution of the applied product	2%
	Inhalation exposure Potential exposure via inhalation	 104 mg/m^3
	Exposure duration: M&L Application – Spraying Post-application	 10 minutes 120 minutes 360 minutes

Calculations Local exposure for Scenario 2 – Spraying systems at low pressure

Meta SPC2

BE comment: During spraying, the operator is exposed to 104 mg/m^3 (spraying model 1) biocidal product containing 19.5% x 2% dilution propionic acid: 0.41 mg/m^3 (DNEL long term, local effects, inhalation = 31 mg/m^3). The risk characterization ratio for long-term local exposure to propionic acid in the diluted bp mixture is 0.013. These are considered acceptable levels.

Calculations Local exposure for Scenario 3 – Soaking baths

Meta SPC2

BE comment: During soaking, the operator is exposed to 0.2 mg/m^3 (dipping model 4) biocidal product containing 19.5% x 2% dilution propionic acid: 0.0008 mg/m^3 (DNEL long term, local effects, inhalation = 31 mg/m^3). The risk characterization ratio for long-term local exposure to propionic acid in the diluted bp mixture is 0.00003. These are considered acceptable levels.

Calculations local exposure for Scenario 4 – Manual cleaning

Meta SPC2

BE comment: During manual cleaning, the operator is exposed to 22.9 mg/m3 (Disinfection model 1&3) biocidal product containing 19.5% x 2% dilution propionic acid: 0.09 mg/m^3 (DNEL long term, local effects, inhalation = 31 mg/m^3). The risk characterization ratio for long-term local exposure to propionic acid in the diluted bp mixture is 0.003. These are considered acceptable levels

For practical reasons and to avoid the repetition of information, only one example (scenario Okehampton) of the FOCUS PEARL output files is presented here.
All relevant input parameters are presented in chapter V of the point 2.2.8 Risk assessment for the environment.

Decanoic Acid - Okehampton - Winter wheat (231d Temission, Tier 2 - monitoring data)

```
* PEARL REPORT: Header
* Results from the PEARL model  (c) Alterra, PBL and RIVM
* PEARL kernel version       : 3.1.2
* SWAP kernel version        : swap3234
* PEARL created on           : 18-Feb-2011
*
* PEARL was called from      : FOCUSPEARL,version 4.4.4
* Working directory          : C:\Users\ear\Documents\PesticideModels\FOCUSPEARL_4_4_4\PearlDB
* Run ID                     : 40
* Input file generated on    : 29-09-2017
* ----------------------------------------------------------------------------
*
* Location           : OKEHAMPTON
* Meteo station      : OKEH-M
* Soil type          : OKEH-S_Soil
* Crop calendar      : OKEH-WCEREALS
* Substance          : Decan
* Application scheme : AUTUMN+SPRING_DECA
* Deposition scheme  : No
* Irrigation scheme  : No
*
* End of PEARL REPORT: Header


* PEARL REPORT: Leaching
* Start date      :   01-Jan-1901
* End date        :   31-Dec-1926
* Target depth    :   1.00 m
* Annual incorporation at 15-Mar; dosage =     5.6500 kg.ha-1; depth =     0.20 m
* Annual incorporation at 15-Sep; dosage =     5.6500 kg.ha-1; depth =     0.20 m

* Leaching summary for compound Decan
* Molar mass (g.mol-1)                                  :    172.3
* Saturated vapour pressure (Pa)                        :  0.217E-03; measured at (C)  25.0
* Solubility in water (mg.L-1)                         :   43.0    ; measured at (C)  20.0
* Half-life (d)                                        :     2.1; measured at (C)  12.0
* Kom (coef. for sorption on organic matter) (L.kg-1) :    153.1
* KF    (overall sorption coefficient of the target layer) (L.kg-1) :      2.36
* Freundlich exponent (-)                              :     0.90
* ----------------------------------------------------------------------------------------------------------------------------
* Period        From          To              Water percolated          Substance leached          Average substance
* number                                  below target depth (mm)   below target depth (kg/ha)   concentration in water
*                                                                                               at target depth (ug/L)
* ----------------------------------------------------------------------------------------------------------------------------
   1     01-Jan-1907 31-Dec-1907                    511.086                  0.0000000                    0.000
   2     01-Jan-1908 31-Dec-1908                    119.948                  0.0000000                    0.000
   3     01-Jan-1909 31-Dec-1909                    443.130                  0.0000000                    0.000
   4     01-Jan-1910 31-Dec-1910                    312.261                  0.0000000                    0.000
   5     01-Jan-1911 31-Dec-1911                    511.624                  0.0000000                    0.000
   6     01-Jan-1912 31-Dec-1912                    511.326                  0.0000000                    0.000
   7     01-Jan-1913 31-Dec-1913                    634.570                  0.0000000                    0.000
   8     01-Jan-1914 31-Dec-1914                    351.176                  0.0000000                    0.000
   9     01-Jan-1915 31-Dec-1915                    269.703                  0.0000000                    0.000
  10     01-Jan-1916 31-Dec-1916                    538.484                  0.0000000                    0.000
  11     01-Jan-1917 31-Dec-1917                    307.114                  0.0000000                    0.000
  12     01-Jan-1918 31-Dec-1918                    420.778                  0.0000000                    0.000
  13     01-Jan-1919 31-Dec-1919                    630.794                  0.0000000                    0.000
  14     01-Jan-1920 31-Dec-1920                    404.470                  0.0000000                    0.000
  15     01-Jan-1921 31-Dec-1921                    287.191                  0.0000000                    0.000
  16     01-Jan-1922 31-Dec-1922                    379.743                  0.0000000                    0.000
  17     01-Jan-1923 31-Dec-1923                    677.259                  0.0000000                    0.000
  18     01-Jan-1924 31-Dec-1924                    496.254                  0.0000000                    0.000
  19     01-Jan-1925 31-Dec-1925                    363.430                  0.0000000                    0.000
  20     01-Jan-1926 31-Dec-1926                    489.869                  0.0000000                    0.000

* The average concentration of Decan closest to the 80th percentile is      0.000000 ug/L

* End of PEARL REPORT: Leaching
```

Decanoic Acid - Okehampton - Maize (231d Temission, Tier 2 - monitoring data)

```
* PEARL REPORT: Header
* Results from the PEARL model  (c) Alterra, PBL and RIVM
* PEARL kernel version       : 3.1.2
* SWAP kernel version        : swap3234
* PEARL created on           : 18-Feb-2011
*
* PEARL was called from      : FOCUSPEARL,version 4.4.4
* Working directory          : C:\Users\ear\Documents\PesticideModels\FOCUSPEARL_4_4_4\PearlDB
* Run ID                     : 22
* Input file generated on    : 29-09-2017
* ----------------------------------------------------------------------------
*
* Location           : OKEHAMPTON
* Meteo station      : OKEH-M
* Soil type          : OKEH-S_Soil
* Crop calendar      : OKEH-MAIZE
* Substance          : Decan
* Application scheme : SPRING_DECA
* Deposition scheme  : No
* Irrigation scheme  : No
*
* End of PEARL REPORT: Header


* PEARL REPORT: Leaching
* Start date      :   01-Jan-1901
* End date        :   31-Dec-1926
* Target depth    :   1.00 m
* Annual incorporation at 15-Mar; dosage =     5.6500 kg.ha-1; depth =     0.20 m

* Leaching summary for compound Decan
* Molar mass (g.mol-1)                                  :    172.3
* Saturated vapour pressure (Pa)                        :  0.217E-03; measured at (C)  25.0
* Solubility in water (mg.L-1)                          :   43.0    ; measured at (C)  20.0
* Half-life (d)                                         :      2.1; measured at (C)  12.0
* Kom (coef. for sorption on organic matter) (L.kg-1) :    153.1
* KF    (overall sorption coefficient of the target layer) (L.kg-1) :      2.36
* Freundlich exponent (-)                               :     0.90
* ----------------------------------------------------------------------------------------------------------------------------
* Period        From          To              Water percolated          Substance leached          Average substance
* number                                  below target depth (mm)   below target depth (kg/ha)   concentration in water
*                                                                                                at target depth (ug/L)
* ----------------------------------------------------------------------------------------------------------------------------
   1     01-Jan-1907 31-Dec-1907                    540.768                  0.0000000                    0.000
   2     01-Jan-1908 31-Dec-1908                    164.747                  0.0000000                    0.000
   3     01-Jan-1909 31-Dec-1909                    429.584                  0.0000000                    0.000
   4     01-Jan-1910 31-Dec-1910                    289.205                  0.0000000                    0.000
   5     01-Jan-1911 31-Dec-1911                    473.746                  0.0000000                    0.000
   6     01-Jan-1912 31-Dec-1912                    535.640                  0.0000000                    0.000
   7     01-Jan-1913 31-Dec-1913                    604.860                  0.0000000                    0.000
   8     01-Jan-1914 31-Dec-1914                    365.942                  0.0000000                    0.000
   9     01-Jan-1915 31-Dec-1915                    260.830                  0.0000000                    0.000
  10     01-Jan-1916 31-Dec-1916                    530.391                  0.0000000                    0.000
  11     01-Jan-1917 31-Dec-1917                    303.747                  0.0000000                    0.000
  12     01-Jan-1918 31-Dec-1918                    452.692                  0.0000000                    0.000
  13     01-Jan-1919 31-Dec-1919                    618.777                  0.0000000                    0.000
  14     01-Jan-1920 31-Dec-1920                    444.251                  0.0000000                    0.000
  15     01-Jan-1921 31-Dec-1921                    325.004                  0.0000000                    0.000
  16     01-Jan-1922 31-Dec-1922                    438.197                  0.0000000                    0.000
  17     01-Jan-1923 31-Dec-1923                    627.162                  0.0000000                    0.000
  18     01-Jan-1924 31-Dec-1924                    544.965                  0.0000000                    0.000
  19     01-Jan-1925 31-Dec-1925                    369.088                  0.0000000                    0.000
  20     01-Jan-1926 31-Dec-1926                    530.203                  0.0000000                    0.000

* The average concentration of Decan closest to the 80th percentile is      0.000000 ug/L

* End of PEARL REPORT: Leaching
```

Decanoic Acid - Okehampton - Grassland (231d Temission, Tier 2 - monitoring data)

```
* PEARL REPORT: Header
* Results from the PEARL model  (c) Alterra, PBL and RIVM
* PEARL kernel version       : 3.1.2
* SWAP kernel version        : swap3234
* PEARL created on           : 18-Feb-2011
*
* PEARL was called from      : FOCUSPEARL,version 4.4.4
* Working directory          : C:\Users\ear\Documents\PesticideModels\FOCUSPEARL_4_4_4\PearlDB
* Run ID                     : 58
* Input file generated on    : 29-09-2017
* ----------------------------------------------------------------------------
*
* Location           : OKEHAMPTON
* Meteo station      : OKEH-M
* Soil type          : OKEH-S_Soil
* Crop calendar      : OKEH-GRASS
* Substance          : Decan
* Application scheme : SPRING_GRASS_DECA
* Deposition scheme  : No
* Irrigation scheme  : No
*
* End of PEARL REPORT: Header


* PEARL REPORT: Leaching
* Start date      :   01-Jan-1901
* End date        :   31-Dec-1926
* Target depth    :   1.00 m
* Annual incorporation at 15-Mar; dosage =     1.1300 kg.ha-1; depth =     0.10 m

* Leaching summary for compound Decan
* Molar mass (g.mol-1)                                 :    172.3
* Saturated vapour pressure (Pa)                       :  0.217E-03; measured at (C)  25.0
* Solubility in water (mg.L-1)                         :   43.0    ; measured at (C)  20.0
* Half-life (d)                                        :     2.1; measured at (C)  12.0
* Kom (coef. for sorption on organic matter) (L.kg-1) :    153.1
* KF    (overall sorption coefficient of the target layer) (L.kg-1) :      2.36
* Freundlich exponent (-)                              :     0.90
* ----------------------------------------------------------------------------------------------------------------------------
* Period        From          To              Water percolated          Substance leached          Average substance
* number                                  below target depth (mm)   below target depth (kg/ha)   concentration in water
*                                                                                                at target depth (ug/L)
* ----------------------------------------------------------------------------------------------------------------------------
   1     01-Jan-1907 31-Dec-1907                   516.408                  0.0000000                    0.000
   2     01-Jan-1908 31-Dec-1908                   135.632                  0.0000000                    0.000
   3     01-Jan-1909 31-Dec-1909                   401.862                  0.0000000                    0.000
   4     01-Jan-1910 31-Dec-1910                   271.998                  0.0000000                    0.000
   5     01-Jan-1911 31-Dec-1911                   455.551                  0.0000000                    0.000
   6     01-Jan-1912 31-Dec-1912                   458.739                  0.0000000                    0.000
   7     01-Jan-1913 31-Dec-1913                   582.500                  0.0000000                    0.000
   8     01-Jan-1914 31-Dec-1914                   303.718                  0.0000000                    0.000
   9     01-Jan-1915 31-Dec-1915                   256.445                  0.0000000                    0.000
  10     01-Jan-1916 31-Dec-1916                   489.267                  0.0000000                    0.000
  11     01-Jan-1917 31-Dec-1917                   272.472                  0.0000000                    0.000
  12     01-Jan-1918 31-Dec-1918                   437.262                  0.0000000                    0.000
  13     01-Jan-1919 31-Dec-1919                   569.851                  0.0000000                    0.000
  14     01-Jan-1920 31-Dec-1920                   369.111                  0.0000000                    0.000
  15     01-Jan-1921 31-Dec-1921                   302.713                  0.0000000                    0.000
  16     01-Jan-1922 31-Dec-1922                   386.288                  0.0000000                    0.000
  17     01-Jan-1923 31-Dec-1923                   602.171                  0.0000000                    0.000
  18     01-Jan-1924 31-Dec-1924                   520.372                  0.0000000                    0.000
  19     01-Jan-1925 31-Dec-1925                   316.136                  0.0000000                    0.000
  20     01-Jan-1926 31-Dec-1926                   503.214                  0.0000000                    0.000

* The average concentration of Decan closest to the 80th percentile is      0.000000 ug/L

* End of PEARL REPORT: Leaching
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2.5 New information on the active substances

No new information on the actives substances has been provided in support of this biocidal product family.

2.6 Residue behaviour

The biocidal products of the ***SOPURCLEAN BPF*** are not sold to non-professionals.

Possible residues in food and beverages are very low and of no concern. Human exposure of the general public is considered not relevant.

Please see section #2.2.6 for additional information.

2.7 Summaries of the efficacy studies

Please see section 3.1 above and the efficacy section 2.2.5 of this PAR which summarises these data.

2.8 Confidential annex

Please see the Confidential P.A.R. in annex.

2.9 Other

Not applicable