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

(submitted by the evaluating Competent Authority)

HYPRED's octanoic acid based products

Product type 4

Active substance : **Octanoic acid**

Case Number in R4BP: BC-LR019297-17

Evaluating Competent Authority: **The Netherlands**

Date: [10/July/2019]

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1 CONCLUSION

The biocidal product family 'HYPRED's octanoic acid based products' consists of products containing 3% to 10% of the active substance octanoic acid.
Products in the family can be used for:

- *meta* SPC 1:
  - Cleaning and disinfecting circuits in dairy industry
  - Cleaning and disinfecting milking equipment and milking robots in farms
- *meta* SPC 2: Disinfecting circuits in breweries, dairy and beverage industries
- *meta* SPC 3: Disinfecting circuits in breweries, dairy and beverage industries
- *meta* SPC 4: Disinfecting or combined cleaning and disinfecting for membranes used in reverse osmosis and nanofiltration in dairy and beverage industries.

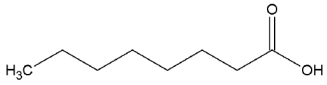
The outcome of the assessment of the 'HYPRED's octanoic acid based products' is specified in the BPC opinion following discussions at the BPC-31 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

SUMMARY

2.1.1. Presentation of the biocidal family

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	Octanoic acid
IUPAC or EC name	Octanoic acid
EC number	204-677-5
CAS number	124-07-2
Index number in Annex VI of CLP	-
Minimum purity / content	99.3%
Structural formula	

B. FAMILY COMPOSITION AND FORMULATION

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

Qualitative and quantitative information on the composition of the biocidal product

Family : *HYPRED's octanoic acid based products*

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Octanoic acid	Octanoic acid	Active substance	124-07-2	204-677-5	3 (TC) *2.98 (pure)*	10 (TC) *9.93 (pure)*
Methanesulfonic acid	Methanesulfonic acid	Non-active substance	75-75-2	200-898-6	0	21
L-(+)-Lactic acid	L-(+)-Lactic acid	Non-active substance	79-33-4	201-196-2	0	17.6
N,N-dimethyl-1-Decanamine, N-oxid	N,N-dimethyl-1-Decanamine, N-oxid	Non-active substance	2605-79-0	220-020-5	2.25	6
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	0	15

Meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid	Octanoic acid	Active substance	124-07-2	204-677-5	3 (TC) *2.98 (pure)*	3 (TC) *2.98 (pure)*
Methanesulfonic acid	Methanesulfonic acid	Non-active substance	75-75-2	200-898-6	21	21
N,N-dimethyl-1-Decanamine, N-oxid	N,N-dimethyl-1-Decanamine, N-oxid	Non-active substance	2605-79-0	220-020-5	2.25	2.25
Ethoxylated alcohol	Ethoxylated alcohol (3 – 6 EO)Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	5	5

Meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid	Octanoic acid	Active substance	124-07-2	204-677-5	10 (TC) *9.93 (pure)*	10 (TC) *9.93 (pure)*
Methanesulfonic acid	Methanesulfonic acid	Non-active substance	75-75-2	200-898-6	14	14
N,N-dimethyl-1-Decanamine, N-oxid	N,N-dimethyl-1-Decanamine, N-oxid	Non-active substance	2605-79-0	220-020-5	4.5	4.5
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	15	15

Meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid	Octanoic acid	Active substance	124-07-2	204-677-5	10 (TC) *9.93 (pure)*	10 (TC) *9.93 (pure)*
L-(+)-Lactic acid	L-(+)-Lactic acid	Non-active substance	79-33-4	201-96-2	17.6	17.6
N,N-dimethyl-1-Decanamine, N-oxid	N,N-dimethyl-1-Decanamine, N-oxid	Non-active substance	2605-79-0	220-020-5	6	6

Meta SPC 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid	Octanoic acid	Active substance	124-07-2	204-677-5	3 (TC) *2.98 (pure)*	3 (TC) *2.98 (pure)*
Methanesulfonic acid	Methanesulfonic acid	Non-active substance	75-75-2	200-898-6	21	21
N,N-dimethyl-1-Decanamine, N-oxid	N,N-dimethyl-1-Decanamine, N-oxid	Non-active substance	2605-79-0	220-020-5	3	3
Ethoxylated alcohol	Ethoxylated alcohol (3 – 6 EO)Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	5	5

The further composition of HYPRED's octanoic acid based products and identity of its ingredients are confidential. This information is provided separately in the confidential annex 3.6.

Information on the substance(s) of concern

Substances of concern are mentioned in the identity section above. For more information regarding assessment of the substances of concern, we refer to the confidential annex section 4.

Endocrine disrupting properties

Concerning the co-formulants, there are no indications for ED properties.None of the meta SPCs are anticipated to have ED potential.
See chapter 2.2.6.1 for more information for human health or chapter 2.3.7 for more information on environment.

C. AUTHORISED USE(S)

Use 1.1 and Use 1.2 in META SPC 1

Table 1: Use # 1.1 – Circulation in dairy industry

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Cleaning and disinfection of circuits in dairy industry
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Cleaning and disinfection of circuits in dairy industry

Application method(s)	Circulation (CIP)
Application rate(s) and frequency	Application rate : Use 1% product solution for bactericidal activity and 1.5% product solution for yeasticidal activity. Frequency : 1 to 3 cycles per day, and 208 to 360 days per year
Category(ies) of user(s)	professionals
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 640, 1000 L

Use-specific instructions for use #1.1

Rinse the circuits with drinking water before disinfection. Apply the product by circulation. Product concentration and contact time : - 1 % bactericidal in 5 minutes - 1.5 % yeasticidal in 15 minutes Temperature : 40 – 85 °C Final rinse with drinking water.

Table 2: Use # 1.2 – Circulation in farms

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Cleaning and disinfection of milking equipment and milking robots in farms
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Cleaning and disinfection of milking equipment and milking robots in farms
Application method(s)	Circulation
Application rate(s) and frequency	Application rate : Use 0.8% product solution for bactericidal activity and 1.5% product solution for yeasticidal activity Frequency : The milk installation is cleaned and disinfected twice a day and the milk tank is cleaned and disinfected once every three days.
Category(ies) of user(s)	professionals
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 640, 1000 L

Use-specific instructions for use #1.2

Machines with or without a programmer. 1) After milking, rinse the equipment with warm drinking water. 2) Apply the solution by circulation at an initial recommended temperature of 60°C minimum to achieve a final temperature of 40-45°C.

Product concentration and contact time :
- 0.8% bactericidal in 10 minutes
- 1.5% yeasticidal in 15 minutes
Do not use at temperature above 75°C.
3) Rinse with cold drinking water.

Use the product twice a day or once a day when alternating with another product.
When alternating, use a cleaner-disinfectant or a cleaning product 1 to 4 times per week depending on the temperature reached in the system.
Contact your supplier for choosing the alternative product and the frequency of use.

Do not mix [name of the authorised product] with an alkaline or chlorinated alkaline product.

Use 2.1 in META SPC 2

Table 4: Use # 2.1 – Circulation

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Disinfection of circuits in breweries, dairy, and beverage industries
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of circuits in breweries, dairy, and beverage industries
Application method(s)	Circulation (CIP)
Application rate(s) and frequency	Application rate : Use 0.4% product solution for bactericidal activity and 0.6% product solution for yeasticidal activity Frequency : 1 to 3 cycles per day, and 208 to 360 days per year
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 640, 1000 L

instructions for use #2.1

Prior to the application of the product, clean with a detergent and rinse with drinking water. Apply the product by circulation. Product concentration and contact time: - 0.4 % bactericidal in 5 minutes - 0.6 % yeasticidal in 15 minutes Temperature : 20 - 85 °C Final rinse with drinking water.

Use 3.1 in META SPC 3

Table 5: Use # 3.1 – Circulation

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Disinfection of circuits in breweries, dairy, and beverage industries
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of circuits in breweries, dairy, and beverage industries
Application method(s)	Circulation (CIP)
Application rate(s) and frequency	Application rate : Use 0.4% product solution. Frequency : 1 to 3 cycles per day, and 208 to 360 days per year
Category(ies) of user(s)	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 640, 1000 L

instructions for use #3.1

Prior to the application of the product, clean with a detergent and rinse with drinking water. Apply the product by circulation. Product concentration : 0.4 % Contact time : - 5 minutes for bactericidal activity - 15 minutes for yeasticidal activity Temperature : 20 - 85 °C Final rinse with drinking water.

Use 4.1 in META SPC 4

Table 6: Use # 4.1 –Membranes in separation process, circulation

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Disinfectant or cleaner-disinfectant for membranes used in reverse osmosis and nanofiltration in dairy and beverage industries.
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfectant or cleaner-disinfectant for membranes used in reverse osmosis and nanofiltration in dairy and beverage industries.
Application method(s)	Circulation
Application rate(s) and frequency	Application rate : Use 0.75% product solution if cleaning is applied prior to the disinfection, and 1% product solution if no cleaning is applied prior to the disinfection Frequency : 1 to 3 cycles per day, and 104 to 312 days per year
Category(ies) of user(s)	professionals
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 640, 1000 L

instructions for use #4.1

Rinse the membranes with drinking water or clean and rinse with drinking water before disinfection. Apply the product by circulation. Product concentration after water rinse: 1 % Product concentration with previous cleaning : 0.75 % Contact time : - 5 minutes for bactericidal activity - 15 minutes for yeasticidal activity Temperature : 40 – 85 °C Final rinse with drinking water.

D. HAZARD AND PRECAUTIONARY STATEMENTS

Classification and Labelling according to Regulation (EC) No 1272/2008:

META SPC 1

Classification	
Hazard category	Skin Corrosion - Category 1B Serious eye damage – Category 1 Specific target organ toxicant – single exposure – Category 3 Substance corrosive to metals – Category 1 Chronic toxicity to the aquatic environment – Category 3
Hazard statement	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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. P501: Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Octanoic acid and methanesulfonic acid contribute to the classification of the mixture as defined in art 18(3) of the CLP regulation.

META SPC 2

Classification	
Hazard category	Skin Corrosion - Category 1B Serious eye damage – Category 1 Substance corrosive to metals – Category 1 Chronic toxicity to the aquatic environment – Category 3 Acute toxicity – Category 4 (per oral route)
Hazard statement	H290: May be corrosive to metals. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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. P501: Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Octanoic acid, methanesulfonic acid, N,N-dimethyl-1-Decanamine, N-oxid and ethoxylated alcohol contribute to the classification of the mixture as defined in art 18(3) of the CLP regulation.

META SPC 3

Classification	
Hazard category	Skin Corrosion - Category 1C Substance corrosive to metals – Category 1Serious eye damage – Category 1 Chronic toxicity to the aquatic environment – Category 3
Hazard statement	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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. P501: Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Octanoic acid contributes to the classification of the mixture as defined in art 18(3) of the CLP regulation..

META SPC 4

Classification	
Hazard category	Skin Corrosion - Category 1B Serious eye damage – Category 1 Specific target organ toxicant – single exposure – Category 3 Substance corrosive to metals – Category 1 Chronic toxicity to the aquatic environment – Category 3
Hazard statement	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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. P501: Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	Octanoic acid and methanesulfonic acid contribute to the classification of the mixture as defined in art 18(3) of the CLP regulation.

E. 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	5 liters	HDPE	Screw cap in HDPE with seal	Professional users	Yes
Jerrycan	10 liters	HDPE	Screw cap in HDPE with seal	Professional users	Yes
Jerrycan	22 liters	HDPE	Screw cap in HDPE with seal	Professional users	Yes
Drum	60 liters	HDPE	Plug in HDPE with washer / gaskets	Professional users	Yes
Drum	120 liters	HDPE	Plug in HDPE with washer / gaskets	Professional users	Yes
Drum	220 liters	HDPE	Plug in HDPE with washer / gaskets	Professional users	Yes
IBC	640 liters	HDPE	Screw cap in HDPE with seal Butterfly valve in HDPE with gasket	Professional users	Yes
IBC	1000 liters	HDPE	Screw cap in HDPE with seal Butterfly valve in HDPE with gasket	Professional users	Yes

2.1.2. Summary of the physical, chemical and technical properties

Property	**Summary**
Physical state, colour and odour at 20 °C and 101.3 kPa	Products included in HYPRED's octanoic acid based product family are colourless to slightly yellow, clear to slightly opalescent liquid with characteristic odour of octanoic acid.
pH	The products in the family are acidic. The pure pH of each product in the family are the following : HYPRACID ONE : pH<1 DEPTACID BD : pH<1 DEPTACID WCM : pH<1 DEPTACID CCB : pH<1 DEPTACID CB : pH range : 2.6 – 3.2
Relative density	Relative densities of each individual product included in the family are the following : HYPRACID ONE : D_4^{20} = 1.090 at 20 °C DEPTACID BD: D_4^{20} = 1.090 at 20 °C DEPTACID WCM: D_4^{20} = 1.088 at 20 °C DEPTACID CCB: D_4^{20} = 1.055 at 20 °C DEPTACID CB: D_4^{20} = 1.059 at 20 °C
Storage stability	Products included in HYPRED's octanoic acid based product family are stable according to accelerated storage test (at 40°C +/-2°C for 8 weeks), low temperature stability test and long term storage test at ambient temperature at 20°C +/- 2°C for 2 years.
Persistent foaming	For all products < 60mL foam persisted after 1 minute when tested according to CIPAC MT47.2.
Dilution stability	All products in HYPRED's octanoic acid based product family at the maximum in use concentration are stable.
Surface tension	HYPRED's octanoic acid based products were considered as surface-active (dilutions had a surface tension of around 29 mN/m at 20°C).
Viscosity	HYPRED's octanoic acid based products were considered to have Newtonian flow properties with viscosities ranging from 5.56 mPa.s to 31.3 mPa.s at 20°C.

2.1.3. Summary of the Human Health Risk Assessment

Endpoint	Brief description
Skin corrosion and irritation	Corrosive to skin CLP : Skin Corr 1B (meta SPC1, meta SPC 2 and meta SPC4) and Skin Corr 1C (meta SPC3) : H314
Eye corrosion/damage and irritation	All products of Hypred's Octanoic acid base products: Corrosive to eyes CLP : Eye Dam 1 : H318
Skin sensitisation	No classification
Sensitization	No classification
Respiratory sensitization (ADS)	No classification
Acute toxicity by oral route	DEPTACID CCB (meta SPC2) is classified for oral acute toxicity cat.4: H302, Harmful if swallowed.
Acute toxicity by inhalation	No classification
Dermal absorption	Not determined for Octanoic acid nor for other components of Hypred's Octanoic acid based products. Dermal absorption values are not required for the human health exposure and risk assessment since a qualitative assessment for local effects is performed.
Other effects	DEPTACID BD and HYPRACID ONE formulas (meta SPC 1) and DEPTACID WCM formula (meta SPC4) are classified as STOT-SE Cat.3: H335, May cause respiratory irritation.
Available toxicological data relating to non-active substance(s)	-
Available toxicological data relating to a mixture	-
Other relevant information	-

Reference values

The risk assessment has been performed as a qualitative assessment on the basis of local effects.

As stated in the assessment report, the available data for octanoic acid are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AECs). No quantitative AELs, ADI or ARfD were derived either.

Risk characterisation

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.	Loading by connecting lines	Primary exposure: depending on the coupling system used, dermal and inhalation exposure may in exceptional cases occur.	professionals
2.	Loading by pouring from jerry cans	Primary exposure: dermal and inhalation exposure	professionals
3	Rinsing of empty containers, drums, jerry cans	Primary exposure: dermal and inhalation exposure	professionals
4.	Application: pumping product through circuits	No exposure possible: completely closed systems	professionals
5.	Rinsing: pumping water through the installations after use	No exposure possible: completely closed systems	professionals
6.	Maintenance of installations	Primary exposure: dermal and inhalation exposure	professionals

Conclusion

In accordance with the approach described in the assessment report on octanoic acid, a qualitative risk characterisation has been performed based on local effects, following the procedure outlined in the "Guidance on the BPR: Volume III, Part B, Risk Assessment (Version 1.1 of April 2015)".

Six exposure scenarios have been assessed for the professional user. No unacceptable risks were identified for the protected professional user during loading by connecting / by pouring undiluted HYPRED's octanoic acid based products in an installation, rinsing product containers or maintenance of installations. Gloves, protective clothing and eye protection have been identified as adequate PPE for these tasks. As the users of the products are professionals, it is assumed that the RMM are indeed applied and PPE is used as instructed. For pumping product through circuits and for pumping water through the installations after use no exposure is foreseen, because of the completely closed systems.

Furthermore, secondary exposure is considered negligible and therefore no adverse effects are expected for general public due to the use of HYPRED's octanoic acid based products.

Due to the nature of the active substance no quantitative dietary risk assessment was carried out. Furthermore presence of relevant amounts of residues of the application solution in food or feeding is not expected with proper operation of CIP systems. Minimal residues of the application solution in food or feed are unlikely to cause local effects due to the high dilution rate in food expected.

2.1.4. Summary of the Environmental Risk Assessment

Fate and behaviour in the environment

The following uses of octanoic acid in PT4 applications are identified in this PAR:

- Disinfection, or combined cleaning and disinfection of circuits in agro-food industries (including dairy, beverage and breweries industries) (scenario 1; uses 1.1, 2.1 and 3.1 in meta-SPCs 1-3))
- Cleaning and disinfection of milking equipment and milking robots in farms (scenario 2; use 1.2 in meta-SPC 1))
- Disinfection or combined cleaning and disinfection of separative membranes in dairy and beverage industries (scenario 3; use 4.1 in meta-SPC 4)

All uses are considered as CIP treatments. Consequently, the cleaning processes are assumed to always take place under closed system conditions. Risk assessment was made for the active substance and two substances of concern (N,N-dimethyl-1-decamine, N-oxide and lactic acid).

The main route of exposure to the environment is via the sewer system, disinfectants end up in a sewage treatment plant. The summed up PEC/PNEC for the STP and sediment compartments are well below 1 for all scenarios and thus acceptable. Although PEC/PNEC ratio above one has been calculated for application in the brewery industry, monitoring data demonstrated that residual fatty acid levels including octanoic acid are low. Unacceptable risks cannot be expected for the concerning products.

The summed up PEC/PNEC for the soil compartment are above 1 for soils exposed to octanoic acid, N,N-dimethyl-1-decamine, N-oxide, and lactic acid present in sewage sludge. It was however demonstrated that octanoic acid disappears quickly from soils even under sterile conditions, which was most likely not related to biodegradation, but to irreversible sorption. Octanoic acid also occurs naturally in the environment, but information on background concentrations are not available. Moreover, all PNEC were estimated due the absence of terrestrial data, which may likely overestimates terrestrial toxicity.

The risks for groundwater and secondary poisoning were quanitatively assessed and found acceptable for the individual substances and their combination.

GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

2.1.5. Administrative information

A. TRADE NAME(S) OF THE PRODUCTS OF THE FAMILY

Trade name in Meta SPC 1	**Country (if relevant)**
HYPRACID ONE DEPTACID BD prevides®MS	EU union

Trade name in Meta SPC 2	**Country (if relevant)**
DEPTACID CCB	EU union

Trade name in Meta SPC 3	**Country (if relevant)**
DEPTACID CB	EU union

Trade name in Meta SPC 4	**Country (if relevant)**
DEPTACID WCM	EU union

B. AUTHORISATION HOLDER

Name and address of the authorisation holder	Name	HYPRED SAS
	Address	55, Boulevard Jules Verger BP 10180 35803 DINARD Cedex
Telephone:	+33 2 99 16 50 00	
Fax:	+ 33 2 99 16 50 20	
E-mail address:	biocide@hypred.com	
Pre-submission phase started on:	27th February 2015	
Pre-submission phase concluded on:	29th May 2015	
Case number in R4BP3:	Pre-submission case number : BC-WA015438-44	

C. APPLICANT (IF DIFFERENT FROM AUTHORISATION HOLDER)

Company Name:	Same as authorisation holder
Address:	
City:	
Postal Code:	
Country:	
Telephone:	
Fax:	
E-mail address:	
Letter of appointment for the applicant to represent the authorisation holder provided	

(yes/no):	

D. PERSON AUTHORISED FOR COMMUNICATION ON BEHALF OF THE APPLICANT

Name:	Isabelle DEMOMENT
Function:	Regulatory Manager
Address:	55, Boulevard Jules Verger
City:	DINARD
Postal Code:	BP 10180
Country:	FRANCE
Telephone:	+33 2 99 16 50 35
Fax:	
E-mail address:	biocide@hypred.com

E. MANUFACTURER(S) OF THE PRODUCTS OF THE FAMILY

Manufacturer of the active substance

Active substance	Octanoic acid
Name of manufacturer	Emery Oleochemicals (M)
Address of manufacturer	Sdn Bhd (63112-D) Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang 42500, Selangor, Malaysia
Location of manufacturing sites	Emery Oleochemicals (M) Sdn Bhd (63112-D) Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang 42500, Selangor, Malaysia

Manufacturer of the product

Name of manufacturer	HYPRED SAS
Address of manufacturer	55, Boulevard Jules Verger – BP10180– 35803 Dinard Cedex - France
Location of manufacturing sites	HYPRED SAS 55, Boulevard Jules Verger – BP10180 - 35803 Dinard Cedex - France HYPRED GmbH Marie-Curie-Straße 23 – 53332 Bornheim – Sechtem Germany HYPRED IBERICA S.L Pol. Ind. Arazuri-Orcoyen C/C nº 32– 31160 Orcoyen – NAVARRA - Spain HYPRED Italia s.r.l. Strada Montodine-Gombito Loc. Cà Nova – 26010

	Ripalta Arpina CR Italy HYPRED POLSKA SP. Z O.O. NIEPRUSZEWO, KASZTANOWA 4, 64-320 BUK Poland AG France S.A.S. Zone Industrielle Le Roineau 72500 Vaas - France Anti-Germ Austria GmbH "Pfongauer Straße 17 5202 Neumarkt am Wallersee" Austria Anti-Germ Deutschland GmbH Oberbrühlstraße 16-18 87700 Memmingen Germany

F. CANDIDATE(S) FOR SUBSTITUTION

HYPRED's octanoic acid based products don't contain an active substance candidate for substitution.

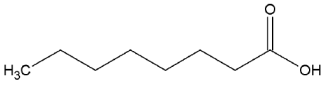
2.1.6. Family composition and formulation

NB: the full composition of the product according to Annex III Title 1 is 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 ☐
No ☒

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	Octanoic acid
IUPAC or EC name	Octanoic acid
EC number	204-677-5
CAS number	124-07-2
Index number in Annex VI of CLP	-
Minimum purity / content	99.3%
Structural formula	

B. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL FAMILY

Please see the confidential annex for further details.

C. INFORMATION ON TECHNICAL EQUIVALENCE

The active substance source is the same source as the one evaluated for inclusion in the union list of approved active substances.

D. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

For information regarding substances of concern we refer to the confidential annex of the PAR, section 4.

E. TYPE OF FORMULATION

SL (concentrate) - Water based liquid

2.1.7. Intended use(s) as applied for by the applicant

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

See 2.1.1 C for the uses evaluated by the eCA and proposed to be authorised. The assessment of the BPF by the eCA starts at paragraph 2.3.

Use 1, Use 2 and Use 3 in META SPC 1

Table 1: Use # 1 – Circulation in dairy industry

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Cleaning and disinfection of circuits in dairy industry
Target organism (including development stage)	- Bacteria : *Staphylococcus aureus, Escherichia Coli, Pseudomonas aeruginosa, Enterococcus hirae* - Yeasts : *candida albicans*
Field of use	Indoor Cleaning and disinfection of circuits in dairy industry
Application method(s)	Circulation
Application rate(s) and frequency	Application rate : 1% bactericidal and 1.5% yeasticidal Frequency : 1 to 3 cycles per day, and 208 to 360 days per year
Category(ies) of users	Professionnal
Pack sizes and packaging material	Opaque HDPE JERRYCAN 5, 10, 22 L Opaque HDPE DRUM 60, 120, 220 L Opaque HDPE CONTAINER 640, 1000 L
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	No: only minimal residues in food or feed can occur which are unlikely to cause any adverse effects.

Use-specific instructions for use #1

Rinse previously the circuits with drinking water. Apply the product by circulation. Concentration and contact time : - 1 % bactericidal in 5 minutes - 1.5 % yeasticidal in 15 minutes Temperature : 40 – 85 °C Final rinse with drinking water.

Table 2: Use # 2 – Circulation in farms

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Cleaning, descaling, disinfection of milking equipment and milking robots in farms
Target organism (including development stage)	- Bacteria : *Staphylococcus aureus, Escherichia Coli, Pseudomonas aeruginosa, Enterococcus hirae* - Yeasts : *candida albicans*
Field of use	Indoor Cleaning, descaling, disinfection of milking equipment and milking robots in farms
Application method(s)	Circulation
Application rate(s) and frequency	Application rate : 0.8% bactericidal, 1.5% yeasticidal Frequency : The milk installation is cleaned and disinfected twice a day and the milk tank is cleaned and disinfected once every three days.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Opaque HDPE JERRYCAN 5, 10, 22 L Opaque HDPE DRUM 60, 120, 220 L Opaque HDPE CONTAINER 640, 1000 L
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	No: only minimal residues in food or feed can occur which are unlikely to cause any adverse effects.

Use-specific instructions for use #2

Machines with or without a programmer.
1) After milking, rinse the equipment with warm drinking water.
2) Apply the solution by circulation at an initial recommended temperature of 60°C minimum to achieve a final temperature of 40-45°C.
Concentration and contact time : 0.8% bactericidal in 10 minutes
1.5% yeasticidal in 15 minutes
Do not use at temperature above 75°C.
3) Rinse with cold drinking water.

Use the product twice every day or once a day when alternating with another product.
Use an alternative product 1 to 2 times per week if the initial temperature is equal or greater than 60 ° C and not exceeding 75°C.
Use an alternative product 3 to 4 times per week if the initial temperature is below 60°C.

Contact your technician for choosing the alternative product.

Do not mix with an alkaline or chlorinated alkaline product.

Table 3: Use # 3 – Separative membranes circulation

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Cleaning and disinfection of separative membranes or disinfection of separative membranes in dairy and beverage industries
Target organism (including development stage)	- Bacteria : *Staphylococcus aureus, Escherichia Coli, Pseudomonas aeruginosa, Enterococcus hirae* - Yeasts : *candida albicans*
Field of use	Indoor Cleaning and disinfection of separative membranes or disinfection of separative membranes in dairy and beverage industries
Application method(s)	Circulation
Application rate(s) and frequency	Application rate : 0.75% with previous cleaning, and 1% without previous cleaning Frequency : 1 to 6 cycles per day, and 104 to 312 days per year
Category(ies) of user(s)	Professionnal
Pack sizes and packaging material	Opaque HDPE JERRYCAN 5, 10, 22 L Opaque HDPE DRUM 60, 120, 220 L Opaque HDPE CONTAINER 640, 1000 L
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	No: only minimal residues in food or feed can occur which are unlikely to cause any adverse effects.

Use-specific instructions for use #3

Rinse with drinking water or clean previously the membranes. Apply the product by circulation Concentration if no cleaning is applied prior to the disinfection: 1 % Concentration if cleaning is applied prior to the disinfection: 0.75 % Contact time : - 5 minutes for bactericidal activity - 15 minutes for yeasticidal activity Temperature : 40 – 85 °C Final rinse with drinking water.

Use 4 in META SPC 2

Table 4: Use # 4 – Circulation

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Disinfection of circuits in dairy beverage and breweries industries
Target organism (including development stage)	- Bacteria : *Staphylococcus aureus, Escherichia Coli, Pseudomonas aeruginosa, Enterococcus hirae* - Yeasts : *candida albicans*
Field of use	Indoor Disinfection of circuits in dairy, beverage and breweries industries
Application method(s)	Circulation
Application rate(s) and frequency	Application rate : 0.4% bactericidal and 0.6% yeasticidal Frequency : 1 to 3 cycles per day, and 208 to 360 days per year
Category(ies) of user(s)	Professionnal
Pack sizes and packaging material	Opaque HDPE JERRYCAN 5, 10, 22 L Opaque HDPE DRUM 60, 120, 220 L Opaque HDPE CONTAINER 640, 1000 L
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	No: only minimal residues in food or feed can occur which are unlikely to cause any adverse effects.

Use-specific instructions for use #4

Prior to the application of the product, clean with a detergent and rinse with drinking water. Apply the product by circulation. Concentration and contact time: - 0.4 % bactericidal in 5 minutes - 0.6 % yeasticidal in 15 minutes Temperature : 20 - 85 °C Final rinse with drinking water.

Use 5 in META SPC 3

Table 5: Use # 5 – Circulation

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	Disinfection of circuits in dairy beverage and breweries industries
Target organism (including development stage)	- Bacteria : *Staphylococcus aureus, Escherichia Coli, Pseudomonas aeruginosa, Enterococcus hirae* - Yeasts : *candida albicans*
Field of use	Indoor Disinfection of circuits in dairy, beverage and breweries industries
Application method(s)	Circulation
Application rate(s) and frequency	Application rate : 0.4% Frequency : 1 to 3 cycles per day, and 208 to 360 days per year
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Opaque HDPE JERRYCAN 5, 10, 22 L Opaque HDPE DRUM 60, 120, 220 L Opaque HDPE CONTAINER 640, 1000 L
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	No: only minimal residues in food or feed can occur which are unlikely to cause any adverse effects.

Use-specific instructions for use #5

Prior to the application of the product, clean with a detergent and rinse with drinking water. Apply the product by circulation. Concentration : 0.4 % Contact time : - 5 minutes for bactericidal activity - 15 minutes for yeasticidal activity Temperature : 20 - 85 °C Final rinse with drinking water.

F. PACKAGING OF THE BIOCIDAL PRODUCT- PROPOSED BY THE APPLICANT

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	5 liters	HDPE, opaque	Screw cap in HDPE with seal	Professional users	Yes
Jerrycan	10 liters	HDPE, opaque	Screw cap in HDPE with seal	Professional users	Yes
Jerrycan	22 liters	HDPE, opaque	Screw cap in HDPE with seal	Professional users	Yes
Drum	60 liters	HDPE, opaque	Pug in HDPE with washer / gaskets	Professional users	Yes
Drum	120 liters	HDPE, opaque	Pug in HDPE with washer / gaskets	Professional users	Yes
Drum	220 liters	HDPE, opaque	Pug in HDPE with washer / gaskets	Professional users	Yes
IBC	640 liters	HDPE, opaque	Screw cap in HDPE with seal Butterfly valve in HDPE with gasket	Professional users	Yes
IBC	1000 liters	HDPE, opaque	Screw cap HDPE with seal Butterfly valve in HDPE with gasket	Professional users	Yes

2.1.8. Directions for use as proposed by the applicant

2.1.9. META SPC 1

A. INSTRUCTIONS FOR USE

See instructions for use in 2.2.3 Intended uses as applied for by the applicant.

B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

Refer to the Safety Data Sheets available for professional user. It contains an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

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.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Do not discharge the product directly to sewer or to the environment.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

Eliminate the product and its packaging in accordance with applicable local and national regulations.

D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Shelf life : 2 years
Conditions of storage : keep only in the original container. Keep container closed. Do not store at temperatures above 40°C.

2.1.10. META SPC 2

A. INSTRUCTIONS FOR USE

See instructions for use in 2.2.3 Intended uses as applied for by the applicant.

B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

Refer to the Safety Data Sheets available for professional user. It contains an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

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.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Do not discharge the product directly to sewer or to the environment.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

Eliminate the product and its packaging in accordance with applicable local and national regulations.

D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Shelf life : 2 years
Conditions of storage : keep only in the original container. Keep container closed. Do not store at temperatures above 40°C.

2.1.11. META SPC 3

A. INSTRUCTIONS FOR USE

See instructions for use in 2.2.3 Intended uses as applied for by the applicant.

B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

Refer to the Safety Data Sheets available for professional user. It contains an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

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.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Do not discharge the product directly to sewer or to the environment.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

Eliminate the product and its packaging in accordance with applicable local and national regulations.

D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Shelf life : 2 years
Conditions of storage : keep only in the original container. Keep container closed. Do not store at temperatures above 40°C.

2.1.12. META SPC 4

A. INSTRUCTIONS FOR USE

See instructions for use in 2.2.3 Intended uses as applied for by the applicant.

B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.
FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

Refer to the Safety Data Sheets available for professional user. It contains an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

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.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!
Do not discharge the product directly to sewer or to the environment.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

Eliminate the product and its packaging in accordance with applicable local and national regulations.

D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Shelf life : 2 years
Conditions of storage : keep only in the original container. Do not store at temperatures above 40°C.

2.1.13. Documentation

A. DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION

Data submitted in relation to family product application are presented in the reference list presented in annex 3.1 (which is a confidential annex).

B. ACCESS TO DOCUMENTATION

The letter of access to the Octanoic Acid dossier for PT4 is submitted in Section 13 in IUCLID (Doc 13-003) in accordance with Article 61 of the BPR. It covers the entire dossier, including but not limited to, the studies as well as the risk assessment, and any argumentation and rationale for data waivers or otherwise included in the Octanoic Acid Dossier submitted by Sopura for product type 4.

C. SIMILAR CONDITIONS OF USE

Outcome of the pre-submission consultation (n° D(2015) 2098) is presented in Section 13 in IUCLID (Doc 13-001) :
"The biocidal product family HYPRED's octanoic based products is deemed to be eligible for Union authorisation."

2.1.14. Other information

No other information

ASSESSMENT OF THE BIOCIDAL FAMILY

2.1.15. Physical, chemical and technical properties

Product	Meta SPC
HYPRACID ONE	1*
DEPTACID BD	1*
DEPTACID CCB	2
DEPTACID CB	3
DEPTACID WCM	4

** these products within meta SPC 1 have the same composition.*

Some of the products mentioned in the table above have multiple trade names. Please refer to the SPC for an overview of trade names for each product. In the phys-chem table the trade names are consistent with the information in the table above.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual observation (internal method : AL1)	HYPRACID ONE (3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	All products included in the family are liquid	Section 3.1 in IUCLID Connan O. (2015) Doc 3.1-001 Doc 3.1-002 Doc 3.1-003 Caillet G. (2015) Doc 3.1-004 Doc 3.1-005
Colour at 20 °C and 101.3 kPa	Visual observation (internal method : AL1)	HYPRACID ONE(3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	All products included in the family are colourless to slightly yellow	Section 3.1 in IUCLID Connan O. (2015) Doc 3.1-001 Doc 3.1-002 Doc 3.1-003 Caillet G. (2015) Doc 3.1-004 Doc 3.1-005
Odour at 20 °C and 101.3 kPa	Olfactory inspection (internal method : AL1)	HYPRACID ONE (3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	All products included in the family have a characteristic odour of octanoic acid	Section 3.1 in IUCLID Connan O. (2015) Doc 3.1-001 Doc 3.1-002 Doc 3.1-003 Caillet G. (2015) Doc 3.1-004 Doc 3.1-005

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Acidity / alkalinity	OECD 122	HYPRACID ONE (3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	All products in the family are acidic. HYPRACID ONE : pH<1 The mean value of the acidity is 11.63 +/- 0.05 % (w/w), calculated as H2SO4. DEPTACID BD : pH<1 The mean value of the acidity is 11.63 +/- 0.05 % (w/w), calculated as H2SO4. DEPTACID WCM : pH<1 The mean value of the acidity is 11.66 +/- 0.05 % (w/w), calculated as H2SO4. DEPTACID CCB : pH<1 The mean value of the acidity is 10.46 +/- 0.04 % (w/w), calculated as H2SO4. DEPTACID CB : pH range : 2.6 – 3.2 The mean value of the acidity is 11.14 +/- 0.04 % (w/w), calculated as H2SO4.	Section 3.2 in IUCLID Connan O. (2015) Doc 3.2-001.1 Doc 3.2-001.2 Doc 3.2-002.1 Doc 3.2-002.2 Doc 3.2-003.1 Doc 3.2-003.2 Caillet G. (2015) Doc 3.2-004.1 Doc 3.2-004.2 Doc 3.2-005.1 Doc 3.2-005.2
eCA remark The products within the family are all acidic. The pH for meta SPC 1, 2 and 4 is <1. The representative product for Meta SPC 3 has a pH of approximately 3 (DEPTACID CB). This is taken into account for evaluation of the corrosiveness to metals. It should be noted that although the measurements were performed to CIPAC MT75.3, the pH of the products is outside the range of the pH buffers used for calibration. It is assumed that the measurements are sufficiently accurate to confirm that the products, with exception of DEPTACID CB, have a pH <2. The product DEPTACID CB, is considered to have a pH >2.				
Relative density / bulk density	OCDE 109	HYPRACID ONE (3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid)	HYPRACID ONE : D_4^{20} = 1.090 at 20 °C DEPTACID BD: D_4^{20} = 1.090 at 20 °C	Section 3.3 in IUCLID Connan O. (2015) Doc 3.3-001

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	DEPTACID WCM: D_4^{20} = 1.088 at 20 °C DEPTACID CCB: D_4^{20} = 1.055 at 20 °C DEPTACID CB: D_4^{20} = 1.059 at 20 °C Density range of each individual product included in HYPRED's octanoic acid based products family are the following : HYPRACID ONE : 1.08 – 1.10 g/cm3 DEPTACID BD : 1.08 – 1.10 g/cm3 DEPTACID WCM : 1.077 – 1.097 g/cm3 DEPTACID CCB : 1.045 – 1.065 g/cm3 DEPTACID CB : 1.048 – 1.068 g/cm3	Doc 3.3-002 Doc 3.3-003 Caillet G. (2015) Doc 3.3-004 Doc 3.3-005
Storage stability test – **accelerated storage**	CIPAC MT 46.3 8 weeks at 40°C pH CIPAC MT75.3 Density: EC A3 Viscosity: OECD114 Foaming: CIPAC MT47.2 Dilution stability CIPAC MT41	HYPRACID ONE (3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	**HYPRACID ONE and DEPTACID BD :** *Packaging in HDPE :* No deviation *Weight loss : 1.8g* *Octanoic acid content (method AL 218)*: Initial 2.95% w/w 8w: 2.87%w/w *Appearance* : Initial: Slightly opalescent colourless liquid 8w: no change *Odour :* Initial: characteristic *8w: no change*	Section 3.4.1 in IUCLID Connan O. (2015) Doc 3.4.1-001.1 Doc 3.4.1-001.2 Doc 3.4.1-001.3 Caillet G. (2015) Doc 3.4.1-001.4 Doc 3.4.1-001.5

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH neat Initial: 0.1 8w: 0.3 *Acidity* : Initial: 11.63 % w/w expressed in H_2SO_4 8w:11.65%w/w expressed in H_2SO_4 *Density :* Initial: 1.090 g/cm^3 8w: no change *Viscosity 20°C (60 rpm)* *Initial:*: 4.2 mPa.s 8w: 5.5 mPa.s *Viscosity 40°C (60 rpm)* : Initial: 3.0 mPa.s 8w: 3.3 mPa.s *pH 1% (w/w)* : Initial: 1.7 8w: 1.8 *Persistent foaming* 1.5% w/w at 20°C, 40°C and 75°C after 1 minute Initial: 10mL, 0mL, 0mL 8w: 9mL, 0mL, 0mL *0.75% w/w at 20°C, 40°C and 75°C* after 1 minute Initial: 8mL, 0mL, 0mL 8w: 7mL, 0mL, 0mL *Stability of the dilution at 1.5% w/w* : Initial: Homogeneous cloudy liquid 8w: Homogeneous cloudy liquid	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			DEPTACID WCM : *Packaging in HDPE :* No deviation *Weight loss : 2.1g* *Octanoic acid content (method AL 218)*: Initial 2.97% w/w 8w: 2.91%w/w *Appearance* : Initial: Slightly opalescent colourless liquid 8w: no change *Odour :* Initial: characteristic 8w: no change *pH neat* : Initial: 0.2 8w: 0.4 *Acidity* expressed in %w/w H_2SO_4 Initial: 11.66 8w: 11.67 *Density :* Initial: 1.088 g/cm^3 8w: 1.087 g/cm^3 *Viscosity 20°C (60 rpm)* : Initial: 4.2 mPa.s 8w: 5.5 mPa.s *Viscosity 40°C (60 rpm)* : Initial: 3.3 mPa.s 8w: 3.3 mPa.s *pH 1% (w/w)* Initial : 1.7 8w: 1.8 *Persistent foaming at 1% w/w (at 20°C, 40°C and 50°C)* : Initial: 10mL, 5mL, 0mL 8w: 8mL, 7mL, 0mL	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			and 0.5% w/w (at 20°C, 40°C and 50°C) : Initial: 7mL, 3mL, 4mL 8w: 5mL, 3mL, 3mL *Stability of the dilution at 1% w/w* : Initial: Homogeneous opalescent liquid 8w: no change **DEPTACID CCB :** *Packaging (HDPE)* Initial: white packaging with no apparent defect, white stopper with no apparent defect 8w: no change, weight loss 0.7g *Octanoic acid content (method AL 218)* Initial: 9.84% w/w 8w: 9.47%w/w *Appearance* : Initial: Clear colourless liquid 8w: Clear slightly yellow liquid *Odour :* Initial: characteristic 8w: characteristic *pH neat* : Initial: 0.2 8w: 0.4 *Acidity* expressed in %w/w H_2SO_4 Initial: 10.46 8w: 10.22 *Density :* Initial: 1.055 g/cm^3	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			8w: 1.054 g/cm^3 *Viscosity 20°C (12 rpm)* : Initial: 26.4 mPa.s 8w: 32.1mPa.s *Viscosity 40°C (12 rpm)* : Initial: 12.8 mPa.s 8w: 14 mPa.s *pH 1% (w/w)* : Initial: 1.9 8w: 2.0 *Persistent foaming at 0.6% w/w (at 20°C)* after 1 mn Initial: 14mL 8w: 6mL *Stability of the dilution at 0.6% w/w* : Initial Homogeneous slightly cloudy liquid 8w: Homogeneous slightly cloudy liquid **DEPTACID CB :** *Packaging in HDPE :* No deviation *Weight loss : 12.1g* *Octanoic acid content (method AL 218)*: Initial: 9.98% w/w 8w: 9.94%w/w *Appearance* : Initial: Clear slightly yellow liquid 8w: Clear slightly yellow liquid *Odour :* Initial: characteristic 8w: characteristic	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH neat Initial: 2.7 8w: 3.2 *Acidity* expressed in %w/w H_2SO_4 Initial: 11.14 8w: 12.02 *Density :* Initial: 1.059 g/cm^3 8w: 1.060 g/cm^3 *Viscosity 20°C (12 rpm)* : Initial: 30.8 mPa.s 8w: 34.6 mPa.s *Viscosity 40°C (12 rpm)* : Initial: 18.6 mPa.s 8w: 20.9 mPa.s *pH 1% (w/w)* : Initial: 3.0 8w: 3.3 *Persistent foaming at 0.6% w/w (at 20°C)* after 1 minute Initial: 45mL 8w: 30mL *Stability of the dilution at 0.6% w/w* : Initial: Homogeneous slightly cloudy liquid 8w: Homogeneous slightly cloudy liquid	
Storage stability test – **long term storage at ambient temperature**	Long term storage test at 20°C +/- 2°C for 2 years According to Guidance on the Biocidal Product Regulation - Vol I Part A Information	HYPRACID ONE (3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	**HYPRACID ONE and DEPTACID BD :** *Packaging in HDPE :* No deviation *Weight loss : 3.3 g* *Octanoic acid content (AL218) (%w/w)*: Initial: 2.95	Section 3.4.1 in IUCLID Connan O. (2015) Doc 3.4.1-003.1 Doc 3.4.1-003.2 Doc 3.4.1-003.3 Caillet G. (2015) Doc 3.4.1-003.4 Doc 3.4.1-003.5

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	requirements pH CIPAC MT75.3 Density: EC A3 Viscosity: OECD114 Foaming: CIPAC MT47.2 Dilution stability CIPAC MT41		2y: 2.95 *Appearance* : Initial: Slightly opalescent colourless liquid 2y: Slightly opalescent colourless liquid *Odour :* Initial: characteristic 2y: characteristic *pH neat* : Initial: 0.1 2y: 0.4 *Acidity* expressed in %w/w H_2SO_4 Initial: 11.63% 2y: 11.51% *Density :* Initial: 1.090 g/cm^3 2y: 1.091 g/cm^3 *Viscosity 20°C (60 rpm)* : Initial: 4.2 mPa.s *2y: 5.7 mPa.s* *Viscosity 40°C (60 rpm)* : Initial: 3.0 mPa.s 2y: 3.2mPa.s *pH 1%w/w*: Initial: 1.7 2y: 1.8 *Persistent foaming after 1 min at 1.5% w/w (at 20°C and 40°C)* Initial: 10mL, 0mL 2y: 4mL, 0mL *0.75% w/w (at 20°C and 40°C)* : Initial: 8mL, 0mL 2y: 4mL, 0mL Tests were also performed at 70°C. No foam was observed at any of	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the time intervals. *Stability of the dilution at 1.5% w/w* : Initial: Homogeneous cloudy liquid 2y: Homogeneous cloudy liquid **DEPTACID WCM :** *Packaging in HDPE :* No deviation *Weight loss : 2.9g* *Octanoic acid content (AL218)* Initial: 2.97%w/w 2y: *3.03%w/w* *Appearance* : initial: Slightly opalescent colourless liquid 2y: Slightly opalescent colourless liquid *Odour :* Initial: characteristic 2y: Characteristic *pH neat* : Initial: 0.2 2y: 0.5 *Acidity* %w/w expressed in H_2SO_4 Initial: 11.66 2y: 11.56 *Density :* Initial: 1.088 g/cm^3 2y: 1.088 g/cm^3 *Viscosity 20°C (60 rpm)* : Initial: 4.2 mPa.s 2y: 5.7 mPa.s *Viscosity 40°C (60 rpm)* : Initial: 3.3 mPa.s 2y: 3.8 mPa.s	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH 1% (w/w): Initial: 1.7 2y: 1.8 *Persistent foaming after 1 min at 1% w/w (at 20°C, 40°C and 50°C:* *Initial: 10mL, 5mL, 0mL* *2y: 8mL, 3mL, 0mL* *0.5% w/w (at 20°C, 40°C and 50°C)* : Initial: 7mL, 3mL, 4mL 2y: 3mL, 3mL, 0mL *Stability of the dilution at 1% w/w* Initial: Homogeneous opalescent liquid 2y: Homogeneous opalescent liquid **DEPTACID CCB :** *Packaging in HDPE :* No deviation *Weight loss : 1.3g* *Octanoic acid content (AL218)*: Initial: 9.84% w/w 2y: 9.47 % w/w *Appearance* : Initial: Clear colourless liquid 2y: Clear colourless liquid *Odour :* Initial: characteristic 2y: Characteristic *pH neat* : Initial: 0.2 2y: 0.6 *Acidity* expressed in % w/w H_2SO_4 Initial: 10.46 2y: 10.13	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Density : Initial 1.055 g/cm^3 2y: 1.055 g/cm^3 *Viscosity 20°C (12 rpm)* : Initial: 26.4 mPa.s 2y: 25.5 mPa.s *Viscosity 40°C (12 rpm)* : Initial: 12.8 mPa.s 2y: 13.7 mPa.s *pH 1% (w/w)* : Initial: 1.9 2y: 2.0 *Persistent foaming at 0.6% w/w after 1 min (at 20°C)* : Initial: 14mL 2y: 4mL *Stability of the dilution at 0.6% w/w* : Initial: Homogeneous slightly cloudy liquid 2y: Homogeneous slightly cloudy liquid **DEPTACID CB :** *Packaging in HDPE :* No deviation *Weight loss : 9.2g* *Octanoic acid content (AL218)*: Initial: 9.98% w/w 2y:10.02%w/w *Appearance* : Initial: Clear slightly yellow liquid 2y: Clear slightly yellow liquid *Odour :* Initial: characteristic 2y: characteristic	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH neat : Initial: 2.7 2y: 3.0 *Acidity* expressed in %w/w H_2SO_4 Initial: 11.14 2y: 12.24 *Density :* Initial: 1.059 g/cm^3 2y: 1.061 g/cm^3 *Viscosity 20°C (12 rpm)* : Initial: 30.8 mPa.s *2y:* 32.2mPa.s *Viscosity 40°C (12 rpm)* : Initial: 18.6 mPa.s 2y: 20.2 mPa.s *pH 1% (w/w)* : Initial: 3.0 2y: 3.1 *Persistent foaming after 1 min at 0.6% w/w (at 20°C)* : Initial: 45mL 2y: 18mL *Stability of the dilution at 0.6% w/w* : Initial: Homogeneous slightly cloudy liquid 2y: Homogeneous slightly cloudy liquid	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 7 days at 0°C	HYPRACID ONE (3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	All products of the family are considered as stable with no separated material after 7 days of storage at 0°C.	Section 3.4 in IUCLID Connan O. (2015) Doc 3.4.1-002.1 Doc 3.4.1-002.2 Doc 3.4.1-002.3 Caillet G. (2015) Doc 3.4.1-002.4 Doc 3.4.1-002.5

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
eCA remark on storage stability All products within the family were tested with regard to stability in HDPE for 2 years at 20°C. All products proved stable, both physically and chemically; no separation was reported in any of the studies. All four meta SPCs have shelf-lives of 24 months at ambient temperature. The accelerated storage stability data was generated at 40°C. Therefore, storage conditions should be limited to storage up to 40°C All low temperature stability studies were performed for 7 days at 0°C, by visual examination. No separation was reported in any of the studies. Therefore, the products are considered stable at low temperatures. The effects of light were not tested. The applicant has indicated that only opaque packaging is used. In addition, sensitiveness to light is not expected considering the active substance is not sensitive to photolysis. The eCA does not consider storage restrictions to be necessary, apart from the maximum storage temperature of 40°C. Substances of concern (SoCs) were not monitored in the storage stability trials as their concentration is not expected to change during storage. Breakdown or formation of SoCs is not expected to occur.				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Data waived : The effect of light is not relevant because products are stored in opaque packaging, so the products are not in contact with light. Octanoic is also not sensitive to photolysis.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Data waived : The effect of temperature is included in the storage stability studies. The humidity was not specifically addressed as all products are aqueous.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Accelerated and long term storage stability tests are conducted in 5L HDPE jerrycans. No change of the packaging (weight, appearance) was observed.	-
Wettability	-	-	Data waived : Not applicable because HYPRED's octanoic acid based	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			products are liquid products	
Suspensibility, spontaneity and dispersion stability	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not suspensions.	-
Wet sieve analysis and dry sieve test	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are liquid products	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are SL formulations.	-
Disintegration time	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are liquid products	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are liquid products *Spray droplet size:* The MMAD is not necessary for the tox/efficacy RA and the products are not sold together with a trigger sprayer or other spraying equipment. The MMAD therefore does not need to be determined.	-
Persistent foaming	CIPAC MT 47.2	HYPRACID ONE: (3% octanoic acid) DEPTACID BD : (3% octanoic acid) DEPTACID WCM: (3% octanoic acid) DEPTACID CCB : (10% octanoic acid) DEPTACID CB : (10% octanoic	In none of the tests, more than 60 mL foam persisted after 1 minute. At 40°C and 70°C, no foam (=0 ml) persisted after 1 minute for HYPRACID ONE and DEPTACID BD at	Section 3.5 in IUCLID Connan O. (2015) Doc 3.5-001 Doc 3.5-002 Doc 3.5-003 Caillet G. (2015) Doc 3.5-004 Doc 3.5-005

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		acid)	0.75% and 1.5% v/v At 40°C and 50°C, no more than 5 ml foam persisted after 1 minute for DEPTACID WCM at 0.5% and 1% v/v"	
eCA remark An abundant set of foaming data was provided for each product in the family. In addition to the results reported above, all shelf-life studies included foaming data at various concentrations and temperatures. The results indicate that by increasing the temperature, foaming is reduced. None of the products produced persistent foam exceeding 60mL after 1 minute.				
Flowability/Pourability/ Dustability	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are liquid products	-
Burning rate — smoke generators	-	-	Data waived : Not applicable data.	-
Burning completeness — smoke generators	-	-	Data waived : Not applicable data.	-
Composition of smoke — smoke generators	-	-	Data waived : Not applicable data.	-
Spraying pattern — aerosols	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not aerosols.	-
Physical compatibility	-	-	Data waived : Not relevant because HYPRED's octanoic acid based products are not co-applied with other substances, mixtures or products	-
Chemical compatibility	-	-	Data waived : Not relevant because HYPRED's octanoic acid based products are not co-applied with other substances, mixtures or products	-
Degree of dissolution and dilution stability	CIPAC MT 41	HYPRACID ONE: (3% octanoic acid) DEPTACID BD : (3% octanoic acid) DEPTACID WCM: (3% octanoic acid) DEPTACID CCB :	All products of the family diluted at their concentration of use : HYPRACID ONE: 1.5% v/v DEPTACID BD :	Section 3.5 in IUCLID Connan O. (2015) Doc 3.5-006 Doc 3.5-007

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(10% octanoic acid) DEPTACID CB : (10% octanoic acid)	1.5% v/v DEPTACID WCM: 1.0% v/v DEPTACID CCB : 0.6% v/v DEPTACID CB : 0.6% v/v in standard water C give stable solutions with no separated material for 18 hours at 20°C +/- 0.2°C.	Doc 3.5-008 Caillet G. (2015) Doc 3.5-009 Doc 3.5-010
eCA remark In addition to the data included above, all storage stability studies included dilution stability data. Each product in the family was tested and no separation was observed in any of the studies.				
Surface tension	OECD 115	HYPRACID ONE: (3% octanoic acid) DEPTACID BD : (3% octanoic acid) DEPTACID WCM: (3% octanoic acid) DEPTACID CCB : (10% octanoic acid) DEPTACID CB : (10% octanoic acid)	The mean surface tension of the products of the family are : HYPRACID ONE (1.5% v/v) : 29.1 mN/m ± 0.1 mN/m at 20.0 °C DEPTACID BD (1.5% v/v) : 29.1 mN/m ± 0.1 mN/m at 20.0 °C DEPTACID WCM (1.0% v/v): 28.9 mN/m ± 0.2 mN/m at 20.0 °C DEPTACID CCB (0.6% v/v) : 29.7 mN/m ± 0.2 mN/m at 20.0 °C DEPTACID CB (0.6% v/v) : 27.1 mN/m ± 0.1 mN/m at 19.9 °C HYPRED's octanoic acid based products were considered as surface-active.	Section 3.8 in IUCLID Demangel. B (2015) Doc 3.8-001 Doc 3.8-002 Doc 3.8-003 Doc 3.8-004 Doc 3.8-005
eCA remark The surface tension of all products in the family indicates the products are surface active at their proposed in-use concentrations, with a surface tension of approximately up to 30mN/m at 20°C. As the products do not contain aliphatic hydrocarbons, no data on the undiluted products is considered required.				
Viscosity	OECD114	HYPRACID ONE	The mean dynamic	Section 3.9 in

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(3% octanoic acid) DEPTACID BD (3% octanoic acid) DEPTACID WCM (3% octanoic acid) DEPTACID CCB (10% octanoic acid) DEPTACID CB (10% octanoic acid)	viscosity of the products of the family are : HYPRACID ONE : 5.56 mPa.s at 20.0 °C ± 0.2 °C and 3.42 mPa.s at 40.0 °C ± 0.2 °C DEPTACID BD : 5.56 mPa.s at 20.0 °C ± 0.2 °C and 3.42 mPa.s at 40.0 °C ± 0.2 °C DEPTACID WCM : 5.61 mPa.s at 20.0 °C ± 0.2 °C and 3.43 mPa.s at 40.0 °C ± 0.2 °C DEPTACID CCB : 25.7 mPa.s at 20.0 °C ± 0.2 °C and 13.0 mPa.s at 40.0 °C ± 0.2 °C DEPTACID CB : 31.3 mPa.s at 20.0 °C ± 0.2 °C and 14.3 mPa.s at 40.0 °C ± 0.2 °C Taking into account the results obtained at 20.0 °C and 40.0 °C, the products were considered to have Newtonian properties in the experimental conditions used.	IUCLID Demangel. B (2015) Doc 3.9-001 Doc 3.9-002 Doc 3.9-003 Doc 3.9-004 Doc 3.9-005
eCA remark The products within the family are not specifically thickened as this is not required from a use nor stability perspective. The data provided is considered sufficient. The viscosity was largely independent of shear rates applied. Shear rate was reported in the studies and was varied from approximately 20 s^{-1} to 120 s^{-1}, using a rotary viscometer.				

Conclusion on the physical and chemical properties

All products within the family are colourless to slightly yellow liquids to be diluted with water prior to use. All products have a low pH of approximately 1, with the exception of DEPTACID CB, the representative product for meta SPC 3 (pH in the range 2 – 3). The

density of the octanoic acid products is within the range of approximately 1.0 to 1.1 g/cm^3.

All products within the family were tested for stability during 8 weeks at 40°C in HDPE, 2 years in HDPE at ambient temperatures and for 7 days at 0°C. All products were physically and chemically stable. Considering the highest temperature tested was 40°C, the storage conditions include restrictions to not store the product at temperatures above 40°C.

Viscosity, surface tension are available, showing products are not viscous, but are surface active at the in-use concentration. Foaming and dilution data show the products can be adequately applied according to the use instructions.

2.1.16. Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	Not explosive HYPRED's octanoic acid based products don't contain substances classified as explosive.	-
eCA remark The product does not contain significant amounts of compounds with the functional groups associated with explosive properties. Applying the criteria of the screening procedures as described in the UN manual of tests and criteria (rev. 6), appendix 6, the product does not need to be considered for explosive properties.				
Flammable gases	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not gases.	-
Flammable aerosols	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not aerosols.	-
Oxidising gases	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not gases	-
Gases under pressure	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not gases	-
Flammable liquids	-	-	Not flammable because HYPRED's octanoic acid based products don't contain	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			substances classified as flammable.	
eCA remark Judging the high content of water and the flashpoints of the main constituents (FP >100 for octanoic acid and the substances of concern methyl sulfonic acid and lactic acid), the flashpoint of the mixture will be >> 60°C.				
Flammable solids	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not solids	-
Self-reactive substances and mixtures	-	-	Not classified because HYPRED's octanoic acid based products are not self-reactive mixtures	-
Pyrophoric liquids	-	-	Not classified None of the components of the formulation are self-heating or pyrophoric.	-
Pyrophoric solids	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not solids	-
Self-heating substances and mixtures	-	-	Not classified None of the components of the formulation are self-heating or pyrophoric.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not mixtures which in contact with	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			water emit flammable gases.	
Oxidising liquids	-	-	HYPRED's octanoic acid based products don't contain substances classified as oxidizing.	-
eCA remark The product does not contain significant amounts of compounds with the functional groups associated with oxidising properties. Applying the criteria of the screening procedures as described in the UN manual of tests and criteria (rev. 6), appendix 6, the product does not need to be considered for classification as oxidising liquid.				
Oxidising solids	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not solids	-
Organic peroxides	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not organic peroxides.	-
Corrosive to metals	-	-	The products HYPRACID ONE, DEPTACID BD, DEPTACID WCM and DEPTACID CCB contains a substance classified as corrosive to metals in quantities higher than 14%, so we considered that the products HYPRACID ONE, DEPTACID BD, DEPTACID WCM and DEPTACID CCB	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			are classified as corrosive to metals. DEPTACID CB doesn't contain substances classified as corrosive to metals and its pH is approximately 3, so DEPTACID CB is not expected to be corrosive to metals.	
eCA remark No tests on corrosiveness to metals are available. All products within the family are classified as corrosive (H314). According to the UN test C.1. for corrosiveness to metals, it may be expected that mixtures classified as corrosive (H314) may be expected to be corrosive to metals as well. Therefore, the eCA accepts no studies were provided and that all products within the family are classified as metal corrosive category 1 (H290).				
Auto-ignition temperatures of products (liquids and gases)	-	-	Not classified because HYPRED's octanoic acid based products are not ignited with a hot surface.	-
eCA remark Due to the flash points and the auto-ignition temperatures of the compounds present in the biocidal products and their high content of water, an auto-ignition temperature of >400°C is expected. It is therefore considered acceptable no auto-ignition temperature study is available.				
Relative self-ignition temperature for solids	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are not solids	-
Dust explosion hazard	-	-	Data waived : Not applicable because HYPRED's octanoic acid based products are liquid.	-

eCA conclusion on classification and labelling related to physical and chemical hazards

With regard to physical and chemical hazards, all Meta SPCs need to be classified as corrosive to metals (H290), based on their classification as corrosive (H314).

Although there is no experimental data, based on the properties of the individual components, the products within the family are not expected to be explosive, oxidising, flammable or self-heating.

2.1.17. Methods for detection and identification

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		
Active substance : octanoic acid	HPLC-UV at 215nm method Hypred's method AL 218	DEPTACID BD, n=5 DEPTACID CCB, n=5	Range: 20.8 – 521.1 mg/L n=5 r^2 = 1.0000 Slope 2862.0 Interc. -3189.4	No inter-ference	98.1-100.8 99.1-99.5	98.8 99.3	1.16 0.13	N/A	Ladril.S, 2015 Doc 5-001 Doc 5-003
Active substance : octanoic acid after hydrolysis	HPLC-UV at 215nm method Hypred's method AL 219	DEPTACID BD, n=5 DEPTACID CCB, n=5	Range: 21.1 – 263.8 mg/L n=5 r^2 = 0.9999 Slope 2915.4 Interc. -6240.8	No inter-ference	98.9 - 101.7 98.4-102.8	100.8 99.7	1.19 1.83	N/A	Ladril.S, 2014 Doc 5-002 Doc 5-004
Analaytical methods for substances of concern No methods were provided or considered necessary considering the substances of concern cannot be formed during storage. Their concentrations are expected to remain stable.									

eCA remark

The applicant has provided two methods, one of which includes an alkaline hydrolysis step to free any esterified octanoic acid and/or lactic acid (method AL 219). The hydrolysis step was not specifically validated. The method is supplementary.

The accuracy included 5 individual experiments, allowing a conclusion to be drawn on repeatability. For the accuracy, a product was formulated with an accurately weighed amount of active substance, which is a comparable approach to spiking a blank product sample. The active substance concentration was approximately 3%.
In addition to the recovery experiments, precision was determined at 5 concentrations with 5 samples each. The %RSD < RSDr (Horwitz criterion).

The method used for analysis of the formulation in the shelf-life data is the one without hydrolysis step (method AL 218). Both methods (AL 218 and AL 219) were validated using two products. It should be noted that the composition of DEPTACID CCB used in the validation study is not the same as included in this application (see confidential annex for

details). The methods are however considered sufficiently validated to accurately determine the active substance content in all products in the family.

Method AL 218
An aliquot of test item is taken, depending on the expected octanoic acid content.

Conditions: HPLC-UV (215nm) with RP C18 column (250x4mm, 5µm film). Isocratic elution: 60/40 water/acetonitrile and 0.04% TFA.

Method AL 219
An aliquot of test item is transferred to a 10mL beaker, depending on the expected octanoic acid content. 2M NaOH is added (1% of the final volume). The solution is warmed to 80°C for 20 minutes, cooled down and transferred to a volumetric 10mL flask, which is then filled to the mark with mobile phase.

Conditions: HPLC-UV (215nm) with RP C18 column (250x4mm, 5µm film). Isocratic elution: 60/40 water/acetonitrile and 0.04% TFA.

Analytical methods for monitoring
Monitoring of the active substance Octanoic acid is not necessary owing to its properties: see statements concerning analytical methods for soil, air, water, animal and human body fluids and tissues. Components of biocidal products classified as toxic or very toxic are considered to be toxicologically relevant components which must be analysed for monitoring purposes if human exposure cannot be excluded (according to: Guidance on the Biocidal Products Regulation, Volume I: Identity/physico-chemical properties/analytical methodology – Part A: Information requirements). Hypred's Octanoic acid based products do not contain toxic or very toxic substances. Therefore, analytical methods for monitoring are not necessary.

Analytical methods for soil
Argumentation adopted from the Assessment repot on Octanoic acid: *Due to the natural occurrence of Octanoic acid in the environment and its rapid metabolism and degradation in soil an analytical method for active substance for the determination of residues in soil is not required.*

Analytical methods for air
An analytical method for air was waived in the Assessment report. *The applicant also regards an analytical method for air as not necessary since, according to the evaluation in the assessment report, accumulation of Octanoic in air is not expected. Furthermore, the products are not applied by spraying but in closed systems (CIP installations).*

Analytical methods for water
Reference is made to the analytical method for Octanoic acid in water submitted with the active substance dossier.

Analytical methods for animal and human body fluids and tissues
Argumentation adopted from the Assessment repot on Octanoic acid: *Since Octanoic acid is not classified as toxic or very toxic, analytical methods for the detection and identification of residues in animal and human body fluids and tissues are not required.*

Analytical methods for monitoring of active substances and residues in food and feeding stuff
No relevant residues of Octanoic or any of the co-formulants can occur due to the intended uses.

2.1.18. Efficacy against target organisms

A. FUNCTION AND FIELD OF USE

Function :

All products of the family are bactericidal and yeasticidal.

Field of use :

PT4 : Food and feed area disinfectants

All products of the family are concentrated liquids intended to be used by professional users.

The field of use of each *meta* SPC of the family is detailed below:

- *meta* SPC 1:
  - Cleaning and disinfecting circuits in dairy industry
  - Cleaning and disinfecting milking equipment and milking robots in farms
- *meta* SPC 2: Disinfecting circuits in breweries, dairy and beverage industries
- *meta* SPC 3: Disinfecting circuits in breweries, dairy and beverage industries
- *meta SPC 4* : Disinfecting or combined cleaning and disinfecting for membranes used in reverse osmosis and nanofiltration in dairy and beverage industries.

B. ORGANISMS TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED

Organisms to be controlled :

Bacteria

Yeast

Objects to be protected :

Circuits, equipment, membranes in membrane separation processes, milking machines.

C. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

Octanoic acid in all the products of the family is used to kill harmful microorganisms (bacteria, yeast).

D. MODE OF ACTION, INCLUDING TIME DELAY

The mode of action of octanoic acid is the following :

Octanoic acid exerts its antimicrobial action by disrupting the cell membrane and inhibiting various metabolic pathways.

E. 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**
Bactericide	*Cleaning and disinfecting milking equipment and milking robot in farms*	*HYPRACID ONE (meta SPC 1)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN1276	Interfering substance : 1% skimmed milk Contact time: 10 minutes Temperature : 40°C Tested concentrations : 0,1 - 0,7 - 0,8 - 0,9 – 1 %v/v	HYPRACID ONE is bactericidal at 0.8%	AF.Gabillet Doc 6.7-001.1
Yeasticide	*Cleaning and disinfecting milking equipment and milking robot in farms*	*HYPRACID ONE (meta SPC 1)*	*Candida albicans*	EN1650	Interfering substance : 1% skimmed milk Contact time: 15 minutes Temperature : 40°C Tested concentrations : 0.5 - 0.75 – 1 - 1,5 and 2%%v/v	HYPRACID ONE is yeasticidal at 1.5%	AF.Gabillet Doc 6.7-001.2
Bactericide	*Cleaning and disinfecting circuits in dairy industry*	*DEPTACID BD (meta SPC 1)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN1276	Interfering substance : 1% skimmed milk Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0.5 - 0.75 – 1 – 1.5 - 2 %v/v	DEPTACID BD is bactericidal at 1%	AF.Gabillet Doc 6.7-002.2
Yeasticide	*Cleaning and disinfecting circuits in dairy industry*	*DEPTACID BD (meta SPC 1)*	*Candida albicans*	EN1650	Interfering substance : 1% skimmed milk Contact time: 15 minutes Temperature : 40°C Tested	*DEPTACID BD* is yeasticidal at 1.5%	AF.Gabillet Doc 6.7-002.4

					concentrations : 0.5 - 0.75 – 1 – 1.5 - 2 %v/v		
Bactericide	*Cleaning and disinfecting circuits in dairy industry*	*DEPTACID BD (meta SPC 1)*	*Enterococcus faecium*	EN1276	Interfering substance : 10 g/L skimmed milk Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0,01 - 0,5 - 1 – 1.5 %v/v	DEPTACID BD is bactericidal at 0.5%	A.Carre Doc 6.7-002.5
Bactericide	*Cleaning and disinfecting separative membrane in dairy and beverage industries*	*DEPTACID WCM (meta SPC 4)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN1276	Interfering substance : 3 g/l bovin albumin Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0,5 - 0,75 – 1 – 1.5 - 2 %v/v	DEPTACID WCM is bactericidal at 0.5%	AF.Gabillet Doc 6.7-003.1
Bactericide	*Cleaning and disinfecting separative membrane in dairy industry*	*DEPTACID WCM (meta SPC 4)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN1276	Interfering substance : 1% skimmed milk Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0,5 - 0,75 – 1 – 1.5 - 2 %v/v	DEPTACID WCM is bactericidal at 1%	M. Teulier Doc 6.7-003.2
Bactericide	*Cleaning and disinfecting separative membrane in beverage industry*	*DEPTACID WCM (meta SPC 4)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN1276	Interfering substance : 1% sucrose Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0,5 - 0,75 – 1 – 1.5 - 2 %v/v	DEPTACID WCM is bactericidal at 0.75%	AF.Gabillet Doc 6.7-003.3
Bactericide	*Disinfecting separative membran*	*DEPTACID WCM (meta SPC 4)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas*	EN1276	Interfering substance : 0.3 g/l bovin albumin Contact time:	DEPTACID WCM is bactericidal at 0.75%	M. Teulier Doc 6.7-003.4

	e in dairy and beverage industries		*aeruginosa, Enterococcus hirae*		5 minutes Temperature : 40°C Tested concentrations : 0.2 – 0.3 – 0.4 - 0,5 - 0,75 %v/v		
Yeasticide	*Cleaning and disinfecting separative membrane in dairy and beverage industries*	*DEPTACID WCM (meta SPC 4)*	*Candida albicans*	EN1650	Interfering substance : 3 g/l bovin albumin Contact time: 15 minutes Temperature : 40°C Tested concentrations : 0,5 - 0,75 – 1 – 1.5 - 2 %v/v	*DEPTACID WCM* is yeasticidal at 0.75%	AF.Gabillet Doc 6.7-003.5
Yeasticide	*Cleaning and disinfecting separative membrane in dairy industry*	*DEPTACID WCM (meta SPC 4)*	*Candida albicans*	EN1650	Interfering substance : 1% skimmed milk Contact time: 15 minutes Temperature : 40°C Tested concentrations : 0,5 - 0,75 – 1 – 1.5 - 2 %v/v	*DEPTACID WCM* is yeasticidal at 1%	AF.Gabillet Doc 6.7-003.6
Yeasticide	*Cleaning and disinfecting separative membrane in beverage industry*	*DEPTACID WCM (meta SPC 4)*	*Candida albicans*	EN1650	Interfering substance : 1% sucrose Contact time: 15 minutes Temperature : 40°C Tested concentrations : 0,5 - 0,75 – 1 – 1.5 - 2 %v/v	*DEPTACID WCM* is yeasticidal at 1%	AF.Gabillet Doc 6.7-003.7
Yeasticide	*Disinfecting separative membrane in dairy and beverage industries*	*DEPTACID WCM (meta SPC 4)*	*Candida albicans*	EN1650	Interfering substance : 0.3 g/l bovin albumin Contact time: 15 minutes Temperature : 40°C Tested concentrations : 0.3 – 0.4 - 0,5 - 0,75 – 1 %v/v	*DEPTACID WCM* is yeasticidal at 0.75%	AF.Gabillet Doc 6.7-003.8
Bactericide	*Cleaning*	*DEPTACID*	*Enterococcus*	EN1276	Interfering	DEPTACID	A. Carre

	and disinfecting separative membrane in dairy industry	*WCM (meta SPC 4)*	*faecium*		substance : 10 g/L skimmed milk Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0,01 - 0,5 - 1 – 1.5 %v/v	WCM is bactericidal at 0.5%	Doc 6.7-003.9
Bactericide	*Disinfecting circuits in dairy, beverage and breweries industries*	*DEPTACID CCB (meta SPC 2)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN1276	Interfering substance : 0.3 g/l bovin albumin Contact time: 5 minutes Temperature : 20°C Tested concentrations : 0.3 – 0.4 - 0,5 - 0,6 - 1 %v/v	DEPTACID CCB is bactericidal at 0.4%	M. Teulier Doc 6.7-004.1
Yeasticide	*Disinfecting circuits in dairy, beverage and breweries industries*	*DEPTACID CCB (meta SPC 2)*	*Candida albicans*	EN1650	Interfering substance : 0.3 g/l bovin albumin Contact time: 15 minutes Temperature : 20°C Tested concentrations : 0.3 – 0.4 - 0,5 - 0,6 - 1 %v/v	*DEPTACID CCB* is yeasticidal at 0.6%	AF.Gabillet Doc 6.7-004.2
Bactericide	*Disinfecting circuits in dairy, beverage and breweries industries*	*DEPTACID CCB (meta SPC 2)*	*Enterococcus faecium*	EN1276	Interfering substance : 0.3 g/l bovin albumin Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0.01 - 0.2 – 0.4 – 0.6 %v/v	DEPTACID CCB is bactericidal at 0.2%	A. Carre Doc 6.7-004.3
Yeasticidal	*Disinfecting circuits in breweries industries*	*DEPTACID CCB (meta SPC 2)*	*Saccharomyces cerevisiae*	EN1650 +A1 (2013)	Interfering substance : 0.3 g/l bovin albumin Contact time: 15 minutes Temperature: 20°C Tested	DEPTACID CCB is yeasticidal at 0.6% v/v	2019-04-16 5480 Yeasticidal efficacy EN1650 DEPTACID CCB S.cerevisae EM

					concentrations: 0.01 – 0.6 – 0.7 – 0.8 - 1.0% v/v		
Bactericide	*Disinfecting circuits in dairy, beverage and breweries industries*	*DEPTACID CB (meta SPC 3)*	*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN1276	Interfering substance : 0.3 g/l bovin albumin Contact time: 5 minutes Temperature : 20°C Tested concentrations : 0.3 – 0.4 - 0,5 – 1 - 2 %v/v	DEPTACID CB is bactericidal at 0.4%	M. Teulier Doc 6.7-005.1
Yeasticide	*Disinfecting circuits in dairy, beverage and breweries industries*	*DEPTACID CB (meta SPC 3)*	*Candida albicans*	EN1650	Interfering substance : 0.3 g/l bovin albumin Contact time: 15 minutes Temperature : 20°C Tested concentrations : 0.3 – 0.4 - 0,5 - 0,6 - 1 %v/v	*DEPTACID CB* is yeasticidal at 0.4%	AF.Gabillet Doc 6.7-005.2
Bactericide	*Disinfecting circuits in dairy, beverage and breweries industries*	*DEPTACID CB (meta SPC 3)*	*Enterococcus faecium*	EN1276	Interfering substance : 0.3 g/l bovin albumin Contact time: 5 minutes Temperature : 40°C Tested concentrations : 0.01 - 0.2 – 0.4 – 0.6 %v/v	DEPTACID CB is bactericidal at 0.4%	A. Carre Doc 6.7-005.3
Yeasticidal	*Disinfecting circuits in breweries industries*	*DEPTACID CB (meta SPC 3)*	*Saccharomyces cerevisiae*	EN1650 +A1 (2013)	Interfering substance : 0.3 g/l bovin albumin Contact time: 15 minutes Temperature: 20°C Tested concentrations: 0.01 – 0.4 – 0.5 – 0.6 - 1.0% v/v	DEPTACID CB is yeasticidal at 0.4% v/v	2019-04-16 5479 Yeasticidal efficacy EN1650 DEPTACID CB S.cerevisae EM

Conclusion on the efficacy of the product

All products of the family are PT 4 concentrated biocidal products, and are effective against bacteria according to EN 1276, and against yeast according to EN 1650.
Products in *meta* SPC 1 are intended to:
1 clean and disinfect circuits in dairy industry
2 clean and disinfect milking equipment and milking robots in farms.

Efficacy of *meta* SPC 1 is demonstrated in suspension tests (EN phase 2 step 1) with HYPRACID ONE and DEPTACID BD. These are both worst-case products, considering efficacy testing for this *meta* SPC. Since all uses are CIP (cleaning in place), suspension tests are sufficient for demonstrating efficacy, and simulated-use tests (EN phase 2 step 2) are not required. Efficacy is demonstrated in suspension tests for the following conditions:
Bactericidal:
0.8% (0.024% AS) in presence of 1% skimmed milk for 10 minutes contact time at 40°C
1.0% (0.030% AS) in presence of 1% skimmed milk for 5 minutes contact time at 40°C
These tests sufficiently demonstrate efficacy against bacteria of products in *meta* SPC 1 under the claimed use conditions:
Use # 1.1 : 1.0% for 5 min
Use # 1.2 : 0.8% for 10 min.

Yeasticidal:
1.5% (0.045% AS) in presence of 1% skimmed milk for 15 minutes contact time at 40°C
These tests sufficiently demonstrate efficacy against yeasts of products in *meta* SPC 1 under the claimed use conditions:
Use # 1.1 : 1.5% for 15 min
Use # 1.2 : 1.5% for 15 min

Products in *meta* SPC 2 are intended to disinfect circuits in breweries, dairy, and beverage industries.
Since use is only CIP (cleaning in place), suspension tests are sufficient for demonstrating efficacy, and simulated-use tests (EN phase 2 step 2) are not required. Efficacy is demonstrated in suspension tests for the following conditions:
Bactericidal :
The representative product, DEPTACID CCB, is bactericidal according to EN1276 when diluted at 0.4% (0.04% AS) in presence of 0.3 g/l bovin albumin for 5 minutes contact time at 20°C.
This test sufficiently demonstrate efficacy against bacteria of products in *meta* SPC 2 under the claimed use conditions:
Use # 2.1 : 0.4% for 5 min

Yeasticidal :
The representative product DEPTACID CCB is yeasticidal (both *C. albicans* and *S. cerevisiae*) according to EN1650 when diluted at 0.6% (0.06% AS) in presence of 0.3 g/l bovin albumin for 15 minutes contact time at 20°C.
This tests sufficiently demonstrate efficacy against yeast of products in *meta* SPC 2 under the claimed use conditions:
Use # 2.1 : 0.6% for 15 min

Products in *meta* SPC 3 are intended to disinfect circuits in breweries, dairy, and beverage industries.
Since use is only CIP (cleaning in place), suspension tests are sufficient for demonstrating

efficacy, and simulated-use tests (EN phase 2 step 2) are not required. Efficacy is demonstrated in suspension tests for the following conditions:
Bactericidal :
The representative product, DEPTACID CB, is bactericidal according to EN1276 when diluted at 0.4% (0.04% AS) in presence of 0.3 g/l bovin albumin for 5 minutes contact time at 20°C.
This test sufficiently demonstrate efficacy against bacteria of products in *meta* SPC 3 under the claimed use conditions:
Use # 3.1 : 0.4% for 5 min
Yeasticidal :
The representative product, DEPTACID CB, is yeasticidal (both *C. albicans* and *S. cerevisiae*) according to EN1650 when diluted at 0.4% (0.04% AS) in presence of 0.3 g/l bovin albumin for 15 minutes contact time at 20°C.
These tests sufficiently demonstrate efficacy against yeast of products in meta SPC 3 under the claimed use conditions:
Use # 3.1 : 0.4% for 15 min

Products in *meta* SPC 4 are intended to disinfect or combined clean and disinfect membranes used in reverse osmosis and nanofiltration in dairy and beverage industries. Since use is only CIP (cleaning in place), suspension tests are sufficient for demonstrating efficacy, and simulated-use tests (EN phase 2 step 2) are not required. Efficacy is demonstrated in suspension tests for the following conditions:

Bactericidal: The representative product, DEPTACID WCM, is bactericidal according to EN1276 at :
0.5% (0.015% AS) in presence of 3 g/l bovin albumin for 5 minutes contact time at 40°C
1.0% (0.030% AS) in presence of 1% skimmed milk for 5 minutes contact time at 40°C
0.75% (0.0225% AS) in presence of 1% sucrose for 5 minutes contact time at 40°C
0.75% (0.0225% AS) in presence of 0.3 g/l bovin albumin for 5 minutes contact time at 40°C
These tests sufficiently demonstrate efficacy against bacteria of products in *meta* SPC 4 under the claimed use conditions:
Use # 4.1 : 1.0% for 5 min (after previous water rinse)
Use # 4.1 : 0.75% for 5 min (after previous cleaning and water rinse)

Yeasticidal: The representative product, DEPTACID WCM, is yeasticidal according to EN1650 at :
0.75% (0.0225% AS) in presence of 3 g/l bovin albumin for 15 minutes contact time at 40°C
1.0% (0.030% AS) in presence of 1% skimmed milk for 15 minutes contact time at 40°C
1.0% (0.030% AS) in presence of 1% sucrose for 15 minutes contact time at 40°C
0.75% (0.0225% AS) in presence of 0.3 g/l bovin albumin for 15 minutes contact time at 40°C
These tests sufficiently demonstrate efficacy against bacteria of products in *meta* SPC 4 under the claimed use conditions:
Use # 4.1 : 1.0% for 15 min (after previous water rinse)
Use # 4.1 : 0.75% for 15 min (after previous cleaning and water rinse)

Reasoning temperature tests Candida albicans.
For products in meta-SPC 1 and meta-SPC 4, Candida albicans have been tested at 40°C (lowest temperature recommended in the instruction for use).

No efficacy test have been conducted on yeast at higher temperature because no resistant temperature yeast are available. 40°C is the maximum temperature for which the test is validated.

For products in meta-SPC 2 and meta-SPC 3, Candida albicans have been tested at 20°C (lowest temperature recommended in the instruction for use).
Efficacy test at 40°C (maximum temperature for which the test is validated) has been considered as not relevant because increase of the temperature have a positive impact on efficacy.
Consequently, the efficient concentration at 40°C will be lower than the efficient concentration at 20°C claimed in the instruction for use.

F. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

Generally, resistance develops under selection pressure in the range of sub lethal biocide concentrations. This concentration range is not reached in use as instructed. The use of the disinfectants contained in the family HYPRED's octanoic acid based products is followed by rinsing with a sufficient quantity of water, leading to a rapid dilution of the active substance to biodegradation level. Consequently, no selective pressure for resistance is given here, either.
The risk of micro-organisms developing resistance to disinfectants of main group 1, which were tested according to international standards, is rated negligibly low in the intended and appropriate use of these products.

G. KNOWN LIMITATIONS

Not relevant.
No limitation of efficacy has been observed following use of octanoic acid based products for the disinfection of equipment, circuits or separative membranes.

H. EVALUATION OF THE LABEL CLAIMS

Label claims of each product including in HYPRED's octanoic acid based products family are presented below. These are examples for the family and acceptable by the e-CA.
For each product, target organisms, contact time and mode of application are described.

DEPTACID BD (*meta* SPC 1, use #1.1)
DEPTACID BD is a bactericidal and yeasticidal detergent disinfectant for circuits in dairy industry.

Rinse the circuits with drinking water before disinfection.
Apply DEPTACID BD by circulation.
Product concentration and contact time :
- 1 % bactericidal in 5 minutes
- 1.5 % yeasticidal in 15 minutes
Temperature :40 - 85 °C
Final rinse with drinking water.

HYPRACID ONE (*meta* SPC 1, use #1.2)
HYPRACID ONE is a bactericide and yeasticide cleaner-disinfectant of milking equipment and milking robots.

Machines with or without a programmer.
1) After milking, rinse the equipment with warm drinking water.
2) Apply the solution by circulation at an initial recommended temperature of 60°C minimum to achieve a final temperature of 40-45°C.
Product concentration and contact time :
- 0.8% bactericidal in 10 minutes
- 1.5% yeasticidal in 15 minutes
Do not use at temperature above 75°C.
3) Rinse with cold drinking water.

Use the product twice a day or once a day when alternating with another product.
When alternating, use a cleaner-disinfectant or a cleaning product 1 to 4 times per week depending on the temperature reached in the system.
Contact your supplier for choosing the alternative product and the frequency of use.

Do not mix HYPRACID ONE with an alkaline or chlorinated alkaline product.

DEPTACID WCM (*meta* SPC 4, use #4.1)
DEPTACID WCM is a bactericidal and yeasticidal product used for disinfection or combined cleaning and disinfection of membranes used in reverse osmosis and nanofiltration in dairy and beverage industries.

Rinse the membranes with drinking water or clean and rinse with drinking water before disinfection.
Apply DEPTACID WCM by circulation.

Product concentration after water rinse: 1 %
Product concentration with previous cleaning: 0.75 %

Contact time :
- 5 minutes for bactericidal activity
- 15 minutes for yeasticidal activity

Temperature : 40 - 85 °C
Final rinse with drinking water.

DEPTACID CCB (*meta* SPC 2, use #2.1)
DEPTACID CCB is a bactericidal and yeasticidal disinfectant for circuits in breweries, dairy and beverage industries.

Prior to the application of the product, clean with a detergent and rinse with drinking water.

Apply DEPTACID CCB by circulation.
Product concentration and contact time:
- 0.4 % bactericidal in 5 minutes
- 0.6 % yeasticidal in 15 minutes

Temperature : 20-85 °C
Final rinse with drinking water.

DEPTACID CB (*meta* SPC 3, use #3.1)
DEPTACID CB is a bactericidal and yeasticidal disinfectant for circuits in breweries, dairy and beverage industries.

Prior to the application of the product, clean with a detergent and rinse with drinking water.

Apply DEPTACID CB by circulation.
Product concentration : 0.4 %
Contact time :
- 5 minutes for bactericidal activity
- 15 minutes for yeasticidal activity

Temperature : 20-85 °C
Final rinse with drinking water.

Differentiation of target organisms by contact time and dosage

In food industries, microbiological hazards are represented mainly by bacteria. It also exists hazards associated to virus and parasites.(See Tables 1, 2, 3 and 4 in Annex to the PAR).

No yeast is considered among the main health hazards. Only a few species are considered opportunistic pathogens for humans and animals and no strain has been at this time identified as causing food-borne diseases. Yeast activity is however considered as a basic requirement for efficacy of PT4 products because some yeasts can cause in some processes manufacturing defects or organoleptic alterations of food.

In the context of good practices and control of food safety, it is essential that each professional user of disinfecting products identifies first the nature of microbiological hazards linked to food process before applying a biocidal product.

In case of hazards directly linked to the presence of yeasts, protocols (dose and contact time) should be adapted in order to reduce this hazard but without applying a daily overdosage on food production plant if only bactericidal activity is required.

It is therefore important for HYPRED's octanoic acid based products that the differentiation of the activity for each separated target organism by dosage and contact time appears into the instructions for use in order to answer properly to hazards occurring in food production process and in order to respect health and environment.

More extensive justification differenti

More extensive justification: (See Appendix I)

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

HYPRED's octanoic acid based products are not intended to be used with other biocidal products.
As stated in the instruction for use #1.2, the products in *meta* SPC1 can be use in alternate with another product:

"Use the product twice a day or once a day when alternating with another product.
When alternating, use a cleaner-disinfectant or a cleaning product 1 to 4 times per week depending on the temperature reached in the system.
Contact your supplier for choosing the alternative product and the frequency of use."

2.1.20. Risk assessment for human health

A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

Skin corrosion and irritation

In vitro skin corrosion studies according to OECD 435 are provided for DEPTACID BD (*meta*SPC 1) and DEPTACID CCB (*meta*SPC2).

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 435, GLP, Reliability 1	DEPTACID BD (3% octanoic acid), 500 µL	In Vitro Membrane Barrier Test Method for Skin Corrosion	The test item disrupted the membrane after 10 minutes and 16 seconds (Corrosive, optional sub-category 1B)	-	F.Floriot (2017) Doc 8.1.1-001
OECD 435, GLP, Reliability 1	DEPTACID CCB (10% octanoic acid), 500 µL	In Vitro Membrane Barrier Test Method for Skin Corrosion	The test item disrupted the membrane after 09 minutes and 05 seconds (Corrosive, optional sub-category 1B)	-	F.Floriot (2017) Doc 8.1.1-002

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Corrosive to skin
Justification for the value/conclusion	*Meta* SPC 1: The pH of products in *meta*SPC is <1. *meta* SPC 1 is classified as skin corr. Cat.1B based on the in vitro test (OECD 435). The tested mixture DEPTACID BD is identical to the composition of *meta* SPC 1 (no range flexibility in the *meta*SPC). *Meta* SPC 2: The pH of products in *meta* SPC is <1. *meta* SPC 2 is classified as skin corr. Cat.1B based on the in vitro test (OECD 435). The tested mixture DEPTACID CCB is identical to the composition of *meta* SPC 2 (no range flexibility in the metaSPC). *Meta* SPC 3: The pH of products in *meta* SPC is >2. Individual components are taking into account in the meta SPC due to lack of mixture specific information and CLP calculation rules can then be applied. The *meta* SPC 3 contains more than 5 % of a substance classified as skin corrosive category 1C. Based on the calculation method *meta* SPC 3 is categorised to be skin corr. Cat 1C. *Meta* SPC 4 : The pH of the *meta* SPC is <1. *meta* SPC 4 is classified as skin corr. Cat.1B based on the two in vitro studies performed for DEPTACID BD and DEPTACID CCB. The concentration of acid and formulants with H314 of *meta* SPC 4 fall

	in the range between the two products tested (see table 3.8.1 Confidential Annex for the composition comparison).
Classification of the product according to CLP	Skin Corr 1B (*meta* SPC 1, *meta* SPC 2 and *meta* SPC 4) and Skin Corr 1C (*meta* SPC 3) :H314

Data waiving (*meta* SPC 3)	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	The composition and toxicological information on each formulants in *meta* SPC 3 is sufficiently known. The calculation method according to the CLP regulation can be applied for the classification purpose.

Eye irritation

No study on eye corrosion and irritation is provided for HYPRED's octanoic acid based products.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Corrosive to eyes
Justification for the value/conclusion	H314 was already assigned to HYPRED's octanoic acid based products.
Classification of the product according to CLP	Eye Dam 1 : H318

Data waiving	
Information requirement	8.2. Eye irritation
Justification	There are valid data available on each of the components sufficient to classify HYPRED's octanoic acid based products according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and synergistic effects between any of the components are not expected. According to the Table 3.3.3 Annex I, Part 3 of the Regulation 1272/2008/EC, HYPRED's octanoic acid based products are classified as Eye Damage category 1 as they are classified skin corrosive category 1 (see above for the justification).

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	*Meta* SPC 1 and 4 : H335 May cause respiratory irritation *Meta* SPC 2 and 3: no classification
Classification of the product according to CLP and DSD	*Meta* SPC 1 and 4 contain a co-formulant with H335 (STOT SE 3 (inhalation)) with concentration higher than the general concentration limit of 20%.

Data waiving	
Information requirement	Annex III of BPR (Regulation (EU) 528/2012), point 8.7.1, "other endpoints"
Justification	The composition and toxicological information on each formulants in the BPF is sufficiently known. The calculation method according to the CLP regulation can be applied for the classification purpose.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising
Justification for the value/conclusion	HYPRED's octanoic acid based products don't contain a component classified as skin sensitizer.
Classification of the product according to CLP and DSD	No classification

Data waiving	
Information requirement	8.3. Skin sensitisation
Justification	HYPRED's octanoic acid based products don't contain a component classified as skin sensitizer.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitising
Justification for the value/conclusion	HYPRED's octanoic acid based products don't contain a component classified as skin or respiratory sensitizer
Classification of the product according to CLP and DSD	No classification

Data waiving	
Information requirement	8.4 Respiratory sensitisation
Justification	HYPRED's octanoic acid based products don't contain a component

	classified as respiratory sensitizer.

Acute toxicity

Acute toxicity by oral route

No study on acute toxicity by oral route is provided for HYPRED's octanoic acid based products.

There are valid data available on each of the components sufficient to classify HYPRED's octanoic acid based products according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

According to the Regulation 1272/2008/EC, the Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for Oral Toxicity:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where:
Ci = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE oral of *meta* SPC 2 is 300 < ATE ≤ 2000 mg/kg bw and therefore *meta* SPC2 is classified as Cat 4, Harmful if swallowed. The SPC 1, 3 and 4 are greater than 2000 mg/kg. So the products in these *meta* SPCs are not classified as fatal, toxic or harmful if swallowed. Please see confidential Annex for the ATE_{oral} calculations.

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE oral of *meta* SPC 2 is 300 < ATE ≤ 2000 mg/kg bw, and of *meta* SPC 1, 3, and 4 are greater than 2000 mg/kg.
Justification for the selected value	Calculation from the ATE values for all relevant ingredients according to the regulation 1272/2008/EC.
Classification of the product according to CLP	*meta* SPC 2: Acute oral toxicity Cat.4 (H302 Harmful if swallowed) *meta* SPC 1, 2 and 4: not classified as fatal, toxic or harmful if swallowed.

Data waiving	
Information requirement	8.5.1. By oral route
Justification	The composition and toxicological information on each formulants in

	the BPF is sufficiently known. The calculation method according to the CLP regulation can be applied for the classification purpose.

Acute toxicity by inhalation

No study on acute toxicity by inhalation is provided for HYPRED's octanoic acid based products.

HYPRED's octanoic acid based products don't contain a component classified for acute toxicity via inhalation.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not relevant
Justification for the selected value	HYPRED's octanoic acid based products don't contain a component classified for acute toxicity via inhalation.
Classification of the product according to CLP	Not classified as fatal, toxic or harmful by inhalation according to CLP.

Data waiving	
Information requirement	8.5.2. By inhalation
Justification	HYPRED's octanoic acid based products don't contain a component classified for acute toxicity via inhalation.

Acute toxicity by dermal route

No study on acute toxicity by dermal route is provided for HYPRED's octanoic acid based products.

There are valid data available on each of the components sufficient to classify HYPRED's octanoic acid based products according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

According to the Regulation 1272/2008/EC, the Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for Dermal Toxicity:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where:
Ci = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE dermal of *meta* SPC1-4 are all greater than 2000 mg/kg. So HYPRED's octanoic acid based products are not classified as fatal, toxic or harmful by contact with skin. Please see confidential Annex for the ATE_{dermal} calculations.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE of the *meta* SPCs are all greater than 2000 mg/kg.
Justification for the selected value	Calculation from the ATE values for all relevant ingredients according to the regulation 1272/2008/EC.
Classification of the product according to CLP	Not classified as fatal, toxic or harmful by contact with skin according to CLP.

Data waiving	
Information requirement	8.5.3. By dermal route
Justification	The composition and toxicological information on each formulants in the BPF is sufficiently known. The calculation method according to the CLP regulation can be applied for the classification purpose.

Information on dermal absorption

Data waiving	
Information requirement	8.6 Information on dermal absorption
Justification	For the active substance no dermal absorption value was derived in the assessment report and no such study has been performed for any product of the BPF. Since for the active substance a qualitative risk assessment for local effects is performed, a dermal absorption value is not relevant. For the substances of concern no quantitative full risk assessment is required and therefore, no dermal absorption values need to be determined for them either; the substances of concern are attributed to band A or B according to CA-Nov14-Doc.5.11.

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

The BPF is assigned with the following hazard classifications:
metaSPC 1 – Skin Corr Cat 1B (H314); STOT-SE Cat 3 (H335)
metaSPC 2 – Skin Corr Cat 1B (H314); Acute Tox (oral) cat 4 (H302)
metaSPC 3 - Skin Corr Cat 1C (H314)
metaSPC 4 – Skin Corr Cat 1B (H314); STOT-SE Cat 3 (H335)

According to the note for discussion on substance of concern (CA-Nov-Doc.5.11), the substances of concern of HYPRED's octanoic acid based products enter in Band A due to the classification of H335 and H302 or in Band B due to H314:

- Methanesulphonic acid : Band B (H335 for metaSPC 1 and 4; H302 for metaSPC 2, H314 for all metaSPCs)
- Ethoxylated alcohol : Band A (H302 for metaSPC 2)
- N,N-dimethyl-1-decamine, N-oxide : Band A (H302 for metaSPC 2)
- L(+) lactic acid : Band B (H314 for metaSPC 3)

For SoCs in Band A /B only application of P-statements or qualitative exposure and risk assessment to determine whether P-statements are sufficient are needed.
For none of the co-formulants a SCOEL value is set, or a draft final CAR was available at the time of the submission of this application. Furthermore none of the co-formulants are identified to enhance the effect of the active substance, or included in the candidate list for the substitution. Therefore no SoCs fall in Band C or D and no quantitative risk assessment for SoCs is required for this BPF.

Assessment for endocrine disrupting properties

According to the ED (endocrine disruptor) criteria with respect to humans established in the Comission Delgated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

According to the CAR there is no evidence for endocrine disruption for the active substance octanoic acid. To examine if any of the co-formulants contained in the product may possess ED properties, a screening of co-formulants was performed by the applicant by using the databases listed in the ECHA/EFSA guidance.

None of the co-formulants triggered an alert for potential ED property except for one co-formulant. For this co-formulant, the screening has shown a potency of endocrine activity based on four positive assays (Toxcast and Tox21). However, no alert has been identified in the other databases. Furthermore, this co-formulant has not been retained for US EPA EDSP Tier 1 assessment and results inconsistent between databases. Additional information serach was performed by CA NL for the co-formulant. As no ED related effects were identified in vivo, it was concluded that no further ED assessment was required for the BPF. The more detailed information is found in the Confidential Annex.

Overall, none of the meta SPCs are anticipated to have ED potential.

Available toxicological data relating to a mixture

No toxicological data relating to a mixture that a substance(s) of concern is a component of is provided.

B. 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.r.	Yes[1]	n.r.	n.r.	n.r.	n.r.	n.r.
Dermal	n.r.	Yes[1]	n.r.	n.r.	n.r.	n.r.	n.r.
Oral	n.r.	No[1]	n.r.	n.r.	n.r.	n.r.	n.r.

[1]As realistic worst case dermal and inhalation exposure is assessed in the following. This is in line with the Assessment report where a similar use (also CIP as for Hypred's products) was assessed

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.	Loading by connecting lines	Primary exposure: depending on the coupling system used, dermal and inhalation exposure may occur.	professionals
2.	Loading by pouring from jerry cans	Primary exposure: dermal and inhalation exposure	professionals
3	Rinsing of empty containers, drums, jerry cans	Primary exposure: dermal and inhalation exposure	professionals
4.	Application: pumping product through circuits	No exposure possible: completely closed systems	professionals
5.	Rinsing: pumping water through the installations after use	No exposure possible: completely closed systems	professionals
6.	Maintenance of installations	Primary exposure: dermal and inhalation exposure	professionals

Industrial Exposure

Not relevant. Hypred's octanoic acid based products are only for professional use.

Professional Exposure

Hypred's octanoic acid based products are used by professional users for:

- *meta* SPC 1
  - Use # 1.1: Circulation in dairy industry
  - Use # 1.2: Circulation in farms
- *meta* SPC 2
  - Use # 2.1: Circulation
- *meta* 3
  - Use # 3.1: Circulation
- *meta* SPC 4
  - Use # 4.1: Separative membranes circulation

All above uses are CIP treatments. This means that the cleaning and disinfection process takes places under closed conditions excluding any contact of the operators with the biocidal products. Also rinsing the circuits with water after the application is a closed process which does not lead to exposure; the rinsing water is directly released into the sewer system.

Nevertheless, during loading, i.e. when drums (60, 120, 220L) or containers (640, 2000 L) are connected to the CIP installations by connecting lines, or when the products are manually filled into smaller CIP installation by pouring from 5, 10 and 22 L jerry cans, dermal and inhalation exposure cannot be fully excluded.

The same applies when empty containers, drums and jerry cans are rinsed with water.

Also during exceptional maintenance work, dermal and inhalation exposure cannot be excluded.

For each scenario, the applicant provided a description of the tasks:

Scenario [1]: Loading by connecting lines

Description of Scenario [1]: Loading by connecting lines
Containers or drums filled with the concentrated biocidal product are connected to a suction pump by connecting transfer lines for applications by circulation. The concentrated product is then automatically diluted to the relevant in-use concentration by means of a dosing device. This automated step is considered relevant for packaging units up to 1000 L. Since octanoic acid exerts only local effects, no quantitative risk assessment is needed. A qualitative risk assessment is provided in the respective section 2.3.5 C. "Risk characterization for human health"

Scenario [2]: Loading by pouring from jerry cans

Description of Scenario [2]: Loading by pouring from jerry cans

The biocidal product is poured into the CIP installation by manual pouring from jerry cans (up to 22 litres). Since octanoic acid exerts only local effects, no quantitative risk assessment is needed. A qualitative risk assessment is provided in the respective section in the respective section 2.3.5 C. "Risk characterization for human health".

Scenario [3]: Rinsing of empty containers, drums and jerry cans

Description of Scenario [3]: Rinsing of empty containers, drums and jerry cans
The product which remains in the empty containers, drums and jerry cans after loading is diluted with water. Since octanoic acid exerts only local effects, no quantitative risk assessment is needed. A qualitative risk assessment is provided in the respective section 2.3.5 C. "Risk characterization for human health".

Scenario [4]: Application – pumping product through circuits

Description of Scenario [4]: Application – pumping product through circuits
The biocidal product with the in-use concentration is pumped automatically through the pipework of CIP installations. Since the application, i.e. disinfection of circuits takes place in a closed system, no exposure of the workers is expected.

Scenario [5]: Rinsing – pumping water through the installations after use

Description of Scenario [5]: Rinsing – pumping water through the installations after use
After disinfection, the pipework of CIP is rinsed with water. Since this post-application task takes place under closed conditions, no exposure of the workers is expected.

Scenario [6]: Maintenance of installations

Description of Scenario [6]: Maintenance of installations
Maintenance is expected to take place outside the cleaning and disinfection cycles, thus the installation can be expected to be free of the product when maintenance work is carried out. However, in a worst-case assumption exposure towards the in-use concentration of 0.4% - 1.5% is considered. Since octanoic acid exerts only local effects, no quantitative risk assessment is needed. A qualitative risk assessment is provided in the respective section 2.3.5 C. "Risk characterization for human health".

These exposure scenarios for professional users are listed in the summary table above. For products with octanoic acid qualitative risk assessment based on local effects are preferred due to the nature of the active substnace, according to the CAR for octanoic acid. Furthermore, in the CAR no AELs or AECs were derived due to the lack of data. In addition, none of the SoCs triggered a requirement for quantitative risk assessment. Therefore for this BPF qualitative risk assessment based on local effects is performed for each scenario, and presented in local risk assessment section under *C. Risk Caracterisation for Human Health*.

Non-Professional Exposure

Hypred's octanoic acid based products are only for professional use. Exposure of non-professionals can therefore be excluded.

Secondary Exposure of the General Public Excluding dietary Exposure

Exposure of general public is not foreseen because the Hypred's octanoic acid based products are for professional use in CIP installation.

Dietary exposure

In the Assessment Report on Octanoic acid it is stated that due to the nature of the active substance no quantitative dietary risk assessment was carried out and that the presence of relevant amounts of residues of application solutions in food or feed would not to be expected with proper operation of the CIP systems. This statement is also valid for Hypred's octanoic acid based products: they are also used for CIP applications at similar application rates as the representative product in the Assessment Report.

It needs to be considered that after circulation of the application solution, the CIP installation is emptied and then rinsed with water. Normally a CIP installation of x litres is rinsed twice with x litres of water. Assuming that after emptying the installation, 1% of the treatment solution remains in the pipework which is then diluted with rinsing water by a factor of 100 and that again 1% remains which is diluted in the food or feed processed in the installations, the theoretical concentration of any component of the products in food or feed is 10^4 times lower than in the treatment solution (which itself contains the respective products at only 0.4 to 1.5%). The dilution factor of 100-fold by rinsing has been used in the CAR for CMIT/MIT (PT11, Jan 2015, eCA FR) based on the RMS judgement.

Moreover, this calculation can be supported by the example for food residue calculation from CIP (example 4) from the draft ARTFood guidance on estimating transfer of biocidal active substances into foods – professional uses.

Residue in food is calculated according to the following equation:

Rfood = Ca.s. x DSsurface x (Ainner surface pipe + 2 x Ainner surface cont) x TF x RF ÷ (Vpipe+ 2 x Vinner surface cont)

Where Estimation of residue transfer into food	
Ca.s.	concentration active substance
DSsurface	2 x 10^{-6} L/cm2 (default)
TF	1
RFTier I	1
Pipe system	
Rpipe	5 cm
Lpipe	2000 cm
Vpipe	Vpipe = Lpipe x $Rpipe^2$ = 2000 cm x 25 cm2 = 50 000 cm3=50 L
Ainner surface pipe	Ainner surface = 2 π Rpipe x Lpipe = 2 π x 5 cm x 2000 cm = 62 832 cm2
Container	
Vcont	900 L
Ainner surface cont	5.94 m2 = 59400 cm2

Using this equation residue of the a.s. in food is calculated to be 1.96x10^{-4} fold lower than in the solution circulated. This calculation results in within the same order of magnitude compared to rinsing twice with a assumed rinsing efficacy of 1%.

Altogether the residues of Octanoic acid in food is considered negligible.

Regarding the substance of concerns, none of the SoCs fall in band C or D for which a full quantitative RA is necessary, therefore no quantitative dietary risk assessment is required.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Information source**	**Short summary**
1.	Plant protection	Commission Directive 2008/127/EC of December 2008 amending Council Directive 91/414/EEC to include several active substances	Octanoic acid was included in Annex I to 91/414/EEC on 1 September 2009 as one of several 'fatty acids C_7 to C_{20}' for uses as insecticide, acaricide and herbicide and plant growth regulator.
		Conclusion on Pesticide Peer Review – Conclusion on the peer review of the pesticide risk assessment of the active substance Fatty acids C7 to C18 (approved under Regulation (EC) No 1107/209 as Fatty acids C7 to C20), EFSA Journal 2013; 11(1):3023	No ADI, AOEL or ARfD were derived for fatty acids. MRL values were not derived.
2.	Food additive	Commission Implementing Regulation (EU) No 872/2012 of October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC	Octanoic acid is listed as flavouring substance for food without restrictions of use.
3.	Feed additive	European Union Register of Feed Additives pursuant to Regulation (EC) No 1831 / 2003; Annex I: List of additives, Edition 214, released 19.08.2015	Octanoic acid is listed under category 2, functional group b as 'natural or corresponding synthetic chemically defined flavouring'
		Scientific opinion on the safety and efficacy of straight-chain primary alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes (chemical group 1) when used as flavourings for all animal species, EFSA Journal 2013; 11(4): 3169	Octanoic acid was considered to be safe for all animal species at the use levels proposed for feed flavouring.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The BPF is used to disinfect drinking water system/membrane and milking equipment, which may lead to the exposure of livestock. However, the exposure is considered negligible with the proper operation of CIP. Please refer to the considerations on dietary exposure above.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Residue in foods is considered negligible. Please refer to the considerations on dietary exposure above.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant since Hypred's octanoic acid based products are only for professional use.

C. RISK CHARACTERISATION FOR HUMAN HEALTH

Due to the nature of the active substance no quantitative AELs were derived for Octanoic acid in the Assessment Report. According to the Assessment Report, the only toxicological concern is the severely irritating property of the medium chain fatty acids, to which Octanoic acid belongs (Assessment Report page 12, chapter 2.2.2.1.; Hazard identification). The available data on Octanoic acid are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AECs) (Assessment Report page 13, chapter 2.2.2.2., Effects assessment). Therefore a qualitative risk assessment for local effects of the representative product was performed in the Assessment Report (the Assessment Report page 13, chapter 2.2.2.3., Exposure assessment).

The same approach is now followed for Hypred's octanoic acid based products, whereby the "Guidance on the BPR: Volume III, Part B, Risk Assessment (Version 1.1 of April 2015)" is followed.

Industrial Uses

Not relevant. Hypred's octanoic acid based products are only for professional use.

Professional Uses

As explained in "Guidance on the BPR: Volume III, Part B, Risk Assessment (Version 1.1 of April 2015)", for local effects where no quantitative dose-response information of relevance to the product/in-use solutions is available, a qualitative assessment needs to be performed.

For a product with local effects, the general approach according to the Guidance on Risk Assessment aims at reducing/avoiding contact with the product/in-use solution. To this end risk mitigation measures need to be derived which must be proportional to the degree of concern for the health hazard. The Guidance suggests the categorisation of hazards (very high, high, medium and low) on the basis of the EU hazard classification system (CLP Regulation).

When applied to Hypred's octanoic acid based products, the categorisation for local effects leads to the attribution of Hypred's products into hazard category "high" due to their strong skin corrosion properties (Skin corrosion 1B or 1C: H314) and in category "low" for respiratory irritation (STOT SE 3: H335). After the dilution of the products in the installations, the solution is considered to be Skin Corr 1B for *meta* SPC 1, *meta* SPC 2 and *meta* SPC4 based on extreme pH at 1%. The diluted solution is therefore categorized in hazard category "high" for *meta* SPC 1, *meta* SPC 2 and *meta* SPC4.

The Guidance on Risk Assessment further suggests that the following indicators of exposure should be provided for each exposure scenario.

- Frequency and duration of potential exposure
- Potential degree of exposure
- Relevant RMM
- PPE already in use or additionally required.

These four exposure indicators are reported for each scenario (scenarios 1-6 of above "summary table: scenarios") in the tables below according to the examples provided in the Guidance on Risk Assessments (Appendix 4-5).

In a final step, this information is evaluated and a conclusion is drawn on the acceptability of the risk. Respective guidance for professional use is provided in Tables 25 and 27 of the Guidance on Risk Assessment. While Table 25 provides qualitative arguments to support acceptability or non-acceptability of risk, table 27 provides guidance for concluding qualitatively on the acceptability for professional exposure.

Scenario [1]: Loading by connecting lines

Hazard			**Exposure**							**Risk**
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin corrosion Cat. 1B or 1C, H314		4	Professionals	Containers or drums containing the product are connected to CIP via installed pipes	Skin Eye RT	Daily Few minutes or less per day	n.r.	Technical and organisational RMM adequate for the high hazard category are achievable Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure Use of gloves, protective clothing and eye protection	Acceptable: No exposure expected since technical and organisational RMM adequate for the high hazard category are achievable
Low	STOT SE 3: H335						negligible degree of exposure due to the low vapour pressure and no aerosol formation is expected.			Acceptable: Based on negligle exposure (low vapour pressure and no aerosol formation) and RMM & PPE triggered by H314 potential risk due to H335 are covered. No additional PPE is needed

Scenario [2]: Loading by pouring from jerry cans

Hazard			**Exposure**							**Risk**
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin corrosion Cat. 1B or		4	Professionals	Product is loaded into CIP by	Skin Eye	Daily Few minutes	Low: splashes	Technical and organisational RMM	Acceptable: Technical and

	1C, H314				manual pouring from jerry cans	RT	or less per day	inhalation	adequate for the high hazard category are achievable Use of gloves, protective clothingand eye protection	organisational RMM adequate for the high hazard category are achievable
Low	STOT SE 3: H335						negligible degree of exposure due to the low vapour pressure and no aerosol formation is expected.			Acceptable: Based on negligle exposure (low vapour pressure and no aerosol formation) and RMM & PPE triggered by H314 potential risk due to H335 are covered. No additional PPE is needed

Scenario [3]: Rinsing of empty containers, drums and jerry cans

Hazard			**Exposure**							**Risk**
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin corrosion Cat. 1B or 1C, H314		4	Professionals	Product remaining in jerry cans after use is diluted with water and then poured into CIP installation	Skin Eye RT	Daily Few minutes or less per day	Low: splashes inhalation	Technical and organisational RMM adequate for the high hazard category are achievable Use of gloves, protective clothing and eye protection	Acceptable: Technical and organisational RMM adequate for the high hazard category are achievable
Low	STOT SE 3: H335						negligible degree of exposure due to the low vapour pressure and no aerosol formation is expected.			Acceptable: Based on negligle exposure (low vapour pressure and no aerosol formation) and RMM & PPE triggered by H314 potential risk due to

										H335 are covered. No additional PPE is needed

Scenario [4]: Application – pumping product through circuits

Hazard			**Exposure**							**Risk**
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin corrosion Cat 1B H314 (Meta SPC1, Meta SPC 2 and Meta SPC 4)		4	Professionals	The product with 0.4-1.5% dilution is pumped through the pipework of CIP installation	n.r.	1 to 3 times a day	n.r.	Not needed because exposure can be excluded (closed system)	Acceptable: No exposure expected
Low	STOT SE 3: H335	-								Acceptable: No exposure expected

Scenario [5]: Rinsing – pumping water through the installations after use

Hazard			**Exposure**							**Risk**
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin corrosion Cat 1B H314 (Meta SPC1, Meta SPC 2 and Meta SPC 4)		4	Professionals	The product with 0.4-1.5% dilution is pumped through the pipework of CIP installation	n.r.	1 to 3 times a day	n.r.	Not needed because exposure can be excluded (closed system)	Acceptable: No exposure expected
Low	STOT SE 3: H335 (Meta SPC1, Meta SPC 2 and	-								Acceptable: No exposure expected

	Meta SPC 4)									

Scenario [6]: Maintenance of installations

Hazard			**Exposure**							**Risk**
Hazard category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk
High	Skin corrosion Cat 1B H314 (Meta SPC1, Meta SPC 2 and Meta SPC 4)		4	Professionals	Exceptional maintenance work on CIP installation with 0.4-1.5% dilution.	Skin Eye RT	Very low frequency Minutes to several hours per day	Low*	Technical and organisational RMM adequate for the high hazard category are achievable Use of gloves, protective clothing and eye protection	Acceptable: + Reversible effects + Installed RMM + Trained professionals + Use of appropriate PPE +Low degree of exposure expected
Low	STOT SE 3: H335 (Meta SPC1, Meta SPC 2 and Meta SPC 4)	-							Technical and organisational RMM as for the high hazard category are achievable Use of gloves, protective clothing and eye protection	Acceptable: + Installed RMM + Trained professionals + Use of appropriate PPE +Low degree of exposure expected

*Maintenance is expected to take place outside the cleaning and disinfection cycles: the installation can therefore be expected to be free of the products when the maintenance work is carried out.

Combined scenarios

Scenarios 4 (application: pumping product through circuit) and 5 (rinsing: pumping water through the installations after use) do not lead to any exposure and do not need to be considered for combined scenarios.

A worker executing work according to scenario 1 (loading by connecting lines) is likely not to execute work according to scenario 2 (loading by pouring from jerry cans) and scenario 3 (rinsing empty containers, drum, jerry cans): it is to be expected that loading by connecting lines takes place in large installations, while loading by pouring takes place in small installations.

Work according to scenario 2 (loading by pouring from jerry cans) and scenario 3 (rinsing empty containers, drum, jerry cans) is expected to be executed by the same workers: the

person pouring the product into the CIP installation will also rinse the empty jerry cans. It is not expected that the combination of both scenarios will significantly increase the risk to the worker.

For maintenance work (scenario 6), it is expected that specialised mechanics execute the work, i.e. other workers than those routinely operating the CIP installation.

Conclusion

Among the six scenarios that have been assessed, no unacceptable risk has been identified for scenario 4 and scenario 5. The risk was considered acceptable for scenario 1-3 and 6 considering RMM already in place and the use of PPE. As adequate PPE, gloves, protective clothing and eye protection are prescribed, the risk is acceptable.

The following sentences will be included in the risk mitigation measures (5.2) of the SPC:

- Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder within the product information).
- Ensure adequate ventilation during the application.

Non-professional Users

Hypred's octanoic acid based products are only for professional use. Exposure to non-professionals can therefore be excluded.

Secondary (Indirect) Exposure as a Result of Use

Exposure of the general public is not foreseen because the Hypred's octanoic acid based products are for professional use in CIP installation.

Indirect Exposure via Food

No relevant residues in food or feed are expected as already described. Minimal residues of the application solution in food or feed are unlikely to cause local effects due to the high dilution rate in food expected.

Combined exposure to several active substances or substances of concern within a biocidal product

The substances of concern fall in band A or B, for which no fully quantitative risk assessment is required (Note for Discussion with Competent Authorities or Biocidal Products: CA-Nov14-Doc.5.11). For the substances of concern triggering H302 (band A), only the application of P-statements and H-statement is required. For the substances of concern triggering H314 (band B), a qualitative exposure and risk assessment is required to determine whether P-statements and H-statements are sufficient or whether other risk mitigation measures need to be applied. For the latter no additional risk mitigation measures are needed because appropriate measures are already proposed based on the skin corrosive character of the Hypred's octanoic acid based products itself.

Conclusion

In accordance with the approach described in the assessment report on octanoic acid, a qualitative risk characterisation has been performed based on local effects, following the

procedure outlined in the "Guidance on the BPR: Volume III, Part B, Risk Assessment (Version 1.1 of April 2015)".

Six exposure scenarios have been assessed for the professional user. No unacceptable risk was identified for the protected professional user during loading by connecting / by pouring undiluted HYPRED's octanoic acid based products in an installation, rinsing product containers or maintenance of installation. As adequate PPE, gloves, protective clothing and eye protection have been identified for these tasks. As the users of the products are professionals, it is justified to assume that the RMM are indeed applied and PPE used as instructed. For pumping product through circuits and for pumping water through the installations after use no exposure is foreseen, because of the completely closed systems.

Furthermore, secondary exposure is considered negligible and therefore no adverse effects are expected for the non-professional and the general public due to the use of HYPRED's octanoic acid based products.

Due to the nature of the active substance no quantitative dietary risk assessment was carried out. Furthermore presence of relevant amounts of residues of the application solution in food or feeding is not expected with proper operation of CIP systems. Minimal residues of the application solution in food or feed are unlikely to cause local effects due to the high dilution rate in food expected.

2.1.21. Risk assessment for animal health

Negligible if the BPF is used in CIP systems properly. HYPRED's octanoic acid based products are used by the professional user in closed systems.

2.1.22. Risk assessment for the environment

A. EFFECTS ASSESSMENT ON THE ENVIRONMENT

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

The components in HYPRED's octanoic acid based products which are classified as hazardous to the aquatic environment are:

- Octanoic acid : Aquatic Chronic 3 – H412
- N,N-dimethyl-1-Decanamine, N-oxide : Aquatic Acute 1 – H400 (M factor = 1) and Aquatic Chronic 2 – H411

Aquatic acute toxicity
When using the table 4.1.1, Environmental Hazards, Appendix I of the Regulation 1272/2008/CE, we can conclude that HYPRED's octanoic acid based products can't be considered as having acute aquatic toxicity because the concentration of N,N-dimethyl-1-Decanamine, N-oxid is lower than 25% (comprised between 2.25 and 6 % w/w) taking the M factor of 1 into account.

Chronic aquatic toxicity
According to the Table 4.1.2 of the Regulation 286/2011/EC which modifies the Regulation 1272/2008/EC, HYPRED's octanoic acid based products are classified as Aquatic Chronic 2 (H412) because of their content Octanoic acid and N,N-dimethyl-1-Decanamine, N-oxide.

In META SPC 3, the co-formulant N-dimethyl-1-Decanamine, N-oxide is a substance of concern for the environment as solely the presence of this compound leads to a classification of the product DEPTACID CB in this META SPC.
In META SPC 3, the co-formulant L-(+)-Lactic acid is a substance of concern as this is an active substance in PT2,3 and 4 and present in the products with a concentration > 0.1 % (i.e. 17.6 % w/w pure ingredient).

Further Ecotoxicological studies

No study on ecotoxicity is provided for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	There are valid data available on each of the components and synergistic effects between any of the components are not expected.

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

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on other target organisms is needed on the basis of intended uses, data available on the active substance or risk assessment.

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

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's octanoic acid based products are not in the form of bait or granules

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

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's octanoic acid based products are not in the form of bait or granules

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

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Assessment for endocrine disrupting properties

As discussed in Section 2.2.6.1, the Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria

become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for HYPRED's octanoic acid based products and these were not tested for potential endocrine disruption properties. HYPRED's octanoic acid based products contain the active substance octanoic acid and various co-formulants (see confidential annex).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. As discussed in the Assessment Report for octanoic acid (December 2013), this active substance is a fatty acid which shows no indication for an endocrine potential.

For the co-formulants a screening was performed by consulting:
- ECHA data for identification of ED and PBT, under REACH or BPR or CLP
- The United States EPA
- The United Nations Environment Program (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

None of the co-formulants triggered an alert for potential endocrine disruption properties. Hence, no further ED assessments are required for HYPRED's octanoic acid based products. Overall, none of the meta SPCs are anticipated to have ED potential.

Foreseeable routes of entry into the environment on the basis of the use envisaged

This dossier is to support the use of octanoic acid in disinfectants of product type PT 4 in food and feed areas. The following uses are defined:
- Cleaning and disinfection, or disinfection of circuits in agro-food industries (including dairy, beverage and breweries industries) (use 1.1, 2.1 and 3.1)
- Cleaning and disinfection of milking equipment and milking robots in farms (use 1.2)
- Cleaning and disinfection or disinfection of separative membranes in dairy and beverage industries (use 4.1)

All uses are considered as CIP treatments. Consequently, the cleaning processes are assumed to always take place under closed system conditions.
The main route of exposure to the environment is via the sewer system, disinfectants end up in a sewage treatment plant. However, in most cases when applied at farms' sites, waste water may be discharged to the slurry pit instead, as farms are not always connected to the sewer. Therefore, the biocide can end up in soil when manure is applied on grass or arable land. Discharge to a local wastewater treatment system may occur as well. However, emission via manure was not addressed in the current product authorisation report as no agreed scenario is available.

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

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant

Justification	Although the BPC opinion requests for a monitoring study to determine octanoic's fate in the sewage treatment plant, no additional test on fate and behaviour in the environment were submitted. The available data as published in the assessment report of the active substance is however sufficient for the risk assessment.

Leaching behaviour (ADS)

Not applicable for the uses assessed.

Testing for distribution and dissipation in soil (ADS)

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on distribution and dissipation in soil is needed on the basis of intended uses, data available on the active substance or risk assessment.

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

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on distribution and dissipation in water and sediment is needed on the basis of intended uses, data available on the active substance or risk assessment.

Testing for distribution and dissipation in air (ADS)

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on distribution and dissipation in air is needed on the basis of intended uses, data available on the active substance or risk assessment.

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)

No data is available for HYPRED's octanoic acid based products.

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's octanoic acid based products are not intended to be sprayed near to surface waters.

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

B. EXPOSURE ASSESSMENT

General information

Assessed PT	PT 4
Assessed scenarios	Scenario 1 (uses 1.1, 2.1 and 3.1): Cleaning and disinfection, or disinfection of circuits in agro-food industries (including dairy, beverage and breweries industries): Meta-SPCs 1, 2, and 3 Scenario 2 (use 1.2): Cleaning and disinfection of milking equipment and milking robots in farms: Meta-SPC 1 Scenario 3 (use 4.1): Cleaning and disinfection or disinfection of separative membranes in dairy and beverage industries: Meta-SPC 4
ESD(s) used	Scenario 1: Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas Scenario 2: Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas Scenario 3: No emission scenario is available for the disinfection of separative membranes. However, the use is similar to the disinfection of circuits in food, milk and drink industries. Therefore, this emission scenario was adapted and also used for the disinfection of membranes in agro-food industries.
Approach	Scenario 1: Average consumption Three different products (see below) can be applied in the agro-food industries for the cleaning and disinfection of circuits. The capacity of such circuits varies between 250L and 3000L. The disinfection is performed 1 to 3 times per day. For the emission estimation it is assumed that a circuit of 3000L is disinfected three times per day as a worst case. The following meta-SPCs can be used: • Meta SPC 1 Highest concentation in concentrated product is 3% w/w octanoic acid and diluted 1.5% w/w max, corresponding to 0.045% w/w octanoic acid in the application solution • Meta SPC 2 Highest concentation in concentrated product is 10% w/w octanoic acid, and 4.5% w/w N-dimethyl-1-Decanamine, N-oxide (SoC), and diluted. 0.6% w/w max, corresponding to 0.06% w/w octanoic acid and 0.027% w/w N-dimethyl-1-Decanamine, N-oxide in the application solution • Meta SPC 3 Highest concentation in concentrated product is 10% w/w octanoic acid, 6% w/w N-dimethyl-1-Decanamine, N-oxide (SoC), and 17.6% w/w Lactic acid (SoC). Product is diluted 0.4% w/w maxcorresponding to 0.04% w/w octanoic acid, 0.024 % w/w N-dimethyl-1-Decanamine, N-oxide, and 0.07% w/w Lactic acid. The worst case for the active substance and N-dimethyl-1-Decanamine, N-oxide is meta-SPC 2. Only this case is assessed and covers the use of the other two products. Meta-SPC3 is worst-case for Lactic acid. Scenario 2: Average consumption

	Meta SPC 1 is used for the cleaning and disinfection of milking equipment and milking robots in farms: • Highest concentation in concentrated product is 3% octanoic acid and diluted 1.5% w/w max, corresponding to 0.045% w/w octanoic acid in the application solution. No substances of concern need to be assessed. Scenario 3: Average consumption For the cleaning and disinfection of separative membranes the product circulates in membrane modules of a size of 500L to 4500L. The membranes will be cleaned and disinfected 1 to 3 times per day. Therefore it was assumed in the emission estimation that a membrane module of 4500L is cleaned and disinfected 3 times per day (worst case). • Highest concentation in concentrated product is 3% w/w octanoic acid and 3% w/w N-dimethyl-1-Decanamine, N-oxide, and diluted 1% w/w max, corresponding to 0.03% w/w octanoic acid and 0.03% N-dimethyl-1-Decanamine, N-oxide in the application solution. (meta SPC 4).
Distribution in the environment	Calculated based on the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015) In agreement with the AR (2013) on octanoic acid.
Groundwater simulation	The calculation of the concentration in groundwater was performed according to the approach described in the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015) where the concentration in pore water of agricultural soil is used as a first indication for groundwater concentrations. Emission of octanoic acid to groundwater has been additionally assessed using PEARL 4.4.4 using a worst-case approach (worst-case location conmbined with a unrealistic high dose) to demonstrate the active substances immobility in soils.
Confidential Annexes	No
Life cycle steps assessed	Production: Not assessed: Hypred is not the manufacturer of the active substance Formulation: assessed (statement) Use: assessed Service life: not assessed, not relevant: no service life after application
Remarks	In META SPCs 2-4, the co-formulant N-dimethyl-1-Decanamine, N-oxide is a substance of concern for the environment as solely the presence of this compound leads to the classification of these metas. Meta-SPC 3 contains the highest concentration (6% N,N-dimethyl-1-decamine, N-oxide). The environmental risk assessment for the component N,N-dimethyl-1-decamine, N-oxide is included in this document. In META SPC 3, the co-formulant L-(+)-Lactic acid (hereafter referred to as Lactic acid) is a substance of concern as this is an active substance in PT2, 3 and 4 and present in the products with a concentration > 0.1 % w/w (i.e. 17.6 % w/w pure ingredient). Lactic acid is included in the risk assessment for meta-SPC 3 (scenario)

Emission estimation

Formulation

The manufacturing process of HYPRED's octanoic acid based products is highly automated to avoid contact of operators with products as much as possible. The same holds true for the filling of containers, drums and jerry cans.
Operators wear adequate protective equipment in accordance with the requirements indicated in the safety data sheets of each component.
Release into the environment during formulation can take place when the manufacturing tank is emptied. In this case automatic rinsing is performed with water, which automatically transferred into the STP.
The production takes place according to national laws and regulations and therefore, it is not necessary to perform human health and environmental risk assessments in the context of this dossier.

A detailed description of the manufacturing and packaging of Hypred's octanoic acid based products is provided in the "file Formulation OA BPF of Hypred.docx" attached to IUCLID in chapter 13.

Uses

Scenario 1: Cleaning and disinfection, or disinfection of circuits in agro-food industries (including dairy, beverage and breweries industries) (uses 1.1, 2.1 and 3.1)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Cleaning and disinfection, or disinfection of circuits in agro-food industries (including dairy, beverage and breweries industries)			
Concentration of active substance in the product			
Octanoic acid	106	g/L	The product (metal-SPC2) contains 10 % w/w octanoic acid, 6% w/w N,N-dimethyl-1-decamine, N-oxide, and 17.6% w/w lactic acid. Density of the product is 1.055 L/kg
N,N-dimethyl-1-decamine, N-oxide	63.3	g/L	
Lactic acid	186	g/L	
Volume of the circuit	3000	L	The volume of the circuit is identical to the total amount of application solution used.
Application rate of biocidal product (undiluted product)	18	L	For the disinfection of a circuits of 3000 L. Product is diluted 0.6% w/w
Concentration of the active substance in the application solution			
Octanoic acid	0.63	g/L	g active substance per L application solution
N,N-dimethyl-1-decamine, N-oxide	0.38	g/L	

Lactic acid	1.1	g/L	
Amount of active substance used for one application			
Octanoic acid	1899	g	g active substance per L application solution
N,N-dimethyl-1-decamine, N-oxide	1139	g	
Lactic acid	3342	g	
Number of disinfection events per day	3	d^{-1}	-
Number of emission days per year	360	d	Information provided by the applicant

Calculations for Scenario 1

The calculation of the emission based on information from the applicant on the amount of octanoic acid used per year in the local plant and according to the ESD for PT4 is provided in Annex 3.2.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	5.7 kg/d octanoic acid 3.4 kg/d N-dimethyl-1-Decanamine, N-oxide 10 kg/d Lactic acid	Daily emission to the sewer system (see Annex 3.2 for the calculation for the active substance)

Scenario 2: Cleaning and disinfection of milking equipment and milking robots in farms (Use 1.2)

Input parameters for calculating the local emission for octanoic acid			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: Cleaning and disinfection of milking equipment and milking robots in farms			
Amount of application solution used for cleaning of the milking installation and the milk storage tank	175	L	According to Table 11 of the ESD PT4 for an application solution of 175 L (sum of 2 x 65 L and 45 L)*
Concentration of active substance in the product	31.6	g/L	The product (meta-SPC 1) contains 3 % w/w octanoic acid. Density of the product is 1.055 L/kg
Concentration of active substance in the application solution	0.47	g/L	0.045 % w/w octanoic acid. Product is diluted 1.5% w/w
Application rate of biocidal product	2.625	L	-

(undiluted product)			
Amount of active substance used for one application	83.1	g	-
Number of disinfection events per day	1	d^{-1}	-

* according to the emission scenario for milking parlour systems in the ESD for PT4 the milking installation will be cleaned and disinfected two times per day with an amount of 65L disinfectant solution and the milk storage tank once per day with 45L disinfectant solution resulting in a total amount of 175L.

The calculation of the emission according to the ESD for PT4 is provided in Annex 3.2.

Resulting local emission to relevant environmental compartments for octanoic acid		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	0.0831 kg/d	Daily emission to the sewer system

Scenario 3: Cleaning and disinfection or disinfection of separative membranes in dairy and beverage industries (Use 4.1)

Input parameters for calculating the local emission for octanoic acid			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: Cleaning and disinfection or disinfection of separative membranes in dairy and beverage industries			
Concentration of the active substance in product			
Octanoic acid	31.6	g/L	The product (meta-SPC4) contains 3% w/w octanoic acid and 3% w/w N,N-dimethyl-1-decamine, N-oxide. Density of the product is 1.055 L/kg
N,N-dimethyl-1-decamine, N-oxide	31.6	g/L	
Concentration of the active substance in the application solution			
Octanoic acid	0.316	g/L	Product is diluted 1% w/w max
N,N-dimethyl-1-decamine, N-oxide	0.316	g/L	
Volume of the circuit	4500	L	The volume of the circuit is identical to the total amount of application solution used.
Application rate of biocidal product (undiluted product)	45	L	For the disinfection of a membrane module of 4500L

Amount of active substance used for one application			-
Octanoic acid	1424	g	-
N,N-dimethyl-1-decamine, N-oxide	1424	g	
Number of disinfection events per day	3	d^{-1}	
Number of emission days per year	312	d	Information provided by the applicant

The calculation of the emission based on information from the applicant on the amount of octanoic acid used per year in the local plant is provided in Annex 3.2.

Resulting local emission to relevant environmental compartments for octanoic acid		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	4.27 kg/d octanoic acid 4.27 kg/d N-dimethyl-1-Decanamine, N-oxide	Daily emission to the sewer system

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	yes	yes	yes	yes	yes	yes	yes	yes	no
Scenario 2	yes	yes	yes	yes	yes	yes	yes	yes	no
Scenario 3	yes	yes	yes	yes	yes	yes	yes	yes	no

Input parameters (only set values) for calculating the fate and distribution in the environment for octanoic acid			
Input	Value	Unit	Remarks
Scenario 1: Cleaning and disinfection, or disinfection of circuits in agro-food industries (including dairy, beverage and breweries industries) Scenario 2: Cleaning and disinfection of milking equipment and milking robots in farms Scenario 3: Cleaning and disinfection or disinfection of separative membranes in dairy and beverage industries			
Molecular weight	144.21	g/mol	Source: ECHA*
Melting point	16.6	°C	Source: ECHA*
Boiling point	237	°C	Source: ECHA*
Henry's law constant (at 12°C)	0.237	Pa m^3 mol^{-1}	Source: ECHA* calculated
Vapour pressure (at 20°C)	8.9 x 10^{-3}	Pa	Source: ECHA*
Water solubility (at 20°C and pH 7)	2.97	g/L	Source: ECHA*
Log octanol/water partition coefficient	3.03	Log 10	Source: ECHA*
Organic carbon/water partition	83.9	L/kg	QSAR estimation

coefficient (Koc)			Source: ECHA*
Biodegradability	Readily biode-gradable	-	Source: ECHA*
DT_{50} for degradation in soil	2.1	d (at 12ºC)	Source: ECHA* Read across from Nonanoic acid
DT_{50} for degradation in air (24 h, $c(OH)_{air}$ = $5x10^5$ molecules/cm^3)	46.1	hr	Source: ECHA*

* Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products. Evaluation of active substances. Assessment Report for octanoic acid product types 4 and 18. December 2013.

Input parameters (only set values) for calculating the fate and distribution in the environment for N-dimethyl-1-Decanamine, N-oxide			
Input	Value	Unit	Remarks
Molecular weight	201.35	g/mol	From ECHA website: Information on Chemicals/REACH/ Registered substances
Melting point	~130	°C	
Vapour pressure (at 25°C)	7.55×10^{-5}	Pa	
Water solubility (at 25°C)	409.5	g/L	
Log octanol/water partition coefficient	0.95	Log 10	
Organic carbon/water partition coefficient (Koc)	1525	L/kg	
Biodegradability	Readily biode-gradable	-	
DT_{50} for degradation in soil	30	d (at 12ºC)	Experimental data lacking. Default value for readily biodegradable substances

Input parameters (only set values) for calculating the fate and distribution in the environment for lactic acid			
Input	Value	Unit	Remarks
Molecular weight	90.08	g/mol	Assessment report for lactic acid PT01-04
Melting point	53.0	°C	
Vapour pressure (at 20°C)	0.4	Pa	
Water solubility (at 25°C)	Miscible	g/L	
Log octanol/water partition coefficient	-0.74	Log 10	
Organic carbon/water partition coefficient (Koc)	20	L/kg	
Henry's law constant (20°C)	3.6E-05	Pa m³/mole	
Biodegradability	Readily, but failing 10-d window	-	
DT_{50} for degradation in soil	90	d (at 12ºC)	Experimental data lacking. Default value for readily biodegradable substances

The distribution in the STP is calculated using SimpleTreat 4 in which the amount of suspended solids in the effluent is in accordance with the Technical Agreements on Biocides (TAB, 2018) increased from 0.0075 mg/L to 0.03 mg/L.

Calculated fate and distribution in the STP for octanoic acid		
Compartment	Percentage [%]	Remarks
	Scenario 1, 2, 3	
Air	0.00	Calculated with SimpleTreat using the above input parameters (Source: ECHA*)
Water	7.93	
Sludge	0.77	
Degraded in STP	91.2	

* Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products. Evaluation of active substances. Assessment Report for octanoic acid product types 4 and 18. December 2013.

Calculated fate and distribution in the STP for N-dimethyl-1-Decanamine, N-oxide		
Compartment	Percentage [%]	Remarks
	Scenario 1, 3	
Air	0.00	Calculated with SimpleTreat using the above input parameters
Water	7.17	
Sludge	11.8	
Degraded in STP	81.0	

Calculated fate and distribution in the STP for Lactic acid		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	0	Calculated with SimpleTreat using the above input parameters
Water	7.99	
Sludge	0.19	
Degraded in STP	91.8	

Calculated PEC values

Summary table on calculated PEC values for the STP route for scenarios 1,2 and 3 for octanoic acid

	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**$PEC_{porewater}$**	**PEC_{air}**
Scenario	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	
1	2.26 $x10^{-1}$	2.26 $x10^{-2}$	5.89 $x10^{-2}$	-	-	$7.97x10^{-3}$	5.02	*
2	$3.26x10^{-3}$	$3.26x10^{-4}$	$8.50x10^{-4}$	-	-	$1.16x10^{-4}$	0.07	*
3	0.169	0.0169	0.0441	-	-	$5.98x10^{-2}$	3.77	*

* Qualitatively assessed

Summary table on calculated PEC values for the STP route for scenario 1 and 3 for N-dimethyl-1-Decanamine, N-oxide

	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**$PEC_{porewater}$**	**PEC_{air}**
Scenario	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/L]	[mg/kg_{wwt}]	[mg/ kg_{wwt}]	[µg/L]	
1	$1.23x10^{-1}$	$1.22x10^{-2}$	$4.15x10^{-1}$	-	-	$7.31x10^{-1}$	19.5	*
3	$1.53x10^{-1}$	$1.53x10^{-2}$	$5.19x10^{-1}$	-	-	$9.13x10^{-1}$	24.36	

* Qualitatively assessed

Summary table on calculated PEC values for the STP route for scenario 1 for lactic acid

	PEC_{STP}	PEC_{water}	PEC_{sed}	$PEC_{sea-water}$	PEC_{seased}	PEC_{soil}	$PEC_{porewater}$	PEC_{air}
Scenario	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/L]	[mg/kg_{wwt}]	[mg/ kg_{wwt}]	[µg/L]	
1	4.00E-01	4.00E-02	4.87E-02	-	-	3.44E-02	62.55	*

* Qualitatively assessed

Primary and secondary poisoning

Please refer to section C. risk characterisation.

C. RISK CHARACTERISATION

The PNEC-values for the risk assessment for octanoic acid were obtained from the Assessment Report (AR) for octanoic acid product types 4 and 18 (December 2013).
For N,N-dimethyl-1-decamine, N-oxide the PNEC-values were taken from the From ECHA website: Information on Chemicals/REACH/ Registered substances. The values for lactic acid were obtained from the assessment report for this substance as a biocide.

Atmosphere

An estimation of photochemical degradation of octanoic acid in air according to the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015) resulted in a half-life of 46.1h (k deg, air = 0.361 d^{-1}; $c(OH)_{air}$ = $5x10^5$ molecules/cm^3). Based on this result an accumulation of octanoic acid in air is not expected.

On the basis of its physical and chemical properties, as e.g. absence of absorption bands in the so-called atmospheric window (800-1200 nm), short atmospheric lifetime and absence of Cl, F, N or S substituents in the molecule, octanoic acid is not expected to display adverse abiotic effects on the atmospheric environment.

Therefore, no adverse biotic effects of octanoic acid in the atmosphere are expected. Furthermore, there are no indications that octanoic acid contributes to depletion of the ozone layer as the compound is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament.

An estimation of photochemical degradation of N,N-dimethyl-1-decamine, N-oxide in air with Epi Suite according to the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015) resulted in a half-life of 15.8 h (24 h; $c(OH)_{air}$ = $5x10^5$ molecules/cm^3). Based on this result long range transport of N,N-dimethyl-1-decamine, N-oxide through the atmosphere is not expected.

L(+) Lactic acid is not considered to be used as fumigant. The vapour pressure of L(+) Lactic acid is 0.4 Pa at 20°C and the Henry constant is 3.6 x 10^{-5} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+) Lactic acid to the atmosphere are unlikely to occur. Due to an estimated half-life in the atmosphere of 2.71 d corresponding to 3.91 d for the chemical lifetime the potential for long-range transport of L(+) Lactic acid in air is indicated (ref. to Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004): "… a chemical that migrates significantly through the air, its half-life in air should be greater than two days …"). However, according to the Guidance part B+C (ECHA, 2017) effects on stratospheric ozone and acidification are not expected because L(+) Lactic acid does not contain halogens, nitrogen or sulphur substituents. L(+) Lactic acid shows no absorption

bands in the so-called atmospheric window (range from 800 to 1200 nm). Therefore, L(+) Lactic acid has no global-warming potential.

Sewage treatment plant (STP)

Octanoic acid: $PNEC_{STP}$= 83.71 mg/L

N,N-dimethyl-1-decamine, N-oxide: $PNEC_{STP}$ = 4.59 mg/L

Lactic acid: $PNEC_{STP}$ = 10 mg/L

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Octanoic acid	
Scenario 1	0.003
Scenario 2	< 0.001
Scenario 3	0.002
N,N-dimethyl-1-decamine, N-oxide	
Scenario 1	0.027
Scenario 3	0.002
Lactic acid	
Scenario 1	0.040

The individual PEC/PNEC ratios for the STP scenario are below the trigger value of 1. Therefore, it is concluded that there is no unacceptable risk for the STP from the proposed uses of octanoic acid in all products of the biocidal product family and the presence of N-dimethyl-1-decamine, N-oxide.

Aquatic compartment

Octanoic acid: $PNEC_{water}$ = 0.0047 mg/L

$PNEC_{sed}$ = 0.0123 mg/kg_{wwt}

N,N-dimethyl-1-decamine, N-oxide: $PNEC_{water}$ = 0.0335 mg/L

$PNEC_{sed}$ = 5.24 mg/kg_{dwt}

2.02 mg/kg_{wwt}

Lactic acid: $PNEC_{water}$ = 3.9 mg/L

$PNEC_{sed}$ = 4.8 mg/kg_{wwt}

The PEC and PNEC values for the sediment compartment are calculated with the equilibrium partitioning method based on the $PEC_{aquatic}$ and $PNEC_{aquatic}$ in line with the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015). Consequently, the PEC/PNEC values for the sediment are identical to the PEC/PNEC values for the aquatic

compartment. Risk ratios for the marine environment have not been calculated either. No marine data is available and therefore the PNEC is derived from aquatic data by applying an additional assessment of ten. Considering that the same factor is also applied for the PEC (additional ten times dilution), the PEC:PNEC ratios for freshwater and the marine environment are equal.

In the following table the calculated PEC/PNEC values are provided for the three different uses (scenarios).

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Octanoic acid				
Scenario 1	**4.80**	**4.79**	**-**	**-**
Scenario 2 (via STP)	0.069	0.069	-	-
Scenario 3	**3.60**	**3.59**	**-**	**-**
N,N-dimethyl-1-decamine, N-oxide				
Scenario 1	0.365	0.205	-	-
Scenario 3	0.456	0.257	-	-
Lactic acid				
Scenario 1	0.010	0.010	-	-

The results show that the PEC/PNEC values for scenario 2 are below 1 and no risk is identified for this use "cleaning and disinfection of milking equipment and milking robots". However, the PEC/PNEC-values for scenario 1 and scenario 3 are above 1. PEC:PNEC ratios above one have been nevertheless accepted for the assessed use in the assessment report for octanoic acid (December 2013) based on a refined environmental risk assessment was performed based on monitoring data for octanoic acid.

Residual fatty acid levels in the effluent of a typical industrial brewery treating dominantly brewery wastewater results in a PEC:PNEC ratio of 0.095 max (A2.10/05, Doc. III A2.10 in the CAR). Considering that emission is similar to the values from the assessment report and the substances's behaviour in waste water will be independent from the type of industry, emission will not result in unacceptable risks for the aquatic environment for all intended uses.

Terrestrial compartment

Octanoic acid: $PNEC_{soil}$ = 0.0075 mg/kg$_{wwt}$

N,N-dimethyl-1-decamine, N-oxide: $PNEC_{soil}$ = 1.02 mg/kg $_{dwt}$ (0.9 mg/kg$_{wwt}$)

Lactic acid $PNEC_{soil}$ = 1.9 mg/kg$_{wwt}$

In the following table the calculated PEC/PNEC values are provided for the three different uses.

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil\ exposure\ via\ sewage\ sludge}$
Octanoic acid	
Scenario 1	**1.07** -
Scenario 2	0.015
Scenario 3	0.802
N,N-dimethyl-1-decamine, N-oxide	
Scenario 1	0.812
Scenario 3	**1.01**
Lactic acid	
Scenario 1	0.018

The individual PEC/PNEC-values for scenario 2 and 3 for soil exposed to octanoic acid present in sewage sludge are below 1.

For scenario 1 the PEC/PNEC ratio is only slightly above 1. The $PNEC_{soil}$ was calculated with the equilibrium partitioning method based on the $PNEC_{water}$. However, it is known that fatty acids are nutrients for microorganisms and are mineralised by microbial activity. Moreover, octanoic acid is ready biodegradable (AR, 2013) and may be highly immobile in soils due to its covalent binding to the soil organic matter. It is therefore concluded that the calculated $PNEC_{soil}$ overestimates the effects on soil microorganisms. Consequently, the slight exceed of the PEC/PNEC for scenario 1 is acceptable.

The PEC/PNEC-value for soil exposed to N,N-dimethyl-1-decamine, N-oxide present in sewage sludge is slightly above 1. Note that by absence of terrestrial data the PNEC was derived from aquatic endpoints. As similar substances are usually less toxic for terrestrial organisms compared to aquatic species, the applied PNEC likely overestimates toxicity in soils. Also not that this substance is registred under REACH in the 100-1000 tonnes/year band and applied in personal care products and detergents that are released to the sewer as well and eventually discharged to soils. Emission from other sources may be therefore significant higher. A slight exceeding is therefore considered acceptable.

Groundwater

The PEC values in groundwater were calculated in line with the approach of the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015) using the pore water concentration in soil as indication for the groundwater level.

The calculated PEC_{gw} value for scenario 2 and for soil exposed to octanoic acid present in sewage sludge is below the limit value of 0.1 µg/L provided for pesticides in the Drinking

Water Directive 98/83/EC. The PECgw-values for scenario 1 and 3 for soil exposed to octanoic acid present in sewage sludge are above (5.02 and 3.77 µg/L respectively) this trigger value.

The approach of the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015) is only a rough estimation in which no removal, dilution or transformation processes (e.g. lateral transport or plant uptake) are taken into account. Therefore, the calculated concentrations are an overestimation of the real concentrations in groundwater. The assessment report demonstrated that octanoic acid binds covalently to the soil's organic matrix due to its functional groups, and therefore is highly immobile in soils. The K_{oc} could be therefore not derived experimentally and the K_{ow}-derived value likely overestimates emission to groundwater. Nevertheless PEARL was run for all relevant locations demonstrating that the concentration in groundwater is well below 0.1 µg/L for a dosage of 1 kg/ha and a mixing depth of 20 cm (max 0.000152 µg/L). As the active substance will not sorb to sewage sludge (based on the applied K_{oc}), the annual emission to soils is considerably lower (0.000299 kg/ha). Conclusively, it cannot expected that octanoic acid leaches to groundwater.

The calculated PEC_{gw} values for scenario 1 for soil exposed to N,N-dimethyl-1-decamine, N-oxide present in sewage sludge is above the limit value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC.

However, the approach of the Guidance on the BPR Volume IV Environment - Part B, Version 1.0 (2015) is only a rough estimation in which no removal, dilution or transformation processes (e.g. lateral transport or plant uptake) are taken into account. Therefore, the calculated concentrations are an overestimation of the real concentrations in groundwater. Leaching to groundwater can be excluded for the substance due to its high adsorption characteristics (Koc 587.5 L/kg) and rapid degradation in soil (default DT_{50} of 30 days). Therefore, concentrations of >0.1 µg/L are not expected. The standards for groundwater are met.

As reported on the ECHA website (Information on Chemicals/REACH/Registered substances) for N,N-dimethyl-1-decamine, N-oxide the DNEL for consumers for ingestion is 0.44 mg/kg bw day. Even if the maximum calculated groundwater concentration of 20.44 µg/L occurred in drinking water, and assuming consumption of 2 litres of water per day, the contribution of N,N-dimethyl-1-decamine, N-oxide to daily normal intake of N,N-dimethyl-1-decamine, N-oxide is acceptable.

The expected lactic acid concentration in groundwater is 62.55 µg/L. Previous PEARL simulations (see the assessment reports for lactic acid) demonstrates that emission to groundwater is likely for some locations, which was nevertheless accepted as the emission from biocidal use will not significantly increase the background concentrations resulting from both natural and other anthropogenic sources. Moreover, a half-life of 90 days was applied in abcense of soil degradation studies. As it may be expected that lactic acid degrades rapidly in soils with half-lives comparable to the active substance (days) emission to groundwater is unlikely.

Primary and secondary poisoning

Primary poisoning

Direct exposure of birds or mammals is considered negligible as there is no direct release of the products to the environment.

Secondary poisoning

It is stated in the AR (2013, p. 26ff) for octanoic acid that the calculated octanol-water partition coefficient (log P_{ow} = 3.03) indicates a potential for bioaccumulation. Therefore, a standard assessment for secondary poisoning was performed as Tier 1 and a refined assessment based on monitoring data as Tier 2. The standard assessment showed an acceptable PEC/PNEC for the terrestrial food chain but for the aquatic food chain the PEC/PNEC was slightly above 1 (PEC/PNEC = 1.5). However, in the refined assessment using the monitoring data (Tier 2) the PEC/PNEC values for the aquatic food chain were also well below 1. The eCA concluded that there is no risk for fish eating and worm eating predators and that the non-compartment specific effects of secondary poisoning are low for the aquatic as well as for the terrestrial food chain (AR, 2013, p. 28).
Furthermore, octanoic acid is a fatty acid and as such a food source for all animals (vertebrates and non-vertebrates). It is used as a carbon source and as such fully metabolised. Therefore, risks for fish eating and worm eating birds and mammals are not expected. The standards for bioaccumulation and secondary poisoning are met.

The risk for bioconcentration in aquatic organisms is considered low for N,N-dimethyl-1-decamine, N-oxide, as the log P_{ow} is < 3 (= 2.7). Bioconcentration and biomagnification is not expected (conform the biomagnification trigger value proposed for Kow in the Guidance on biocide legislation, Part B, volume IV) and the risk for bioconcentration of N,N-dimethyl-1-decamine, N-oxide in birds and mammals is therefore considered acceptable.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

- STP
- Surface water and sediment via STP and manure application
- Soil and groundwater via sewage sludge and manure application

Screening Step 2: Identification of relevant substances

Summary of relative toxic units			
	Relevant component 1 octanoic acid	Relevant Component 2 N,N-dimethyl-1-decamine, N-oxide	Relevant component 3 lactic acid
Content in the product [w/w %]	3-10	2.25-6	17.6
Concerned environmental compartment (Aquatic compartment)			
$PNEC_{water}$	0.0047 mg/L	0.0335 mg/L[1]	3.9 mg/L
Concerned environmental compartment (soil)			
$PNEC_{soil}$	0.0075 mg/kg_{wwt}	1.02 mg/kg_{dwt}[1] equivalent to 0.9 mg/kg_{wwt}	1.9 mg/L

[1] from safety data sheet of the supplier (print date 5/22/2015) attached to section 13 of IUCLID

Screening Step 3: Screen on synergistic interactions

There are no indications for synergistic effects.

Screening step	
	Significant exposure of environmental compartments? Yes
	Number of relevant substances: 3
	Indication for synergistic effects for the product or its constituents in the literature? No

Conclusion: Mixture toxicity needs to be assessed.

Tiered approach

Tier 1. PEC/PNEC summation

Summary table on calculated PEC/PNEC values				**Summation**
	Octanoic acid	**N,N-dimethyl-1-decamine, N-oxide**	**Lactic acid**	
	$PEC/PNEC_{STP}$			
Scenario 1	0.003	0.027	0.040	0.070
Scenario 2	< 0.001	-	-	< 0.001
Scenario 3	0.002	0.02	-	0.004
	$PEC/PNEC_{water}$			
Scenario 1	0.095	0.365	0.010	0.470
Scenario 2 (via STP)	0.069	-		0.069
Scenario 3	0.095	0.257	-	0.352
	$PEC/PNEC_{sed}$			
Scenario 1	0.095	0.205	0.010	0.362
Scenario 2 (via STP)	0.16	-	-	0.16
Scenario 3	$8.59x10^{-2}$	0.257	-	0.343
	$PEC/PNEC_{soil}$ exposure via sewage sludge			
Scenario 1	**1.07**	0.812	0.018	**1.90**
Scenario 2	0.015	-	-	0.015
Scenario 3	0.802	**1.01**	-	**1.81**

The summed up PEC/PNEC for the STP, water and sediment compartments are well below 1 for all scenarios and thus acceptable

The summed up PEC/PNEC for the soil compartment are above 1 for scenario 1and 3 for soil exposed to octanoic acid and N,N-dimethyl-1-decamine, N-oxide present in sewage sludge. As explained previously, a slight exceeding is acceptable.

The risks for groundwater and secondary poisoning were qualitatively assessed and found acceptable for the individual substances and their combination.

Conclusion: the risks for all compartments are acceptable for the uses in scenarios 2 and 3. For scenario 1 the risks for all compartments are also acceptable as N,N-dimethyl-1-decamine, N-oxide is not considered to be a substance of concern in these products.

Aggregated exposure (combined for relevant emmission sources)

See Annex 3.7

2.1.23. Measures to protect man, animals and the environment

A. RECOMMENDED METHODS AND PRECAUTIONS

Methods and precautions concerning handling and use

Personal protective equipment :

Eye/face protection :
Use safety glasses or facial screen in conformity with the EN 166 standard.

Hand protection :
Use chemical resistant gloves approved to EN 374.
Examples of prefered materials for insulating gloves:
Butyl rubber.
Nitril.

Skin protection :
Wear boots and a protective cloth with chemical resistance.

Thermal hazards :
Not applicable

Health measures :
Safety shower and eye wash fountain near to workplace.
After using, wash systematically all personal protective equipment.
Handle in accordance with good industrial hygiene practices and the safety instructions.

Methods and precautions concerning storage

Shelf life : 2 years
Conditions of storage : keep only in the original container. Keep container closed. Keep in a cool place. Keep away from products sensitive to acids.

Methods and precautions concerning transport

For meta SPC 1, meta SPC 2 and meta SPC4

ROAD TRANSPORT: *Rail/Route (RID/ADR)*
UN no : 3265
UN proper shipping name : CORROSIVE LIQUID, ACIDIC ORGANIC, N.O.S.
Class : 8
Packing group : II
Hazard code : 80
Label : 8

Tunnel code : E
Environmental hazard : No
Special precautions for user : No information.

MARITIME TRANSPORT :
IMDG
UN no :3265
UN proper shipping name : CORROSIVE LIQUID, ACIDIC ORGANIC, N.O.S.
Class : 8

Packing group : III
Marine pollutant : No
Special precautions for user : No information.
EmS number : F-A,S-B
Comply with the provisions of the IMDG on the physical separation of materials.

For meta SPC3

ROAD TRANSPORT: *Rail/Route (RID/ADR)*
UN no : 3265
UN proper shipping name : CORROSIVE LIQUID, ACIDIC ORGANIC, N.O.S.
Class : 8
Packing group : III
Hazard code : 80
Label : 8

Tunnel code : E
Environmental hazard : No
Special precautions for user : No information.

MARITIME TRANSPORT :
IMDG
UN no :3265
UN proper shipping name : CORROSIVE LIQUID, ACIDIC ORGANIC, N.O.S.
Class : 8

Packing group : II
Marine pollutant : No
Special precautions for user : No information.
EmS number : F-A,S-B

Methods and precautions concerning fire

HYPRED's octanoic acid based products are non flammable.

Hazardous decomposition products :

META SPC 1, 2 and 4:

Formation of toxic products through combustion: carbon oxides, sulphur oxides.
In presence of metal, release of hydrogen that is flammable and/or explosive if it catches fire.

META SPC 3 :

None to our knowledge in standard conditions of use

Extinguishing media :

META SPC 1, 2 and 4:

Suitable extinguishing media :
Spray water, foam or dry ice.
Agents compatible with other products involved into fire.

Unsuitable extinguishing media :
High pressure water jet

META SPC 3 :

Suitable extinguishing media :
Pulverized water.
Foam, powder, carbon dioxide.
Agents compatible with other products involved into fire.

Unsuitable extinguishing media :
High pressure water jet

Advice for firefighters :

Wear independent respiratory equipment and protective suit.
Collect contaminated firefighting water separately, must not be discharged into the drains.
Keep containers cool by spraying with water if exposed to fire

Measures to protect environment

Do not discharge the product directly to sewer or to the environment.

B. IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE

None to our knowledge.

C. SPECIFIC TREATMENT IN CASE OF AN ACCIDENT

First aid measures

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.

IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open.
Remove contact lenses if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER or doctor/physician.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.
When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

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.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Emergency measures to protect the environment in case of accidental release

Evacuate non-essential staff and those not equipped with individual protection equipement.

Evacuate the personnel to a safe location.
Keep people upwind and away from the location of the flow/leak.
Use personal protection equipment.

Small spillage: Pump in a reservoir of help.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

D. POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE

Soil: Collect contaminated soil in a suitable container and dispose off as hazardous waste.

E. PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING

Eliminate the product and its packaging in accordance with applicable local and national regulations.

F. PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT

Not relevant, as the products are used in closed system, so there is no application equipment.

G. SPECIFY ANY REPELLENTS OR POISON CONTROL MEASURES INCLUDED IN THE PRODUCT

No repellent or poison control measures have been included in the preparation and are present to prevent action against non-target organisms.
No contact with non-target organisms is likely.

2.1.24. Assessment of a combination of biocidal products

Not relevant : HYPRED's octanoic acid biocidal products are not intended to be authorised for the use with other biocidal products.

2.1.25. Comparative assessment

Not relevant : HYPRED's octanoic acid biocidal products are not containing an active substance meeting the exclusion criteria.

3. ANNEXES

LIST OF STUDIES FOR THE BIOCIDAL FAMILY

BPR datapoint	Study N°	Author	Year	Title	Owner of data	Data protection claimed y/n	Confidentiality request submitted y/n
3.1	No report n° Doc 3.1-001	R. Périon HYPRED	2015	Appearance of HYPRACID ONE	HYPRED	n	n
3.1	No report n° Doc 3.1-002	R. Périon HYPRED	2015	Appearance of DEPTACID BD	HYPRED	n	n
3.1	No report n° Doc 3.1-003	R. Périon HYPRED	2015	Appearance of DEPTACID WCM	HYPRED	n	n
3.1	No report n° Doc 3.1-004	G. Caillet HYPRED	2015	Appearance of DEPTACID CCB	HYPRED	n	n
3.1	No report n° Doc 3.1-005	G. Caillet HYPRED	2015	Appearance of DEPTACID CB	HYPRED	n	n
3.2	No report n° Doc 3.2-001.1	O. Connan HYPRED	2015	Physico-chemical tests on HYPRACID ONE - Determination of pH values	HYPRED	y	n
3.2	No report n° Doc 3.2-001.2	O. Connan HYPRED	2015	Physico-chemical tests on HYPRACID ONE - Determination of the acidity	HYPRED	y	n
3.2	No report n° Doc 3.2-002.1	O. Connan HYPRED	2015	Physico-chemical tests on DEPTACID BD - Determination of pH values	HYPRED	y	n
3.2	No report n° Doc 3.2-002.2	O. Connan HYPRED	2015	Physico-chemical tests on DEPTACID BD - Determination of the acidity	HYPRED	y	n
3.2	No report n° Doc 3.2-003.1	O. Connan HYPRED	2015	Physico-chemical tests on DEPTACID WCM - Determination of pH values	HYPRED	y	n
3.2	No report n° Doc 3.2-003.2	O. Connan HYPRED	2015	Physico-chemical tests on DEPTACID WCM - Determination of the acidity	HYPRED	y	n
3.2	No report n° Doc 3.2-004.1	G. Caillet HYPRED	2015	Physico-chemical tests on DEPTACID CCB - Determination of pH values	HYPRED	y	n
3.2	No report n° Doc 3.2-004.2	G. Caillet HYPRED	2015	Physico-chemical tests on DEPTACID CCB - Determination of the acidity	HYPRED	y	n
3.2	No report n° Doc 3.2-005.1	G. Caillet HYPRED	2015	Physico-chemical tests on DEPTACID CB -	HYPRED	y	n

				Determination of pH values			
3.2	No report n° Doc 3.2-005.2	G. Caillet HYPRED	2015	Physico-chemical tests on DEPTACID CB - Determination of the acidity	HYPRED	y	n
3.3	No report n° Doc 3.3-001	O. Connan HYPRED	2015	Physico-chemical tests on HYPRACID ONE - Determination of the Relative Density	HYPRED	y	n
3.3	No report n° Doc 3.3-002	O. Connan HYPRED	2015	Physico-chemical tests on DEPTACID BD - Determination of the Relative Density	HYPRED	y	n
3.3	No report n° Doc 3.3-003	O. Connan HYPRED	2015	Physico-chemical tests on DEPTACID WCM - Determination of the Relative Density	HYPRED	y	n
3.3	No report n° Doc 3.3-004	G. Caillet HYPRED	2015	Physico-chemical tests on DEPTACID CCB - Determination of the Relative Density	HYPRED	y	n
3.3	No report n° Doc 3.3-005	G. Caillet HYPRED	2015	Physico-chemical tests on DEPTACID CB - Determination of the Relative Density	HYPRED	y	n
3.4	No report n° Doc 3.4-001.1	O. Connan HYPRED	2015	Accelerated stability test 40°C +/- 2 for 8 weeks HYPRACID ONE	HYPRED	y	n
3.4	No report n° Doc 3.4-001.2	O. Connan HYPRED	2015	Accelerated stability test 40°C +/- 2 for 8 weeks DEPTACID BD	HYPRED	y	n
3.4	No report n° Doc 3.4-001.3	O. Connan HYPRED	2015	Accelerated stability test 40°C +/- 2 for 8 weeks DEPTACID WCM	HYPRED	y	n
3.4	No report n° Doc 3.4-001.4	G. Caillet HYPRED	2015	Accelerated stability test 40°C +/- 2 for 8 weeks DEPTACID CCB	HYPRED	y	n
3.4	No report n° Doc 3.4-001.5	G. Caillet HYPRED	2015	Accelerated stability test 40°C +/- 2 for 8 weeks DEPTACID CB	HYPRED	y	n
3.4	No report n° Doc 3.4-002.1	O. Connan HYPRED	2015	Low temperature stability test HYPRACID ONE	HYPRED	y	n
3.4	No report n° Doc 3.4-002.2	O. Connan HYPRED	2015	Low temperature stability test DEPTACID BD	HYPRED	y	n
3.4	No report n° Doc 3.4-002.3	O. Connan HYPRED	2015	Low temperature stability test DEPTACID WCM	HYPRED	y	n
3.4	No report n° Doc 3.4-002.4	G. Caillet HYPRED	2015	Low temperature stability test DEPTACID CCB	HYPRED	y	n

3.4	No report n° Doc 3.4-002.5	G. Caillet HYPRED	2015	Low temperature stability test DEPTACID CB	HYPRED	y	n
3.4	No report n° Doc 3.4-003.1	O. Connan HYPRED	2015	Long term storage test 20 +/- 2°C, 2 years HYPRACID ONE	HYPRED	y	n
3.4	No report n° Doc 3.4-003.2	O. Connan HYPRED	2015	Long term storage test 20 +/- 2°C, 2 years DEPTACID BD	HYPRED	y	n
3.4	No report n° Doc 3.4-003.3	O. Connan HYPRED	2015	Long term storage test 20 +/- 2°C, 2 years DEPTACID WCM	HYPRED	y	n
3.4	No report n° Doc 3.4-003.4	G. Caillet HYPRED	2015	Long term storage test 20 +/- 2°C, 2 years DEPTACID CCB	HYPRED	y	n
3.4	No report n° Doc 3.4-003.5	G. Caillet HYPRED	2015	Long term storage test 20 +/- 2°C, 2 years DEPTACID CB	HYPRED	y	n
3.5	No report n° Doc 3.5-001	O. Connan HYPRED	2015	Determination of persistent foaming of HYPRACID ONE	HYPRED	y	n
3.5	No report n° Doc 3.5-002	O. Connan HYPRED	2015	Determination of persistent foaming of DEPTACID BD	HYPRED	y	n
3.5	No report n° Doc 3.5-003	O. Connan HYPRED	2015	Determination of persistent foaming of DEPTACID WCM	HYPRED	y	n
3.5	No report n° Doc 3.5-004	G. Caillet HYPRED	2015	Determination of persistent foaming of DEPTACID CCB	HYPRED	y	n
3.5	No report n° Doc 3.5-005	G. Caillet HYPRED	2015	Determination of persistent foaming of DEPTACID CB	HYPRED	y	n
3.5	No report n° Doc 3.5-006	O. Connan HYPRED	2015	Dilution stability of HYPRACID ONE aqueous solutions	HYPRED	y	n
3.5	No report n° Doc 3.5-007	O. Connan HYPRED	2015	Dilution stability of DEPTACID BD aqueous solutions	HYPRED	y	n
3.5	No report n° Doc 3.5-008	O. Connan HYPRED	2015	Dilution stability of DEPTACID WCM aqueous solutions	HYPRED	y	n
3.5	No report n° Doc 3.5-009	G. Caillet HYPRED	2015	Dilution stability of DEPTACID CCB aqueous solutions	HYPRED	y	n
3.5	No report n° Doc 3.5-010	G. Caillet HYPRED	2015	Dilution stability of DEPTACID CB aqueous solutions	HYPRED	y	n
3.8	No report n° Doc 3.8-001	B. Demangel DEFITRACES	2015	Surface tension test on HYPRACID ONE	HYPRED	y	n
3.8	No report n° Doc 3.8-002	B. Demangel DEFITRACES	2015	Surface tension test on DEPTACID BD	HYPRED	y	n

3.8	No report n° Doc 3.8-003	B. Demangel DEFITRACES	2015	Surface tension test on DEPTACID WCM	HYPRED	y	n
3.8	No report n° Doc 3.8-004	B. Demangel DEFITRACES	2015	Surface tension test on DEPTACID CCB	HYPRED	y	n
3.8	No report n° Doc 3.8-005	B. Demangel DEFITRACES	2015	Surface tension test on DEPTACID CB	HYPRED	y	n
3.9	No report n° Doc 3.9-001	B. Demangel DEFITRACES	2015	Viscosity test on HYPRACID ONE	HYPRED	y	n
3.9	No report n° Doc 3.9-002	B. Demangel DEFITRACES	2015	Viscosity test on DEPTACID BD	HYPRED	y	n
3.9	No report n° Doc 3.9-003	B. Demangel DEFITRACES	2015	Viscosity test on DEPTACID WCM	HYPRED	y	n
3.9	No report n° Doc 3.9-004	B. Demangel DEFITRACES	2015	Viscosity test on DEPTACID CCB	HYPRED	y	n
3.9	No report n° Doc 3.9-005	B. Demangel DEFITRACES	2015	Viscosity test on DEPTACID CB	HYPRED	y	n
5	No report n° Doc 5-001	S.Ladril HYPRED	2015	AL 218 v02 Quantification of octanoic acid by HPLC	HYPRED	y	n
5	No report n° Doc 5-002	S.Ladril HYPRED	2015	AL 219 v02 Quantification of octanoic acid by HPLC after alkaline hydrolysis	HYPRED	y	n
5	No report n° Doc 5-003	S.Ladril HYPRED	2015	AL 218 method validation report	HYPRED	y	n
5	No report n° Doc 5-004	S.Ladril HYPRED	2015	AL 219 method validation report	HYPRED	y	n
6.7	No report n° Doc 6.7-001.1	AF. Gabillet LMH	2015	Bactericidal efficiency test according to the methodology of the norme NF EN 1276 (March 2010) on HYPRACID ONE	HYPRED	y	n
6.7	No report n° Doc 6.7-001.2	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) HYPRACID ONE	HYPRED	y	n
6.7	No report n° Doc 6.7-002.2	AF. Gabillet LMH	2015	Bactericidal efficiency test according to the methodology of the norme NF EN 1276 (March 2010) on DEPTACID BD (skimmed milk)	HYPRED	y	n
6.7	No report n° Doc 6.7-002.4	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID BD (skimmed milk)	HYPRED	y	n
6.7	No report n° Doc 6.7-003.1	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID BD (skimmed milk)	HYPRED	y	n

6.7	No report n° Doc 6.7-003.2	AF. Gabillet LMH	2015	Bactericidal efficiency test according to the methodology of the norme NF EN 1276 (March 2010) on DEPTACID WCM (skimmed milk)	HYPRED	y	n
6.7	No report n° Doc 6.7-003.3	AF. Gabillet LMH	2015	Bactericidal efficiency test according to the methodology of the norme NF EN 1276 (March 2010) on DEPTACID WCM (sucrose)	HYPRED	y	n
6.7	No report n° Doc 6.7-003.4	AF. Gabillet LMH	2015	Bactericidal efficiency test according to the methodology of the norme NF EN 1276 (March 2010) on DEPTACID WCM (clean conditions)	HYPRED	y	n
6.7	No report n° Doc 6.7-003.5	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID WCM (dirty conditions)	HYPRED	y	n
6.7	No report n° Doc 6.7-003.6	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID WCM (skimmed milk)	HYPRED	y	n
6.7	No report n° Doc 6.7-003.7	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID WCM (sucrose)	HYPRED	y	n
6.7	No report n° Doc 6.7-003.8	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID WCM (clean conditions)	HYPRED	y	n
6.7	No report n° Doc 6.7-004.1	M. Teulier LMH	2015	Bactericidal efficiency test according to the methodology of the norme NF EN 1276 (March 2010) on DEPTACID CCB	HYPRED	y	n
6.7	No report n° Doc 6.7-004.2	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID CCB	HYPRED	y	n
6.7	No report n° Doc 6.7-005.1	M. Teulier LMH	2015	Bactericidal efficiency test according to the	HYPRED	y	n

				methodology of the norme NF EN 1276 (March 2010) on DEPTACID CB			
6.7	No report n° Doc 6.7-005.2	AF. Gabillet LMH	2015	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID CB	HYPRED	y	n
6.7	5480	M. Teulier LMH	2019	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID CCB S.cerevisae	HYPRED	y	n
6.7	5479	M. Teulier LMH	2019	Yeasticidal efficiency test according to the standard NF EN 1650 + A1 (July 2013) DEPTACID CB S.cerevisae	HYPRED	y	n
8.1.1	No report n° CTX-PH-17/0334 Doc 8.1.1-001	L. Floriot Phycher Bio Developpement	2017	DEPTACID BD In vitro Membrane Barrier Test Method for Skin Corrosion	HYPRED	y	n
8.1.1	No report n° CTX-PH-17/0335 Doc 8.1.1-002	L. Floriot Phycher Bio Developpement	2017	DEPTACID CCB In vitro Membrane Barrier Test Method for Skin Corrosion	HYPRED	y	n
13	Doc 13-001	ECHA	2015	Outcome pre-submission consultation : UP-APP outcome_Hypred_2015-05-29	HYPRED	y	n
13	Doc 13-002	HYPRED	2015	Lack of efficacy of lactic acid in DEPTACID CB	HYPRED	y	n
13	Doc 13-003	SOPURA	2015	Letter of access to the Octanoic Acid dossier for PT4	HYPRED	y	n
13	Doc 13-010	HYPRED	2015	Supporting document for better understanding of the family	HYPRED	y	n
13	Doc 13-011	HYPRED	2015	Detailed description of the manufacturing and packaging of HYPRED's octanoic acid based products	HYPRED	y	n

OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

Scenario 1: emission estimation for DEPTACID CCB (Meta SPC 2)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of biocidal active substance used per year in the local plant	*Qa.i.*	1944	[kg.yr^{-1}]	Based on the information provided by the applicant
Number of emission days per year	*Temission*	360	[d .yr^{-1}]	Based on the information provided by the applicant
Fraction released to wastewater	F_{water}	1	[-]	D
Fraction of substance eliminated due to on site pre-treatment of the plant waste water	F_{elim}	0		
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D
Capacity of the off-site STP	CAP_{STP}	2000	[m^3 .d^{-1}]	D
Output				
Local Emission to waste water	*Elocal*	**5.40**	[kg/d]	O
Influent concentration of active substance in the off-site STP	$C_{influent}$	**2.70**	[mg.l^{-1}]	O
Calculation $C_{influent} = (Qa.i. / Temission) \cdot 1{,}000 \cdot (1 - F_{dis}) (1 - F_{elim}) \cdot F_{water} / CAP_{STP}$				

Scenario 2: emission estimation for HYPRACID One (Meta SPC 1)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Concentration of active ingredient	C_{form}	0.45	[$g.l^{-1}$]	S
Amount of disinfectant used for cleaning of the milking installation 130 (= 2 • 65)	$Vform_{inst}$	130	[$l.d^{-1}$]	D
Amount of disinfectant used for cleaning of the milk storage tank	$Vform_{tank}$	45	[$l.d^{-1}$]	D
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D
Fraction of the emission to waste water	F_{water}	1	[-]	D
Output				
Quantity of active ingredient used	Qa.i.	78.75	[$g.d^{-1}$]	O
Local emission to waste water	$Elocal_{water}$	**0.07875**	[$kg.d^{-1}$]	O
Model calculation				
$Qa.i. = C_{form} \bullet (Vform_{inst} + Vform_{tank})$ $Elocal_{water} = Qa.i. \bullet (1 - F_{dis}) \bullet F_{water} / 1000$				

Scenario 3: emission estimation for DEPTACID WCM (Meta SPC 4)

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of biocidal active substance used per year in the local plant	*Qa.i.*	1263.6	[$kg.yr^{-1}$]	based on the information provided by the applicant
Number of emission days per year	*Temission*	312	[$d .yr^{-1}$]	based on the information provided by the applicant
Fraction released to wastewater	F_{water}	1	[-]	D
Fraction of substance eliminated due to on site pre-treatment of the plant waste water	F_{elim}	0	[-]	D
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D
Capacity of the off-site STP	CAP_{STP}	2000	[$m^3 .d^{-1}$]	D
Output				
Local Emission to waste water	*Elocal*	**4.05**	[kg/d]	O
Influent concentration of active substance in the off-site STP	$C_{influent}$	**2.03**	[$mg.l^{-1}$]	O
Calculation				
$Elocal = (Qa.i. / T_{emission}) \cdot (1 - Fdis) \cdot (1 - F_{elim}) \cdot F_{water}$				
$C_{influent} = (Qa.i. / Temission) \cdot 1{,}000 \cdot (1 - F_{dis}) \cdot (1 - F_{elim}) \cdot F_{water} / CAP_{STP}$				

NEW INFORMATION ON THE ACTIVE SUBSTANCE

No data.

RESIDUE BEHAVIOUR

Not relevant:
Only minimal residues of the products are expected to occur in food and feed and unlikely to cause effects due to the execution of a rinsing step and due to the high dilution rate in food.

SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

Summary of the efficacy studies are presented in part 2.3.4.

CONFIDENTIAL ANNEX

Sections 3.6 – 6 can be found in the separate confidential document.

AGGREGATED EXPOSURE (COMBINED FOR RELEVANT EMMISSION SOURCES)

Since no guidance on aggregate exposure is available and this part of the PAR is therefore rudimentary, no detailed assessment is provided here.

Nevertheless, following the decision tree below an aggregated exposure assessment is triggered.

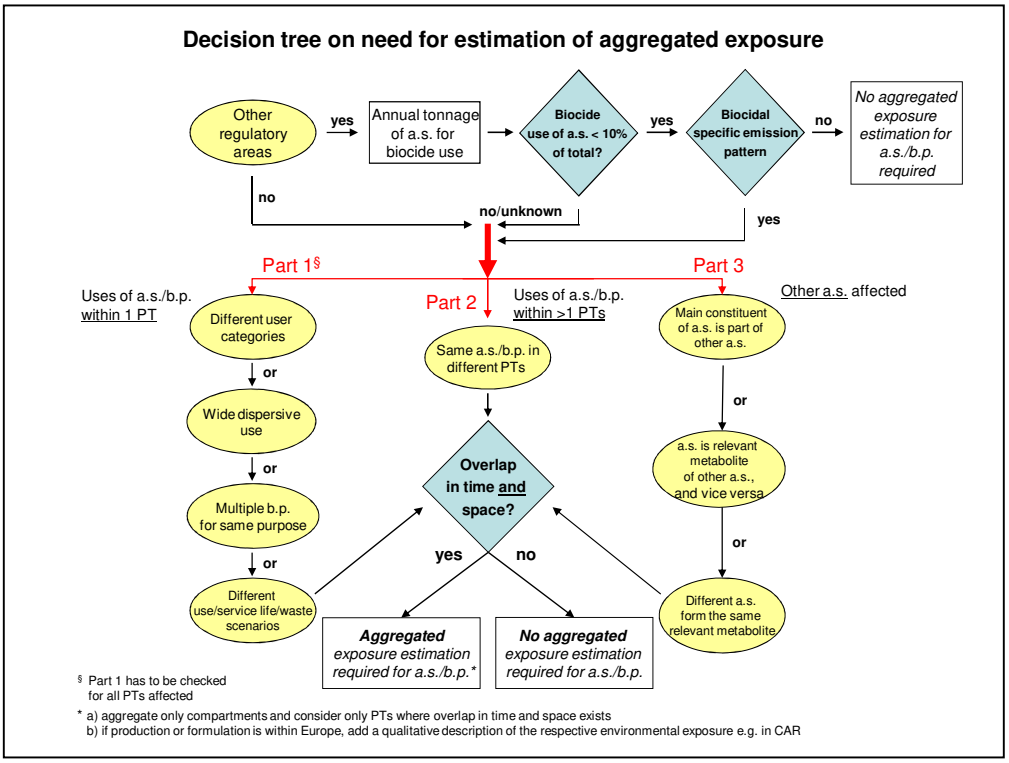


Figure 1: Decision tree on the need for estimation of aggregated exposure

The aggregated exposure assessment is applicable for the STP emission route for scenarios 1, 2 and 3. The sum of the risks for the substances octanoic acid and N,N-dimethyl-1-decamine, N-oxide (substance of concern in META SPC 3 with applications in scenario 1) for all scenarios is indicated in the table below.

$\Sigma PEC/PNEC_{STP}$	$\Sigma PEC/PNEC_{water}$	$\Sigma PEC/PNEC_{sed}$			$\Sigma PEC/PNEC_{soil}$
0.075	0.891	0.874			**3.73**

Conclusion:

The summed up PEC/PNEC for the STP, water and sediment are well below 1 and thus acceptable.

The risks for groundwater and secondary poisoning were qualitatively assessed and found acceptable.

The summed up PEC/PNEC are above 1 for soil exposed to octanoic acid and N,N-dimethyl-1-decamine, N-oxide present in sewage sludge. This is however considerd acceptable as explained elsewhere.

For the products in scenario 1 the risks for all compartments are acceptable as N,N-dimethyl-1-decamine, N-oxide is not considered to be a substance of concern in these products. The risks for all compartments are acceptable for the uses in scenarios 2 and 3.

APPENDIX I: MORE EXTENSIVE JUSTIFICATION FOR DIFFERENTIATION (RELATED TO PAGE 76: DIFFERENTIATION OF TARGET ORGANISMS BY CONTACT TIME AND DOSAGE)

Differentiation of target organisms by contact time and dosage

"In food industries, microbiological hazards are represented mainly by bacteria. It also exists hazards associated to virus and parasites. Tables 1, 2, 3 and 4 presented below list the main microbiological hazards in food industries according to FAO, WHO, EFSA/ECDC and ANSES.

No yeast is considered among the main health hazards. Only a few species are considered opportunistic pathogens for humans and animals and no strain has been at this time identified as causing food-borne diseases.
On the opposite, in some food sectors, yeasts can contribute in the manufacture of food products : dairy industries (cheese), beverage industries (beer, fruit juice), bakery (bread), other industries (biomass production and proteins)….

Yeast activity is however considered as a basic requirement for efficacy of PT4 products because some yeasts can cause in some processes manufacturing defects or organoleptic alterations of food.

In the context of good practices and control of food safety, it is essential that each professional user of disinfecting products identifies first the nature of microbiological hazards linked to food process (hazard identification, determination of acceptable levels, evaluation and management measures) before applying a biocidal product.

Indeed, professional users must optimize the use of biocide for both health and environment by making a reasonable choice of the product based on antimicrobial activity spectrum needed (bactericidal, yeasticidal…).
In case of hazards directly linked to the presence of yeasts, protocols (dose and contact time) should be adapted in order to reduce this hazard but without applying a daily overdosage on food production plant if only bactericidal activity is required.

It is therefore important for HYPRED's octanoic acid based products that the differentiation of the activity for each separated target organism by dosage and contact time appears into the instructions for use in order to answer properly to hazards occurring in food production process and in order to respect health and environment."

Table 1 : Example of biological hazard according to FAO (Food and Agriculture Organization of the United Nations).

Bacterial spores	*Clostridium botulinum* *Clostridium perfringens* *Bacillus cereus*
Non-spores bacteria	*Brucella abortis* *Brucella suis* *Campylobacter spp.* *Escherichia coli enteropathogène* (E.coli 0157, H7, EHEC, EIEC, ETEC,EPEC) *Listeria monocytogenes* *Salmonella spp. (S.typhimurium, S enteritidis)* *Shigella (S. dysenteriae)* *Staphylococcus aureus* *Streptococcus pyogenes* *Vibrio cholerae* *Vibrio parahaemolyticus* *Vibrio vulnificus* *Yersinia enterocolitica*
Virus	Hepatitis A and Hepatitis E virus Group of Norwalk virus (norovirus) Rotavirus
Protozoa and parasites	*Cryptosporidium parvum, Diphyllobotrium latum* *Entamoeba histolytica, Ascaris lumbricoides* *Giardia lamblia, Taenia solium, Taenia saginata* *Trichinella spiralis*

Table 2 : Main hazards responsible to foodborne diseases in the world according to the WHO (World Health Organization)

Bacteria	*Brucella spp* *Mycobacterium bovis* *Campylobacter spp.* *Escherichia coli entéropathogènes* *Escherichia coli entérotoxinogènes* *Escherichia coli entérohemorragiques* *Listeria spp* *Salmonella enterica non typhoïdes* *Salmonella Typhi et S paratyphy* *Shigella spp.* *Vibrio cholerae*
Virus	Hepatitis A virus norovirus
Protozoa and parasites	*Cryptosporidium spp, Entamoeba histolytica* *Ecchinococcus multilocularis, E granulosus* *Giardia spp, Ascaris spp. , Taenia solium* *Toxoplasma gondii, Clonorchis sinensis* *Doives intestinales , Fasciola spp, Trichinella spp* *Opisthorchis spp, paragominue spp..*
Fungi	*Aflatoxines,*

Source : WHO Estimate of the Global burden of Foodborne diseases. 2015

Table 3 : Main microbiological agents involved in food-borne diseases (including water) in Europe according to l'EFSA and ECDC (European Food Safety Autority , European centre for Disease prevention and Control)

Bacterial spores	*Clostridium botulinum,* *Clostridium perfringens* *Bacillus cereus*
Non-spore bacteria	*Brucella spp* *Mycobacterium bovis* *Campylobacter spp* *Escherichia coli enterohémorragiques (shiga toxin-producing E.coli)* *Listeria monocytogenes* *Salmonella spp.* Cronobacter spp *Staphylococcus aureus et entérotoxines staphylococciques* *Yersinia spp* *Vibrio spp*
Virus	Norovirus and calicivirus Hepatitis A virus , other viruses
Protozoa and parasites	*Trichinella spp - Ecchinococcus - Toxoplasma gondii* *Cryptosporidium spp - Anisakis spp - Cysticercus, Sarcocystis..*

Source : European Food safety Authority and Centre for Disease prevention and Control (EFSA and ECDC) - The European summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017. EFSA Journal 2018; 16 (12):5500 www.efsa.europe

Table 4 : List of biological hazards transmitted by food according to l'ANSES (French Agency for food, environmental and Occupational health & Safety)

Bacterial spores	*Clostridium botulinum, C. neurotoxinogènes* *Clostridium perfringens* *Bacillus cereus*
Non-spore bacteria	*Brucella spp* *Campylobacter jejuni, Campylobacter coli* *Escherichia coli enterohémorragiques* *Listeria monocytogenes* *Salmonella spp.* Cronobacter spp *Staphylococcus aureus et enterotoxines staphylococciques* *Vibrio parahaemolyticus* *Yersinia enterocolitica, yersinia pseudotuberculosis*
Virus	Hepatitis A virus – Hepatitis E virus Norovirus - Rotavirus
Protozoa and parasites	*Cryptosporidium spp, - Diphyllobotrium latum - Gardia duodenalis* *Ecchinococcus multilocularis - Toxoplasma gondii* *Entamoeba histolytica /E dispar - Cyclospora cayetanensis* *Taenia solium/ Cysticercus cellulosae - Fasciola hepatica* *Taenia saginata/Cysticercus bovis - Trichinella spp -* *Anisakis spp et Pseudoterranova spp*
Fungi	*Aspergillus flavus and other fungi producing aflatoxins* *Penicillum expansum et other fungi producing palutine* *Aspergilli et Penicillia producing'ochratoxin*