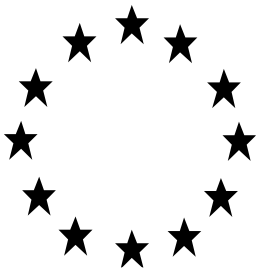
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION

submitted by the competent authority



PROCULAC

Product types 2, 4

Lactic acid as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-BX088824-03

Competent Authority: Latvia

Date: 15 January 2024

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Changes history table

Application type	eCA	Case number in the refMS	Decision date	Assessment carried out
SA-APP	LV	BC-BX088824-03	15/01/2024	First authorisation

1 Conclusion

The biocidal product *Proculac* is ready to use liquid containing the active substance Lactic acid. *Proculac* is used for disinfection of hard non-porous surfaces which are not used for direct contact with food or feeding stuffs (product type 2) and for disinfection of hard non-porous surfaces which have contact with food and feeding stuffs (product type 4). The product is used by professional and non-professional users and intended against bacteria and yeasts.

The overall conclusion of the evaluation is that *Proculac* meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the hard non-porous surfaces disinfection, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals, and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, *Proculac* does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substance Lactic acid is listed in Annex I of Regulation (EU) 528/2012;
2. The product does not contain any substance of concern;
3. The product does not contain any nanomaterials;
4. The product is sufficiently effective;
5. The handling of the product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is not necessary.

The product should be considered not to have endocrine-disrupting properties.

More information is available in section 2.8 of the PAR and in the confidential annex.

Composition

The qualitative and quantitative information on the non-confidential composition of the product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.4 of the SPC.

The manufacturer of the active substance is listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

- Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage

[1] *Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006*

and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

- Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

- Methods for detection and identification

Validated analytical method for the determination of the concentration of the active substance is available. More information on the analytical methods for the active substance is available in section 3.4 of the PAR.

- Efficacy against target organisms

The product has been shown to be efficacious against bacteria and yeasts. More information is available in section 3.5 of the PAR.

- Risk assessment for human health

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

- Dietary risk assessment

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

- Risk assessment for animal health

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

- Risk assessment for the environment

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Post-authorisation conditions

None.

2 Information on the biocidal product

2.1 Product types and type of formulation

Table 2.1 Product types and type of formulation

Product types	PT2 – Disinfectants not intended for direct application to humans or animals PT4 – Food and feed area
Type of formulation	Ready-to-use water-based liquid

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use	Use description	PT	Target organisms	Application method	Application rate	User category	Conclusion (eCA/ refMS)	Comment (eCA/refMS)
1	Disinfectant for hard clean non-porous surfaces without direct contact with food or feeding stuff	PT2	Bacteria Yeasts	Spraying and pouring	150 ml/m^2	non-professional professional	Acceptable	Not intended for medical area
2	Disinfectant for hard clean non-porous surfaces which has contact with food and feeding stuffs	PT4	Bacteria Yeasts	Spraying and pouring	150 ml/m^2	non-professional professional industrial	Acceptable	Not intended for milk industry and cold storage rooms.

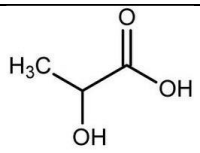
2.3 Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance(s) in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	Lactic acid
Chemical name	Lactic acid
EC number	200-018-0
CAS number	50-21-5
Index number in Annex VI of CLP	-
Minimum purity / content	-
Structural formula	

2.5 Information on the source(s) of the active substance(s)

The information on the source of the active substance is not applicable.

2.6 Candidate for substitution

Lactic acid does not meet the conditions laid down in Article 10 of Regulation (EU) No. 528/2012, and therefore is not considered as a candidate for substitution.

Lactic acid is listed in Annex I of the Regulation (EU) No 528/2012 under the Category 1 – Substances authorized as food additives according to Regulation (EC) No 1333/2008.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

For Lactic acid no ED assessment is required because active substance is included in Annex I of the BPR.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) No 2017/2100 were identified for the non-active substances contained in the biocidal product. More details are presented in the confidential annex.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	**Labelling**
Hazard Class and Category code	No classification according to CLP Regulation (EC) No 1272/2008	N/A
Hazard Pictograms	N/A	
Signal word	N/A	N/A
Hazard statements	N/A	N/A
Precautionary statements	N/A	N/A
Supplemental hazard statements	N/A	

2.9 Letter of access

For Lactic acid CAS 50-21-5 no LoA is required because active substance is included in Annex I of the BPR- Category 1.

2.10 Data submitted in relation to product authorisation

Please refer to the reference list in Annex 1 for a list of studies for the biocidal products.

2.11 Similar conditions of use across the Union

For simplified authorisation application this section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging[3]	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	25 L	HDPE	Cap HDPE	Professional & non-professional, industrial	Yes
Bottle	5 L	HDPE	Cap HDPE	Professional & non-professional industrial	Yes
Bottle	1 L	HDPE	Cap HDPE	Professional & non-professional industrial	Yes
HDPE – Hight density polyethylene					

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa	Visual	[redacted] 0.9% (w/w) AS	Transparent liquid	[redacted] Report No. SS_2022_106
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual	[redacted] 0.9% (w/w) AS	Liquid	[redacted] Report No. SS_2022_106
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual	[redacted] 0.9% (w/w) AS	Transparent – colorless	[redacted] Report No. SS_2022_106
3.1.3.	Odour at 20 °C and 101.3 kPa	No distinct odour	[redacted] 0.9% (w/w) AS	No distinct odour	[redacted] Report No. SS_2022_106
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3 CIPAC MT 191	[redacted] 0.9% (w/w) AS	pH=2.5 Acidity=0.5 g/100g (as H_2SO_4)	[redacted] Report No. SS_2022_106
3.3.	Relative density	EEC Method A3 (at 20 °C)	[redacted] 0.9% (w/w) AS	1.003	[redacted] Report No. SS_2022_106
3.4.1.1.	Storage stability test – **accelerated storage**	CIPAC MT 46.4 Storage for 2 weeks at 54°C. Tested packaging: 1 L HDPE bottle	[redacted] 0.9% (w/w) AS	<u>Lactic acid content</u>: T_0: 0.84-0.85% w/w T_{14}: 0.87-0.88% w/w <u>pH:</u> T_0: 2.5 T_{14}: 2.3	[redacted] Report No. SS_2022_106

[2] *The tested item [redacted] is identical to biocidal product Proculac.*

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				Acidity: T_0: 0.5 g/100g (as H_2SO_4) T_{14}: 0.5 g/100g (as H_2SO_4) Weigt loss = 0.01% Appearance of the tested samples did not change after 2 weeks of storage at 54°C. No signs of deformation, leak, discolouration was observed after 2 weeks.	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	CIPAC MT 46.4 Storage at ambient temperature (25°C/60% RH) for 1 year Tested packaging: 1 L HDPE bottle	[redacted] 0.9% (w/w) AS	Lactic acid content: T_0: 0.84-0.85% T_{12m}: 0.86-0.87% pH: T_0: 2.5 T_{12m}: 2.4 Acidity: T_0: 0.5 g/100g (as H_2SO_4) T_{12m}: 0.5 g/100g (as H_2SO_4) Weigt loss = 0.07% Appearance of the tested samples did not change after 12	[redacted] Report No. SS_2022_106

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				months of storage at 25°C/60% RH. No signs of deformation, leak, discolouration was observed after 12 months.	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 Storage at 0 °C for one week	[redacted] [redacted] [redacted] 0.9% (w/w) AS	Appearance of the tested samples did not change. No precipitation, separation or flocculation was observed.	[redacted] Report No. SS_2022_106
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	Opaque packaging. According to literature Lactic acid don't undergo direct photolysis in sunlight.	waiver
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Product is water-based and packaging is closed. No effect of humidity is expected. No effect is expected in normal conditions of storage. See results of accelerated and 1 year storage for confirmation.	waiver

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.4 Storage for 2 weeks at 54°C Storage at ambient temperature (25°C/60% RH) for 1 year. Tested packaging: 1 L HDPE bottle	[redacted] 0.9% (w/w) AS	No signs of deformation, leak, discolouration was observed after 2 weeks at 54°C or after 12 months at 25°C/60% RH. HDPE is resistant to Lactic acid.	[redacted] Report No. SS_2022_106
3.5.1.	Wettability	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.3.	Wet sieve analysis and dry sieve test	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.5.	Disintegration time	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	-	Product is a ready to use liquid. Although the product can be used in spray applications, it is not sold in or together with spraying equipment. The risk assessment	waiver

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				is not requested under the simplified procedure. The MMAD is not relevant to demonstrate efficacy.	
3.5.7.	Persistent foaming	-	-	Product is ready-to-use and not diluted with water prior to use.	waiver
3.5.8.	Flowability/pourability/dustability	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.9.	Burning rate — smoke generators	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.10.	Burning completeness — smoke generators	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.11.	Composition of smoke — smoke generators	-	-	Product is ready-to-use liquid formulation.	waiver
3.5.12.	Spraying pattern — aerosols / spray	-	-	Product is not aerosol	waiver
3.6.1.	Physical compatibility	-	-	Not applicable, product not to be mixed with other products.	waiver
3.6.2.	Chemical compatibility	-	-	Not applicable, product not to be mixed with other products.	waiver
3.7.	Degree of dissolution and dilution stability	-	-	Product is ready-to-use liquid formulation.	waiver
3.8.	Surface tension	OECD 115	[redacted]	33.3 mN/m	[redacted] Report No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			[redacted] 0.9% (w/w) AS		SS_2022_106
3.9.	Viscosity	OECD 114	[redacted] 0.9% (w/w) AS	1.1 mPa*s at 20 °C 0.75 mPa*s at 40 °C	[redacted] Report No. SS_2022_106

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is colourless ready-to-use liquids. The pH is 2.5. The product is surface active. The density is 1.003. The viscosity at 20°C is 1.1 mPa*s. The product is stable for 14 days at 54°C and for 12 months at room temperature. No changes in the appearance of the tested item occur or content of active substance. **Shelf life:** 24 months at room temperature.

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
4.1.	Explosives	-	-	The explosives properties are screened based on composition and structural considerations of active substance and co-formulant. More detailed information can be found in Conf. Annex to the PAR. The product contains a large amount of water which is considered as phlegmatizer of explosive properties. No further testing is needed. Not explosive.	waiver
4.2.	Flammable gases	-	-	Not applicable, product is a liquid.	waiver
4.3.	Flammable aerosols	-	-	Not applicable, product is not an aerosol.	waiver
4.4.	Oxidising gases	-	-	Not applicable, product is a liquid.	waiver
4.5.	Gases under pressure	-	-	Not applicable, the product is a liquid, not a gas under pressure.	waver
4.6.	Flammable liquids	EU A.9 - closed cup	[redacted] [redacted] [redacted] 0.9% (w/w) AS	No flash point was detected below 100°C. The product is not flammable.	[redacted] Report No. DNA 7379
4.7.	Flammable solids	-	-	Not applicable, product is a liquid.	waiver
4.8.	Self-reactive substances and mixtures	-	-	The self-reactive properties are screened based on composition and structural considerations of active substance and co-formulant. More detailed information can be found in Conf. Annex to the PAR.	waiver

[3] *The tested item [redacted] is identical to biocidal product Proculac.*

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
				The product contains a large amount of water. No further testing is needed. Not self-reactive.	
4.9.	Pyrophoric liquids	-	-	According to the SDSs provided by the suppliers, none of the component of the product is classified as pyrophoric liquid. The product itself is high diluted aqueous solution and the long experience of the applicant in handling the products confirms no concern related to pyrophoric properties. As well, during the stability studies at a temperature of 54°C during two weeks, the product is not spontaneously ignited when in contact with air.	waiver
4.10.	Pyrophoric solids	-	-	Not applicable, product is a liquid.	waiver
4.11.	Self-heating substances and mixtures	-	-	According to the Guidance on the application of the CLP criteria, section 2.11.4.2, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating.	waiver
4.12.	Substances and mixtures which in contact with water emit flammable gases	-	-	Not applicable, product is a liquid.	waiver
4.13.	Oxidising liquids	-	-	Oxidising properties are not anticipated due the structural composition of active substance and co-formulant. More detailed information can be found in Conf. Annex to the PAR.	waiver
4.14.	Oxidising solids	-	-	Not applicable, product is a liquid.	waiver
4.15.	Organic	-	-	The products do not contain organic peroxides.	waiver

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
	peroxides				
4.16.	Corrosive to metals	UN manual of tests and criteria Part III, 37.4 (test C.1)	PROCULAC [redacted] 0.9% (w/w) AS	Not classified as corrosive to metals. The product shows a negative result for corrosion to metal. After 7 days of testing: Aluminium: max 1.80% (100% liquid) Steel: max 7.1% (100% liquid) The weight loss is below the threshold of 13.5%. No localizes corrosion has been observed. Therefore, no metallographic analyses were needed.	[redacted] Report No. 22/000369346
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	EEC A.15	[redacted] 0.9% (w/w) AS	The flash point measured is > 100°C. Moreover, the product is known to be stable at room temperature and do not ignite spontaneously. This waiving is supported by the result of a study, stating that auto-ignition temperature is not below 400°C.	[redacted] (2023) Report No. DNA 7491
4.17.2.	Relative self-ignition temperature for solids	-	-	Not applicable, product is a liquid.	waiver
4.17.3.	Dust explosion hazard	-	-	Not applicable, product is a liquid.	waiver

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for any physical hazards.

3.4 Methods for detection and identification

This section is not required for an application in accordance with Article 25 of the Regulation (EU) No 528/2012. However, since the method is being used for the storage stability tests, it has been validated.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
The validation of the analytical method was performed in terms of specificity, linearity, accuracy and repeatability according to SANCO 3030/99 rev.5 guidelines. Analysis is done by HPLC-UV equipped with automatic autosampler, thermostated column compartment.											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Lactic acid	N=5 R^2 = 1.00 Linearity validated in the range 0.69 – 1.89 g/100g	UV-Spectrum	1	5	96-99	98	1.14	0.84%	5	-	[redacted] Report No. 22.524315.0002

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method (SANCO 3030/99 rev.5 guidelines) for the determination of Lactic acid in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. Active substance not classified as toxic or very toxic. In additional, the following points are considered: • Lactic acid is a naturally occurring alpha-hydroxy acid. Lactic acid is normally found in the blood and interstitial fluid of humans at a level of 10 mg/dl (U.S. EPA, 2008). • Lactic acid approved for use as a food additive (E270) according Regulation (EU) No. 1333/2008. Lactic acid has been approved in the EU as a food additive without an ADI or upper limit (Directive 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMA 2008). • Lactic acid also occurs naturally in the soil. Furthermore, Lactic acid is ubiquitous in the environment from natural and man-made sources making it impossible to determine the exact source.

3.5 Assessment of efficacy against target organisms

PROCULAC is developed based on Lactic acid as an active substance which provides efficacy of the biocidal product. The efficacy studies on bactericidal and yeasticidal activity have been performed with a concentrated biocidal product containing 2.9% w/w Lactic acid. The tested product has the same backbone formulation. In practise, Proculac is simply 30% v/v dilution of tested formulation. Therefore, the read-across between two formulations is applicable. More details in confidential annex to the PAR.

The applied standards for suspension (phase 2, step 1) and quantitative non-porous surface (phase 2, step 2) tests are appropriate to support the claim for the evaluation of bactericidal and yeasticidal activity.

The following standards were used:

- EN 1276:2019 – Chemical disinfectant and antiseptics. Quantitative suspension test of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial domestic and institutional areas – Test method and requirements (phase 2, step 1).
- EN 13697:2019 - Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2).
- EN 1650:2019 - Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)

Efficacy has been successfully demonstrated for the intended uses and target organisms. Full details of the test conditions, test results and necessary statements are provided.

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

PROCULAC is used for disinfection of hard clean non-porous surfaces removing bacteria and yeasts (PT2 and PT4).

The product is applied by fully wetting all hard clean non-porous surface via spraying or pouring. In case of pouring the silicone or rubber window/floor wiper is used for product distribution[4]. The pouring is intended for large surfaces (e.g. tables, floors).

Application rate: Apply the product by fully wetting all surface (apply approx. 150 ml per 1 m^2)[5].

Product type 2 – domestic and institutional area. Professional and non-professional users. The product is not intended to be used in the healthcare area.

Product type 4 - domestic, institutional and industrial area with a direct contact with food and feed, including the meat industry (early markets, mass caterers, meat shops and processors, fish shops, slaughterhouses). Professional and non-professional users. The product is not intended to be used in the milk industry.

[4] The product is applied onto surface by pouring, followed by spreading over the surface using a silicone or rubber window or floor wiper, as a way of distributing the product without any real mechanical action. As no wipes/mops are proposed for product distribution, no test in line with EN 16615 is needed.
[5] The application rate was set based on drying test.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

In solution, Lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the Lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported. Decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.

3.5.3 Efficacy data

Table 3.8 Efficacy data

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference**	**Number in IUCLID section 6.7/Test report title**
PT2 & PT4 Use 1 Use 2	[redacted] 2.9% (w/w) Lactic acid	Bactericidal activity: *- Escherichia coli ATCC 10536* *- Enterococcus hirae ATCC 10541* *- Staphylococcus aureus ATCC 6538* *- Pseudomonas aeruginosa ATCC 15442* *- Salmonella typhimurium ATCC 13311*	EN 1276 (2019) phase 2, step 1 test Concentrations tested: undiluted (80%), 30% (v/v), 1 % (v/v) Diluent: distilled water Contact time: 2-5 min Dirty condition[6] (3 g/L BSA) Temperature 20°C [redacted]	The undiluted and 30 % (v/v) product demonstrated > 5 log reduction for all bacterial species tested under dirty conditions and both tested contact times (2 and 5 min). Acceptance criteria for test results, as given in EN 1276 fulfilled	[redacted] Report No.23/000064339	EN 1276 - bacteria
PT2 & PT4 Use 1 Use 2	[redacted] 2.9% (w/w) Lactic acid	Yeasticidal activity: *- Candida albicans ATCC 10231*	EN 1650 (2019) phase 2, step 1 test Concentrations tested: undiluted (80%), 30% (v/v), 1 % (v/v) Diluent: distilled water Clean condition (0.3 g/L BSA)	The undiluted product demonstrated > 4 log reduction for yeast species tested under clean conditions and both tested contact times (30 and 60 min).	[redacted] Report No.23/000067851	EN 1650 - Yeasts

[6] The product is intended to be used on pre-cleaned surfaces. The testing under the dirty conditions covers the clean conditions.

			Contact time: 30-60 min Temperature: 20°C [redacted]	The 30 % (v/v) product demonstrated > 4 log reduction for yeast species tested under clean conditions and both tested contact times (60 min). Acceptance criteria for test results, as given in EN 1650 fulfilled		
PT2 & PT4 Use 1 Use 2	[redacted] 2.9% (w/w) Lactic acid	Bactericidal activity: *- Escherichia coli ATCC 10536* *- Enterococcus hirae ATCC 10541* *- Staphylococcus aureus ATCC 6538* *- Pseudomonas aeruginosa ATCC 15442* *- Salmonella typhimurium ATCC 13311*	EN 13697 (2019) phase 2, step 2 test Concentrations tested: undiluted (100%), 30% (v/v), 1 % (v/v) Diluent: distilled water Contact time: 5-15-30 min Clean condition (0.3 g/L BSA) Temperature 20°C [redacted]	The undiluted and 30 % (v/v) product demonstrated > 4 log reduction for all bacterial species tested under clean conditions and all tested contact times (5, 15 and 30 min). Acceptance criteria for test results, as given in EN 13697 fulfilled	[redacted] Report No.23/000059760	EN 13697 - Bacteria
PT2 & PT4 Use 1 Use 2	[redacted] 2.9% (w/w) Lactic acid	Yeasticidal activity: *- Candida albicans ATCC 10231*	EN 13697 (2019) phase 2, step 2 test Concentrations tested: undiluted (100%), 30% (v/v), 1 % (v/v) Clean condition (0.3 g/L BSA) Diluent: distilled water Contact time: 30-60 min	The undiluted product demonstrated > 3 log reduction for yeast species tested under clean conditions and both tested contact times (30 and 60 min). The 30 % (v/v) product	[redacted] Report No.23/000067860	EN 13697 - Yeasts

			Temperature: 20°C [redacted]	demonstrated > 3 log reduction for yeast species tested under clean conditions and both tested contact times (60 min). Acceptance criteria for test results, as given in EN 13697 fulfilled		

3.5.4 Efficacy assessment

The efficacy was demonstrated according to EN Standard methods for phase 2, step 1 tests (EN 1276 and EN 1650) and phase 2 step 2 test (EN 13697) for undiluted and 30% v/v dilution of concentrated product which covers the claimed PROCULAC composition (0.9% active substance content).

3.5.5 Conclusion on efficacy

The ready-to-use product (PROCULAC) meets the bactericidal and yeasticidal activity for PT2 and PT4 under the clean conditions (pre-cleaning is necessary) at room temperature.

Contact time:

- PT2: 5 min against bacteria (mandatory organism)
- PT2: 60 min against yeasts (optional organism)

As the product is intended to be used by professional and non-professional users it is not feasible to differentiate target organisms by contact time. The claimed contact time is 60 minutes.

- PT4: 5 min against bacteria (mandatory organism)
- PT4: 60 min against yeasts (mandatory organism)

As both target organisms are mandatory it is not possible to differentiate target organisms by contact time. The claimed contact time is 60 minutes.

Application rate: According to field study (drying test) after the application of PROCULAC at an application rate of 150 ml/m², the surface remains wet throughout the entire contact time of 60 minutes.

3.5.6 Occurrence of resistance and resistance management

Development of resistance is considered unlikely due to the non-specific mode of action. Moreover, according to information included in the scientific literature (Theron MM., 2010) concludes that no clear scientific evidence exists that target organisms have developed resistance against the organic's acid, such as Lactic acid.

3.5.7 Known limitations

No limitation on efficacy was detected.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

Not relevant.

3.6 Risk assessment for human health

For simplified authorisation, data related to human health are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

The product does not contain substances that meet any of the criteria defined in the EU SoC guidance (CA-Nov14-Doc.5.11).

3.6.1 Assessment of effects on human health

There are no human health data available for the products.

However, to support non-classification, an evaluation has been performed applying the principles related to the mixture indicated in the CLP Regulation (EC No.1272/2008).

3.6.1.1 Skin corrosion and irritation

Table 3.9 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	No corrosive or irritating to skin
Justification for the value/conclusion	Criteria: • in the absence of any other information, a mixture is considered corrosive to skin (Skin Corrosion Category 1) if it has a pH ≤ 2; • a mixture is considered corrosive to skin if the sum of all ingredients of a mixture classified as Skin Corrosion is ≥ 5 %. • a mixture is considered irritant to skin if the sum of all ingredients of a mixture classified as Skin Corrosion / Irritation is ≥ 1 %. The pH value of the products is > 2.0. Also, considering the content of active substance and co-formulant in the product, no classification is needed. More details in Confidential annex to the PAR.
Classification of the product according to CLP	No classification required.

Table 3.7 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.1, Skin corrosion or skin irritation
Justification	The exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the biocidal product themselves is not required.

3.6.1.2 Eye irritation

Table 3.11 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eye
Justification for the value/conclusion	Criteria: ○ in the absence of any other information, a mixture is considered to cause serious eye damage (Category 1) if it has a pH ≤ 2; ○ a mixture is classified skin corrosive, category 1; ○ a mixture is considered as Serious Eye Damage if the sum of all ingredients of a mixture classified as Serious Eye Damage is ≥ 3 %. ○ a mixture is considered as Eye irritation if the sum of all ingredients of a mixture classified as Serious Eye Damage / Eye Irritation is ≥ 1 %. The pH value of the product is > 2.0. The product is not classified Skin corr. 1. Also, considering the content of active substance and co-formulant in the product, no classification is needed. More details in Confidential annex to the PAR.
Classification of the product according to CLP	No classification required.

Table 3.8 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.2, Eye irritation
Justification	The exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the biocidal product themselves is not required.

3.6.1.3 Respiratory tract irritation

Table 3.9 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	According to the CLP Regulation Section 3.8.3.4.5., when extrapolating toxicity of a mixture that contains Category 3 ingredient for specific target organ toxicity after single exposure, a generic concentration limit of 20 % is appropriate. Based on available data on the composition of the product and according to the classification rules laid down in the CLP regulation, no classification for the respiratory tract irritation is required.
Classification of the product according to CLP	No classification required.

Table 3.14 Data waiving

Data waiving	
Information requirement	There are no testing requirements for respiratory irritation under the BPR.
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory tract irritation. The assessment is based on the available data on the composition of the product and according to the classification rules laid down in the CLP Regulation.

3.6.1.4 Skin sensitization

Table 3.10 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	According to the CLP regulation Section 3.4.3.3, a mixture shall be classified as skin sensitizer when at least one ingredient has been classified as skin sensitizer and it is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 of CLP. The active substance and co-formulant is not classified as skin sensitizers.
Classification of the product according to CLP	No classification required.

Table 3.16 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.3, Skin sensitisation
Justification	the exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixture can be made according

	to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the of the biocidal product themselves is not required.

3.6.1.5 Respiratory sensitization

Table 3.17 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitisers
Justification for the value/conclusion	The product does not include any respiratory sensitisator.
Classification of the product according to CLP	No classification required.

Table 3.18 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.4, Respiratory sensitization (ADS)
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. The assessment is based on the available data on the composition of the products of the BPF and according to the classification rules laid down in the CLP Regulation.

3.6.1.6 Acute oral toxicity

Table 3.19 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acute oral toxic
Justification for the selected value	Based on available data on the composition of the product and according to the classification rules laid down in the CLP regulation, no classification is required for the acute toxicity by oral route as active substance and co-formulant is not classified as Acute Tox. (oral).
Classification of the product according to CLP	No classification required.

Table 3.20 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1, Acute toxicity by oral route
Justification	The exact composition is known. For each of the individual component in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the biocidal product themselves is not required.

3.6.1.7 Acute inhalation toxicity

Table 3.21 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acute inhalation toxic
Justification for the selected value	Based on available data on the composition of the product and according to the classification rules laid down in the CLP regulation, no classification is required for the acute toxicity by inhalation as active substance and co-formulant is not classified as Acute Tox. (inhalation).
Classification of the product according to CLP	No classification required.

Table 3.22 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2, Acute toxicity by inhalation
Justification	The exact composition is known. For each of the individual component in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the biocidal product themselves is not required.

3.6.1.8 Acute dermal toxicity

Table 3.23 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acute dermal toxic
Justification for the selected value	Based on available data on the composition of the product and according to the classification rules laid down in the CLP regulation, no classification is required for the acute dermal toxicity as active substance and co-formulant is not classified as Acute Tox. (dermal).
Classification of the product according to CLP	No classification required.

Table 3.24 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3 "Acute toxicity by dermal route"
Justification	The exact composition is known. For each of the individual components in the product, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the biocidal product themselves is not required.

3.6.2 Information on dermal absorption

Table 3.25 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.6 "Dermal absorption"
Justification	For simplified authorisation, data related to dermal absorption are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.3 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).

3.6.4 Other

3.6.4.1 Food and feeding stuffs studies

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.4.3 Other test(s) related to the exposure to humans

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.5 Available toxicological data relating to endocrine disruption

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.

The product contains Lactic acid as the active substance and 1 co-formulant as mixture. The product was not tested for potential endocrine disruption properties.

For Lactic acid no ED assessment is required because active substance is included in Annex I of the BPR.

A screening phase for co-formulant composed of two ingredients was performed by the Applicant. The co-formulant is not subject to a decision regarding endocrine disrupting properties. For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

3.6.6 Exposure assessment and risk characterisation for human health

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.7 Monitoring data

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.8 Dietary risk assessment

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.6.10 Overall conclusion on risk assessment for human health

The product meets the criteria for simplified authorization and no classification is proposed for human health, as the criteria for classification under Regulation (EC) 1272/2008 are not met. Therefore, there is no concern and risk regarding the human health.

3.7 Risk assessment for animal health

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8 Risk assessment for the environment

Risk assessment for the environment is not required for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

No studies are provided for the product.

Lactic acid is not classified for environmental hazards.

However, to support no environmental hazard associated to the product, an evaluation related to acute and chronic aquatic toxicity of co-formulant has been performed applying the principles related to the mixture indicated in the CLP regulation.

According to SDS, co-formulant is classified for environmental hazards (Acute Chronic).

Following to method described in Section 4.1.3.5.5 of CLP regulation, the concentration of the component multiplied by corresponding M-factors is lower than 25% for all sub-categories. More details in Confidential annex to the PAR.

Therefore, the product is not classified for environmental hazards.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

Not relevant.

3.8.1.2 Endpoints for the product

Not relevant.

3.8.1.3 Substance(s) of concern

No substances of concern regarding environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). More details in confidential annex to the PAR.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

A screening phase for co-formulant was performed by the Applicant. The co-formulant is not subject to a decision regarding endocrine disrupting properties. For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

3.8.2 Emission estimation

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8.3 Exposure calculation and risk characterisation

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8.4 Primary and secondary poisoning

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8.5 Mixture toxicity

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8.6 Aggregated exposure (combined for relevant emission sources)

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8.7 Overall conclusion on the risk assessment for the environment

The product meets the criteria for simplified authorization and no classification is proposed for environment, as the criteria for classification under Regulation (EC) 1272/2008 are not met. Therefore, there is no concern and risk regarding the environmental hazards.

3.9 Assessment of a combination of biocidal products

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.10 Comparative assessment

Not relevant for simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

4 Appendices

4.1 Calculations for exposure assessment

No calculation is needed as the product is eligible for simplified authorization.

4.2 New information on the active substance and substance of concern

No new information on the active substance(s) is available.

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
[redacted]	2022	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour) 3.2 Acidity, alkalinity (pH) 3.3 Relative density (liquids) and bulk, tap density (solids) (relative density) 3.4.1 Storage stability tests (storage stability and reactivity towards container	Appearance (at 20°C and 101.3 kPa).001 Acidity, alkalinity.001 Relative density (liquids) and bulk, tap density (solids).001 Storage stability tests.001 Surface tension.001 Viscosity.001	Stability Study Report (T14dd) - PROCULAC Report No.: SS_2022_106 ; Study No.: SS_2022_106	Study report	[redacted]	No	Yes

		material) 3.8 Surface tension (surface tension) 3.9 Viscosity (viscosity)						
[redacted]	2023	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Storage stability tests.001	Stability Study Interim Report (12 Months) - PROCULAC - Batch M-PL00001 Report No.: SS_2022_106	Study report	[redacted]	No	Yes
[redacted]	2023	4.6 Flammable liquids (flash point of flammable liquids)	Flammable liquids.001	Certificate of Analysis of PROCULAC Formulation to determine the Flashpoint using EEC A9 - Screening of PROCULAC for Flash Point Report No.: DNA7379	Study report	[redacted]	No	Yes
[redacted]	2023	4.16 Corrosive to metals (corrosive to metals)	Corrosive to metals.001	Determination of the corrosivity to metals of PROCULAC (Project Globuz-Ede-2200001) test sample Report No.: 22/000369346	Study report	[redacted]	No	Yes

[redacted]	2023	4.17 Auto-ignition temperature	Auto-ignition temperature (liquids and gases).001	Certificate of Analysis of [redacted] Formulation to Determinethe Auto-IgnitionTemperature using EEC A15. Report No.:DNA7491	Study report	[redacted]	No	Yes
[redacted]	2022	5 Methods of detection and identification (methods for the analysis of the (formulated) product)	Methods of detection and identification.001	Validation of the analytical procedure for the determination of the active substance Lactic acid (CAS 50-21-5) in the product "PROCULAC" by HPLC-UV Report No.: 22.524315.0002	Study report	[redacted]	Yes	Yes
[redacted]	2023	6.7 Efficacy data to support these claims (efficacy data)	EN 1276 - bacteria	PROCULAC - Evaluation of bactericidal activity according to BS EN 1276:2019 Report No.: 23/000064339	Study report	[redacted]	No	Yes
[redacted]	2023	6.7 Efficacy data to support these claims (efficacy data)	EN 13697 - bacteria	PROCULAC - Evaluation of bactericidal activity for general and specific purpose disinfection according to BS EN 13697:2015 + A1:2019 Report No.: 23/000059760	Study report	[redacted]	No	Yes

[redacted]	2023	6.7 Efficacy data to support these claims (efficacy data)	EN 1650 - Yeasts	PROCULAC - Evaluation of yeasticidal activity for general purpose disinfection according to BS EN 1650:2019 Report No.: 23/000067851	Study report	[redacted]	No	Yes
[redacted]	2023	6.7 Efficacy data to support these claims (efficacy data)	EN 13697 - Yeasts	PROCULAC - Evaluation of yeasticidal activity for general purpose disinfection according to BS EN 13697:2015 + A1:2019 Report No.: 23/000067860	Study report	[redacted]	No	Yes
[redacted]	2023	6.7 Drying test	Drying test	Drying test	Study report	[redacted]	No	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

4.4.2 Guidance documents

- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C), 2022
- Guidance on the BPR: Volume II Efficacy (Part A), 2022
- Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), 2023

4.4.3 Legal texts

- Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation, BPR)
- Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP)

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.