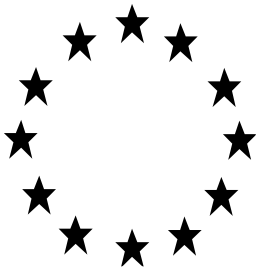
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR SIMPLIFIED AUTHORISATION APPLICATION

(submitted by the competent authority)



SALVESAFE H

Product type 1

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

Case Number in R4BP: BC-PB075365-42

Competent Authority: Latvia

Date: 1 August 2023

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Changes history table

Application type	eCA	Case number in the refMS	Decision date	Assessment carried out
SA-APP	LV	BC-PB075365-42	5 December 2022	First authorisation
SA-NPF	LV	BC-QF083799-14	26 January 2023	Notification of product in product family for simplified authorisation
SA-MIC	LV	BC-CU085557-08	8 May 2023	Simplified authorisation minor change on request: - addition of a new perfume; - notification of product in product family
SA-NPF	LV	BC-LV086976-88	1 August 2023	Notification of product in product family for simplified authorisation

1 Conclusion

The BPF SALVESAFE H consists of products containing the active substance Lactic acid. The products are ready to use liquids. The BPF is used for hand disinfection by industrial, professional and non-professional users for the control of bacteria, yeasts and enveloped viruses.

The BPF consists of 1 meta-SPC.

The overall conclusion of the evaluation is that the BPF meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the hand 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 of the BPF as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the BPF 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, the BPF 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 BPF does not contain any substance of concern;
3. The BPF does not contain any nanomaterials;
4. The BPF is sufficiently effective;
5. The handling of the BPF 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 BPF 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 BPF 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 products 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 and transportation of the biocidal products. More information is available in section 3.2 of

[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

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 BPF has been shown to be efficacious against bacteria, yeasts and enveloped viruses. 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

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

Description	Due date
Data showing satisfactory chemical and physical properties for the product after ambient storage in the commercial packaging for the required shelf life (24 months) must be provided. The specification proposed and properties tested should be in accordance with "Guidance on information requirements" (ECHA, Nov. 2014). All relevant properties should be determined prior to and after storage.	No later than 18 months after the authorisation date.

2 Information on the biocidal product family

2.1 Product type and type of formulation

Table 2.1 Product type and type of formulation

Product type	PT 1 - Human hygiene (Disinfectants)
Type(s) of formulation	AL - other liquids

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 BPF

Use	Use description	PT	Target organisms	Application method	Application rate	User category	Conclusion
1	Disinfectant soap for hands	PT 1	Bacteria Yeasts Enveloped viruses	Foaming Manual	3 mL	non-professional professional industrial	Acceptable

2.3 Similarity of the group of products for which the authorisation as a biocidal product family is sought

Information on the similarity of composition is provided in the confidential annex.

Table 2.3 Overview regarding the similarity of the intended uses

Use number	Product type	Reference[1]	Use pattern[2]
1	PT1	#1	Human hygiene

[1, 2] As indicated in the Note for Guidance "Implementing the concept of biocidal product family" (CA-July19-Doc4.2-Final).

Only one intended use is claimed by the applicant. All products of the BPF have a similar level of risk and efficacy.

2.4 Identity and composition

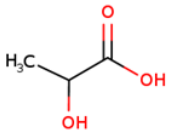
The determination whether the identity and composition of the biocidal products within the BPF are identical or not identical to the identity and composition of the products evaluated in connection with the inclusion of the active substance in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the meta-SPC and of the individual products is detailed in sections 2.1 and 7.0 of the SPC,

respectively. Information on the full composition is provided in the confidential annex.

2.5 Identity of the active substance

Table 2.4 Identity of the active substance

Main constituent	
Common name	Lactic acid
Chemical name	2-hydroxypropanoic acid
EC number	200-018-0
CAS number	50-21-5
Index number in Annex VI of CLP	-
Minimum purity / content	-
Structural formula	

2.6 Information on the source of the active substance

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

2.7 Candidate(s) for substitution

Lactic acid is not candidate for substitution. Lactic acid is listed in Annex I of Regulation EU No.528/2012 Category I.

2.8 Assessment of the endocrine-disrupting properties of the biocidal product family

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 BPF.

2.9 Classification and labelling

Table 2.5 Classification and labelling of the BPF

Meta SPC 1	**Classification**	**Labelling**
Hazard Class and Category code	none	none
Hazard Pictograms	none	none
Signal word(s)	none	none
Hazard statements	none	none
Precautionary statements*	none	none
Supplemental hazard statements	none	
Notes	none	

2.10 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.

2.11 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.

2.12 Similar conditions of use across the Union

For simplified authorisation application this section is not relevant.

3 Assessment of the biocidal product family

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	0.05 to 2 litres	HDPE or LDPE or PET or PE or PP	Pump head, PP-PE	Professional Industrial Non-professional	YES
Drum	10 to 210 litres	HDPE	CAP, HDPE/PE	Professional Industrial	YES
Jerry can	1 to 5 litres	HDPE or LDPE	CAP, HDPE/PE	Non-professional	YES
Jerry can	1 to 60 litres	HDPE or LDPE	CAP, HDPE/PE	Professional Industrial	YES
Pouches	0.05 to 5 litres	LDPE or LLDPE	Cap pump, PP-PE	Professional Industrial Non-professional	YES
Doypack	1 to 2 litres	PE	CAP, PE	Professional Industrial Non-professional	YES
PET – polyethylene terephthalate; PE – Polyethylene; HDPE – Hight density polyethylene; LDPE - Low density polyethylene; LLDPE - Linear low density polyethylene; PP – Polypropylene					

3.2 Physical, chemical, and technical properties

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Nevertheless, the applicant provided data for all products within family.

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, Colour and Odour at 20 °C and 101.3 kPa	Visual check and Organoleptic examination	All products within family (1.98% w/w of Lactic acid)	Salvesafe H0	Colourless liquid with characteristic odour	Revol B., Hisiger S. (2022) No. 2022/077
				Salvesafe H1	Colourless liquid with minty odour	Revol B., Hisiger S. (2022) No. 2022/078
				Salvesafe H2	Colourless liquid with apple odour	Revol B., Hisiger S. (2022) No. 2022/079
				Salvesafe H3	Colourless liquid with almond odour	Revol B., Hisiger S. (2022) No. 2022/080
				Salvesafe H4	Light yellow liquid with honeysuckle odour	Revol B., Hisiger S. (2022) No. 2022/081
				Salvesafe H5	Light yellow liquid with vanilla-coconut odour	Revol B., Hisiger S. (2022) No. 2022/082
				Salvesafe H6	Light yellow liquid with green-floral odour	Revol B., Hisiger S. (2022) No. 2022/083
				Salvesafe H7	Light yellow liquid with coco odour	Revol B., Hisiger S. (2022) No. 2022/084
				Salvesafe H8	Colourless liquid with raspberry odour	Revol B., Hisiger S. (2022) No. 2022/085

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Salvesafe H9	Colourless liquid with fruity odour	Revol B., Hisiger S. (2022) No. 2022/086
				Salvesafe H10	Colourless liquid with cherry odour	Revol B., Hisiger S. (2022) No. 2022/087
				Salvesafe H0_R	Light yellow liquid with characteristic odour	Revol B., Hisiger S. (2022) No. 2022/099
				Salvesafe H0_RC	Pink liquid with characteristic odour	Revol B., Hisiger S. (2022) No. 2022/112
				Salvesafe H1_R	Light yellow liquid with minty odour	Revol B., Hisiger S. (2022) No. 2022/100
				Salvesafe H2_R	Light yellow liquid with apple odour	Revol B., Hisiger S. (2022) No. 2022/101
				Salvesafe H3_R	Light yellow liquid with almond odour	Revol B., Hisiger S. (2022) No. 2022/102
				Salvesafe H4_R	Light yellow liquid with honeysuckle odour	Revol B., Hisiger S. (2022) No. 2022/103
				Salvesafe H5_R	Light yellow liquid with vanilla-coconut odour	Revol B., Hisiger S. (2022) No. 2022/104
				Salvesafe H6_R	Light yellow liquid with green-floral odour	Revol B., Hisiger S. (2022) No. 2022/105
				Salvesafe H7_R	Light yellow liquid with coco odour	Revol B., Hisiger S. (2022) No. 2022/106
				Salvesafe H8_R	Light yellow liquid with raspberry odour	Revol B., Hisiger S. (2022) No. 2022/107
				Salvesafe H9_R	Light yellow liquid with	Revol B., Hisiger

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					fruity odour	S. (2022) No. 2022/108
				Salvesafe H10_R	Light yellow liquid with cherry odour	Revol B., Hisiger S. (2022) No. 2022/109
				Salvesafe H0_F	Colourless liquid with characteristic odour	Revol B., Hisiger S. (2022) No. 2022/088
				Salvesafe H1_F	Colourless liquid with minty odour	Revol B., Hisiger S. (2022) No. 2022/089
				Salvesafe H2_F	Colourless liquid with apple odour	Revol B., Hisiger S. (2022) No. 2022/090
				Salvesafe H3_F	Colourless liquid with almond odour	Revol B., Hisiger S. (2022) No. 2022/091
				Salvesafe H4_F	Light yellow liquid with honeysuckle odour	Revol B., Hisiger S. (2022) No. 2022/092
				Salvesafe H5_F	Light yellow liquid with vanilla-coconut odour	Revol B., Hisiger S. (2022) No. 2022/093
				Salvesafe H6_F	Light yellow liquid with green-floral odour	Revol B., Hisiger S. (2022) No. 2022/094
				Salvesafe H7_F	Light yellow liquid with coco odour	Revol B., Hisiger S. (2022) No. 2022/095
				Salvesafe H8_F	Colourless liquid with raspberry odour	Revol B., Hisiger S. (2022) No. 2022/096
				Salvesafe H9_F	Colourless liquid with fruity odour	Revol B., Hisiger S. (2022) No. 2022/097
				Salvesafe H10_F	Colourless liquid with cherry odour	Revol B., Hisiger S. (2022) No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
						2022/098
				Salvesafe H0_R1	Light yellow liquid with characteristic odour	Revol B., Hisiger S. (2023) No. 2023/103
				Salvesafe H11	Light yellow liquid with neutral odour	Revol B., Hisiger S. (2023) No. 2023/154
				Salvesafe H11_F	Light yellow liquid with neutral odour	Revol B., Hisiger S. (2023) No. 2023/154
3.2.	pH value	CIPAC MT 75.3	All products within family (1.98% w/w of Lactic acid) T_0 – initial results T_{14} – after 14 days of accelerated storage	Salvesafe H0	T_0=2.65 T_{14}=2.76	Revol B., Hisiger S. (2022) No. 2022/077
				Salvesafe H1	T_0=2.67 T_{14}=2.78	Revol B., Hisiger S. (2022) No. 2022/078
				Salvesafe H2	T_0=2.63 T_{14}=2.78	Revol B., Hisiger S. (2022) No. 2022/079
				Salvesafe H3	T_0=2.67 T_{14}=2.80	Revol B., Hisiger S. (2022) No. 2022/080
				Salvesafe H4	T_0=2.70 T_{14}=2.80	Revol B., Hisiger S. (2022) No. 2022/081
				Salvesafe H5	T_0=2.71 T_{14}=2.79	Revol B., Hisiger S. (2022) No. 2022/082
				Salvesafe H6	T_0=2.65 T_{14}=2.79	Revol B., Hisiger S. (2022) No. 2022/083
				Salvesafe H7	T_0=2.65 T_{14}=2.72	Revol B., Hisiger S. (2022) No. 2022/084
				Salvesafe H8	T_0=2.70 T_{14}=2.76	Revol B., Hisiger S. (2022) No. 2022/085

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Salvesafe H9	T_0=2.66 T_{14}=2.80	Revol B., Hisiger S. (2022) No. 2022/086
				Salvesafe H10	T_0=2.67 T_{14}=2.80	Revol B., Hisiger S. (2022) No. 2022/087
				Salvesafe H0_R	T_0=2.68 T_{14}=2.79	Revol B., Hisiger S. (2022) No. 2022/099
				Salvesafe H0_RC	T_0=2.66 T_{14}=2.75	Revol B., Hisiger S. (2022) No. 2022/112
				Salvesafe H1_R	T_0=2.70 T_{14}=2.79	Revol B., Hisiger S. (2022) No. 2022/100
				Salvesafe H2_R	T_0=2.72 T_{14}=2.80	Revol B., Hisiger S. (2022) No. 2022/101
				Salvesafe H3_R	T_0=2.70 T_{14}=2.79	Revol B., Hisiger S. (2022) No. 2022/102
				Salvesafe H4_R	T_0=2.69 T_{14}=2.75	Revol B., Hisiger S. (2022) No. 2022/103
				Salvesafe H5_R	T_0=2.69 T_{14}=2.79	Revol B., Hisiger S. (2022) No. 2022/104
				Salvesafe H6_R	T_0=2.67 T_{14}=2.76	Revol B., Hisiger S. (2022) No. 2022/105
				Salvesafe H7_R	T_0=2.69 T_{14}=2.79	Revol B., Hisiger S. (2022) No. 2022/106
				Salvesafe H8_R	T_0=2.69 T_{14}=2.80	Revol B., Hisiger S. (2022) No. 2022/107
				Salvesafe H9_R	T_0=2.67	Revol B., Hisiger

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_{14}=2.76	S. (2022) No. 2022/108
				Salvesafe H10_R	T_0=2.65 T_{14}=2.69	Revol B., Hisiger S. (2022) No. 2022/109
				Salvesafe H0_F	T_0=2.60 T_{14}=2.74	Revol B., Hisiger S. (2022) No. 2022/088
				Salvesafe H1_F	T_0=2.59 T_{14}=2.75	Revol B., Hisiger S. (2022) No. 2022/089
				Salvesafe H2_F	T_0=2.65 T_{14}=2.73	Revol B., Hisiger S. (2022) No. 2022/090
				Salvesafe H3_F	T_0=2.63 T_{14}=2.74	Revol B., Hisiger S. (2022) No. 2022/091
				Salvesafe H4_F	T_0=2.62 T_{14}=2.73	Revol B., Hisiger S. (2022) No. 2022/092
				Salvesafe H5_F	T_0=2.61 T_{14}=2.70	Revol B., Hisiger S. (2022) No. 2022/093
				Salvesafe H6_F	T_0=2.65 T_{14}=2.77	Revol B., Hisiger S. (2022) No. 2022/094
				Salvesafe H7_F	T_0=2.62 T_{14}=2.76	Revol B., Hisiger S. (2022) No. 2022/095
				Salvesafe H8_F	T_0=2.62 T_{14}=2.75	Revol B., Hisiger S. (2022) No. 2022/096
				Salvesafe H9_F	T_0=2.63 T_{14}=2.75	Revol B., Hisiger S. (2022) No. 2022/097
				Salvesafe H10_F	T_0=2.66 T_{14}=2.74	Revol B., Hisiger S. (2022) No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
						2022/098
				Salvesafe H0_R1	T_0=2.66 T_{14}=2.73	Revol B., Hisiger S. (2023) No. 2023/103
				Salvesafe H11	T_0=2.67 T_{14}=2.74	Revol B., Hisiger S. (2023) No. 2023/154
				Salvesafe H11_F	T_0=2.61 T_{14}=2.70	Revol B., Hisiger S. (2023) No. 2023/155
3.3.	Relative density	EEC Method A3	All products within family (1.98% w/w of Lactic acid) T_0 – initial results T_{14} – after 14 days of accelerated storage	Salvesafe H0	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2022) No. 2022/077
				Salvesafe H1	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2022) No. 2022/078
				Salvesafe H2	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2022) No. 2022/079
				Salvesafe H3	T_0=1.029 T_{14}=1.029	Revol B., Hisiger S. (2022) No. 2022/080
				Salvesafe H4	T_0=1.029 T_{14}=1.029	Revol B., Hisiger S. (2022) No. 2022/081
				Salvesafe H5	T_0=1.029 T_{14}=1.029	Revol B., Hisiger S. (2022) No. 2022/082
				Salvesafe H6	T_0=1.028 T_{14}=1.029	Revol B., Hisiger S. (2022) No. 2022/083
				Salvesafe H7	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2022) No. 2022/084
				Salvesafe H8	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2022) No. 2022/085

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Salvesafe H9	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2022) No. 2022/086
				Salvesafe H10	T_0=1.029 T_{14}=1.029	Revol B., Hisiger S. (2022) No. 2022/087
				Salvesafe H0_R	T_0=1.029 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/099
				Salvesafe H0_RC	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2022) No. 2022/112
				Salvesafe H1_R	T_0=1.029 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/100
				Salvesafe H2_R	T_0=1.029 T_{14}=1.029	Revol B., Hisiger S. (2022) No. 2022/101
				Salvesafe H3_R	T_0=1.029 T_{14}=1.030	Revol B., Hisiger S. (2022) No. 2022/102
				Salvesafe H4_R	T_0=1.029 T_{14}=1.030	Revol B., Hisiger S. (2022) No. 2022/103
				Salvesafe H5_R	T_0=1.029 T_{14}=1.030	Revol B., Hisiger S. (2022) No. 2022/104
				Salvesafe H6_R	T_0=1.029 T_{14}=1.030	Revol B., Hisiger S. (2022) No. 2022/105
				Salvesafe H7_R	T_0=1.029 T_{14}=1.030	Revol B., Hisiger S. (2022) No. 2022/106
				Salvesafe H8_R	T_0=1.029 T_{14}=1.030	Revol B., Hisiger S. (2022) No. 2022/107
				Salvesafe H9_R	T_0=1.029	Revol B., Hisiger

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_{14}=1.029	S. (2022) No. 2022/108
				Salvesafe H10_R	T_0=1.029 T_{14}=1.029	Revol B., Hisiger S. (2022) No. 2022/109
				Salvesafe H0_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/088
				Salvesafe H1_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/089
				Salvesafe H2_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/090
				Salvesafe H3_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/091
				Salvesafe H4_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/092
				Salvesafe H5_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/093
				Salvesafe H6_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/094
				Salvesafe H7_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/095
				Salvesafe H8_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/096
				Salvesafe H9_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No. 2022/097
				Salvesafe H10_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2022) No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
						2022/098
				Salvesafe H0_R1	T_0=1.029 T_{14}=1.029	Revol B., Hisiger S. (2023) No. 2023/103
				Salvesafe H11	T_0=1.028 T_{14}=1.028	Revol B., Hisiger S. (2023) No. 2023/154
				Salvesafe H11_F	T_0=1.027 T_{14}=1.027	Revol B., Hisiger S. (2023) No. 2023/155
3.4.1.1.	Storage stability test – **accelerated storage**	CIPAC MT46.3 14 days at 54°C (+/- 2°C) in glass bottle Content of Lactic acid - HPLC method pH - CIPAC MT 75.3 Density - EEC Method A3 Viscosity 20°C - OECD 114 Surface tension - OECD 115	All products within family (1.98% w/w of Lactic acid)	Appearance of the tested samples did not change after 2 weeks of storage at 54°C. Max Δ pH = ± 0.16 Max Δ surface tension = ± 0.4 mN/m Max Δ density = ± 0.002 Max Δ viscosity = ± 59 mPa*S The variation of AS content < 10%. The content of AS for each product is listed below:		
				Salvesafe H0	T_0=2.02 % (w/w) T_{14}=2.06 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/077
				Salvesafe H1	T_0=2.03 % (w/w) T_{14}=2.06 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/078
				Salvesafe H2	T_0=2.01 % (w/w) T_{14}=2.05 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/079
				Salvesafe H3	T_0=2.01 % (w/w) T_{14}=2.04 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/080
				Salvesafe H4	T_0=2.04 % (w/w) T_{14}=2.04 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/081
				Salvesafe H5	T_0=2.01 % (w/w) T_{14}=2.05 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/082
				Salvesafe H6	T_0=2.01 % (w/w)	Revol B., Hisiger

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_{14}=2.00 % (w/w)	S. (2022) No. 2022/083
				Salvesafe H7	T_0=2.03 % (w/w) T_{14}=2.04 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/084
				Salvesafe H8	T_0=1.99 % (w/w) T_{14}=2.04 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/085
				Salvesafe H9	T_0=2.02 % (w/w) T_{14}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/086
				Salvesafe H10	T_0=2.03 % (w/w) T_{14}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/087
				Salvesafe H0_R	T_0=2.04 % (w/w) T_{14}=2.06 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/099
				Salvesafe H0_RC	T_0=2.01 % (w/w) T_{14}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/112
				Salvesafe H1_R	T_0=2.05 % (w/w) T_{14}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/100
				Salvesafe H2_R	T_0=2.06 % (w/w) T_{14}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/101
				Salvesafe H3_R	T_0=2.06 % (w/w) T_{14}=2.03 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/102
				Salvesafe H4_R	T_0=2.05 % (w/w) T_{14}=2.03 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/103
				Salvesafe H5_R	T_0=2.06 % (w/w) T_{14}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/104
				Salvesafe H6_R	T_0=2.04 % (w/w) T_{14}=2.00 % (w/w)	Revol B., Hisiger S. (2022) No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
						2022/105
				Salvesafe H7_R	T_0=2.05 % (w/w) T_{14}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/106
				Salvesafe H8_R	T_0=2.04 % (w/w) T_{14}=2.03 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/107
				Salvesafe H9_R	T_0=2.04 % (w/w) T_{14}=2.05 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/108
				Salvesafe H10_R	T_0=2.05 % (w/w) T_{14}=2.00 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/109
				Salvesafe H0_F	T_0=1.94 % (w/w) T_{14}=1.98 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/088
				Salvesafe H1_F	T_0=1.93 % (w/w) T_{14}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/089
				Salvesafe H2_F	T_0=1.98 % (w/w) T_{14}=1.95 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/090
				Salvesafe H3_F	T_0=1.95 % (w/w) T_{14}=1.96 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/091
				Salvesafe H4_F	T_0=1.96 % (w/w) T_{14}=1.98 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/092
				Salvesafe H5_F	T_0=1.95 % (w/w) T_{14}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/093
				Salvesafe H6_F	T_0=1.98 % (w/w) T_{14}=1.96 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/094
				Salvesafe H7_F	T_0=1.97 % (w/w) T_{14}=1.93 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/095

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Salvesafe H8_F	T_0=1.94 % (w/w) T_{14}=1.95 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/096
				Salvesafe H9_F	T_0=1.95 % (w/w) T_{14}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/097
				Salvesafe H10_F	T_0=1.94 % (w/w) T_{14}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/098
				Salvesafe H0_R1	T_0=2.01 % (w/w) T_{14}=2.03 % (w/w)	Revol B., Hisiger S. (2023) No. 2023/103
				Salvesafe H11	T_0=2.00 % (w/w) T_{14}=2.03 % (w/w)	Revol B., Hisiger S. (2023) No. 2023/154
				Salvesafe H11_F	T_0=1.97 % (w/w) T_{14}=1.99 % (w/w)	Revol B., Hisiger S. (2023) No. 2023/155
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Content of Lactic acid - HPLC method pH - CIPAC MT 75.3 Density - EEC Method A3 Viscosity 20°C - OECD 114 Surface tension - OECD 115	All products within family (1.98% w/w of Lactic acid)	On-going (starting from February 2022). Ongoing long-term storage stability for 24 months will be set as a post authorisation data requirement according to Technical Agreements for Biocides / Analytical Methods and Physicochemical Properties (APCP) Version 2.0, February 2020 #4.2.1.3. Shelf-life decision tree: "A shelf life will be granted based on an accelerated storage stability test (variation < 10% of AS content). A provisional shelf-life up to 2 years could be granted." Measurements at the beginning (T_0) of the tests and after 5 months are available (T_{5m}). Appearance of the tested samples did not		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				change after 5 months of storage at room temperature. No changes in packaging (PET, HDPE) or closure. Max change of packaging weight = 0.3 g. Max Δ pH = ± 0.13 Max Δ surface tension = ± 0.3 mN/m Max Δ density = ± 0.001 Max Δ viscosity = ± 45 mPa*S The variation of AS content < 10%. The content of AS for each product is listed below:		
				Salvesafe H0	RPET bottle T_0=2.02 % (w/w) T_{5m}=2.03 % (w/w) PET bottle T_0=2.02 % (w/w) T_{5m}=2.00 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/129
				Salvesafe H1	RPET bottle T_0=2.03 % (w/w) T_{5m}=2.00 % (w/w) PET bottle T_0=2.03 % (w/w) T_{5m}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/130
				Salvesafe H2	RPET bottle T_0=2.01 % (w/w) T_{5m}=2.03 % (w/w) PET bottle T_0=2.01 % (w/w) T_{5m}=1.98 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/131
				Salvesafe H3	RPET bottle T_0=2.01 % (w/w) T_{5m}=1.98 % (w/w) PET bottle T_0=2.01 % (w/w) T_{5m}=2.02 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/132
				Salvesafe H4	RPET bottle	Revol B., Hisiger

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_0=2.04 % (w/w) T_{5m}=2.00 % (w/w) PET bottle T_0=2.04 % (w/w) T_{5m}=2.03 % (w/w)	S. (2022) No. 2022/133
				Salvesafe H5	RPET bottle T_0=2.01 % (w/w) T_{5m}=2.00 % (w/w) PET bottle T_0=2.01 % (w/w) T_{5m}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/134
				Salvesafe H6	RPET bottle T_0=2.01 % (w/w) T_{5m}=1.97 % (w/w) PET bottle T_0=2.01 % (w/w) T_{5m}=1.97 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/135
				Salvesafe H7	RPET bottle T_0=2.03 % (w/w) T_{5m}=2.04 % (w/w) PET bottle T_0=2.03 % (w/w) T_{5m}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/136
				Salvesafe H8	RPET bottle T_0=1.99 % (w/w) T_{5m}=2.02 % (w/w) PET bottle T_0=1.99 % (w/w) T_{5m}=2.03 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/137
				Salvesafe H9	RPET bottle T_0=2.02 % (w/w) T_{5m}=2.02 % (w/w) PET bottle T_0=2.02 % (w/w) T_{5m}=2.00 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/138
				Salvesafe H10	RPET bottle T_0=2.03 % (w/w)	Revol B., Hisiger S. (2022) No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_{5m}=1.97 % (w/w) PET bottle T_0=2.03 % (w/w) T_{5m}=2.00 % (w/w)	2022/139
				Salvesafe H0_R	HDPE bottle T_0=2.04 % (w/w) T_{5m}=2.00 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/151
				Salvesafe H0_RC	HDPE bottle T_0=2.01 % (w/w) T_{5m}=2.02 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/162
				Salvesafe H1_R	HDPE bottle T_0=2.05 % (w/w) T_{5m}=2.04 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/152
				Salvesafe H2_R	HDPE bottle T_0=2.06 % (w/w) T_{5m}=2.00 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/153
				Salvesafe H3_R	HDPE bottle T_0=2.06 % (w/w) T_{5m}=2.02 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/154
				Salvesafe H4_R	HDPE bottle T_0=2.05 % (w/w) T_{5m}=2.02 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/155
				Salvesafe H5_R	HDPE bottle T_0=2.06 % (w/w) T_{5m}=2.03 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/156
				Salvesafe H6_R	HDPE bottle T_0=2.04 % (w/w) T_{5m}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/157
				Salvesafe H7_R	HDPE bottle T_0=2.05 % (w/w) T_{5m}=2.01% (w/w)	Revol B., Hisiger S. (2022) No. 2022/158
				Salvesafe H8_R	HDPE bottle T_0=2.04 % (w/w) T_{5m}=2.05% (w/w)	Revol B., Hisiger S. (2022) No. 2022/159
				Salvesafe H9_R	HDPE bottle T_0=2.04 % (w/w) T_{5m}=2.05% (w/w)	Revol B., Hisiger S. (2022) No. 2022/160

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Salvesafe H10_R	HDPE bottle T_0=2.05 % (w/w) T_{5m}=2.05% (w/w)	Revol B., Hisiger S. (2022) No. 2022/161
				Salvesafe H0_F	PET bottle T_0=1.94 % (w/w) T_{5m}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/140
				Salvesafe H1_F	PET bottle T_0=1.93 % (w/w) T_{5m}=1.97 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/141
				Salvesafe H2_F	PET bottle T_0=1.98 % (w/w) T_{5m}=1.95 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/142
				Salvesafe H3_F	PET bottle T_0=1.95 % (w/w) T_{5m}=1.99 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/143
				Salvesafe H4_F	PET bottle T_0=1.96 % (w/w) T_{5m}=2.01 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/144
				Salvesafe H5_F	PET bottle T_0=1.95 % (w/w) T_{5m}=1.96 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/145
				Salvesafe H6_F	PET bottle T_0=1.98 % (w/w) T_{5m}=1.96 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/146
				Salvesafe H7_F	PET bottle T_0=1.97 % (w/w) T_{5m}=1.97 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/147
				Salvesafe H8_F	PET bottle T_0=1.94 % (w/w) T_{5m}=1.98 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/148
				Salvesafe H9_F	PET bottle T_0=1.95 % (w/w) T_{5m}=1.96 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/149
				Salvesafe H10_F	PET bottle T_0=1.94 % (w/w) T_{5m}=1.97 % (w/w)	Revol B., Hisiger S. (2022) No. 2022/150
				Salvesafe H0_R1	Read across with	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					SalveSafe H0_R	
				Salvesafe H11	RPET bottle T_0=2.00 % (w/w) T_{5m}=2.02 % (w/w) PET bottle T_0=2.00 % (w/w) T_{5m}=2.03 % (w/w)	Revol B., Hisiger S. (2023) No. 2023/157
				Salvesafe H11_F	In progress	-
eCA remark: According to (1) CA-July12-Doc.6.2d – Final and (2) BPC document on applicability time of new guidance and guidance-related documents the Technical Agreements for Biocides / Analytical Methods and Physicochemical Properties (APCP) Version 3.0, September 2022 #4.2.1.6 Shelf-life decision tree -simplified authorisation process is not applicable for this application. The application was submitted before the discussions on this took place at CG level.						
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	-	All products within family (1.98% w/w of Lactic acid)	According to Annex IV of the BPR Regulation EU n.528/2012 and according to ECHA "Guidance on the BPR: Volume I Parts A+B+C Version 2.0 2018", low temperature stability test is required except if the label gives clear instructions that the product must not be stored under conditions of ≤ 0°C. The labels of all the products included in the BPF contain the information "Protect from cold and frost"		waiver
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	All products within family (1.98% w/w of Lactic acid)	See results of accelerated storage in transparent glass bottle and in addition intermediate results of long-term storage, which is performed at room temperature in transparent or translucent packaging's. According to literature Lactic acid don't undergo direct photolysis in sunlight.		waiver

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	All products within family (1.98% w/w of Lactic acid)	Products are 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 storage for confirmation.	waiver
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	All products within family (1.98% w/w of Lactic acid)	No reactivity towards container material has been observed during 5 months' storage stability studies.	waiver
3.5.1.	Wettability	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use liquid formulations.	waiver
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	All products within family (1.98% w/w of Lactic acid)	products are not suspensions.	waiver
3.5.3.	Wet sieve analysis and dry sieve test	-	All products within family (1.98% w/w of Lactic acid)	Products are ready-to-use liquid formulations.	waiver
3.5.4.	Emulsifiability, re-emulsifiability, and emulsion stability	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use liquid formulations.	waiver
3.5.5.	Disintegration time	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use liquid formulations.	waiver

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	All products within family (1.98% w/w of Lactic acid)	All products of the family are ready to use liquids. The products are not used in spray applications; therefore, the products are not sold in or together with spraying equipment. The risk assessment is not requested under the simplified procedure. The MMAD is not relevant to demonstrate efficacy.	waiver
3.5.7.	Persistent foaming	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use and not diluted with water prior to use.	waiver
3.5.8.	Flowability/pourability/dustability	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use liquid formulations.	waiver
3.5.9.	Burning rate — smoke generators	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use liquid formulations.	waiver
3.5.10.	Burning completeness — smoke generators	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use liquid formulations.	waiver
3.5.11.	Composition of smoke — smoke generators	-	All products within family (1.98% w/w of Lactic acid)	products are ready-to-use liquid formulations.	waiver
3.5.12.	Spraying pattern — aerosols / spray	-	All products within family (1.98% w/w of Lactic acid)	Products are not aerosol and the product is not intended to be used via spraying.	waiver
3.6.1.	Physical compatibility	-	All products within family (1.98% w/w of Lactic acid)	Not applicable, products not to be mixed with other products.	waiver

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
3.6.2.	Chemical compatibility	-	All products within family (1.98% w/w of Lactic acid)	Not applicable, products not to be mixed with other products.		waiver
3.7.	Degree of dissolution and dilution stability	-	All products within family (1.98% w/w of Lactic acid)	Products are ready-to-use liquid formulation.		waiver
3.8.	Surface tension	OECD 115	All products within family (1.98% w/w of Lactic acid) T_0 – initial results T_{14} – after 14 days of accelerated storage	Salvesafe H0	T_0=30.6 mN/m T_{14}=30.9 mN/m	Revol B., Hisiger S. (2022) No. 2022/077
				Salvesafe H1	T_0=29.8 mN/m T_{14}=30.2 mN/m	Revol B., Hisiger S. (2022) No. 2022/078
				Salvesafe H2	T_0=29.8 mN/m T_{14}=30.0 mN/m	Revol B., Hisiger S. (2022) No. 2022/079
				Salvesafe H3	T_0=30.4 mN/m T_{14}=30.2 mN/m	Revol B., Hisiger S. (2022) No. 2022/080
				Salvesafe H4	T_0=30.1 mN/m T_{14}=29.9 mN/m	Revol B., Hisiger S. (2022) No. 2022/081
				Salvesafe H5	T_0=30.6 mN/m T_{14}=30.9 mN/m	Revol B., Hisiger S. (2022) No. 2022/082
				Salvesafe H6	T_0=29.8 mN/m T_{14}=29.8 mN/m	Revol B., Hisiger S. (2022) No. 2022/083
				Salvesafe H7	T_0=30.7 mN/m T_{14}=30.7 mN/m	Revol B., Hisiger S. (2022) No. 2022/084
				Salvesafe H8	T_0=30.5 mN/m T_{14}=30.4 mN/m	Revol B., Hisiger S. (2022) No. 2022/085
				Salvesafe H9	T_0=30.0 mN/m T_{14}=30.1 mN/m	Revol B., Hisiger S. (2022) No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
						2022/086
				Salvesafe H10	T_0=30.6 mN/m T_{14}=30.4 mN/m	Revol B., Hisiger S. (2022) No. 2022/087
				Salvesafe H0_R	T_0=30.5 mN/m T_{14}=30.1 mN/m	Revol B., Hisiger S. (2022) No. 2022/099
				Salvesafe H0_RC	T_0=30.8 mN/m T_{14}=30.9 mN/m	Revol B., Hisiger S. (2022) No. 2022/112
				Salvesafe H1_R	T_0=30.6 mN/m T_{14}=30.9 mN/m	Revol B., Hisiger S. (2022) No. 2022/100
				Salvesafe H2_R	T_0=30.6 mN/m T_{14}=30.2 mN/m	Revol B., Hisiger S. (2022) No. 2022/101
				Salvesafe H3_R	T_0=30.9 mN/m T_{14}=30.6 mN/m	Revol B., Hisiger S. (2022) No. 2022/102
				Salvesafe H4_R	T_0=30.9 mN/m T_{14}=30.7 mN/m	Revol B., Hisiger S. (2022) No. 2022/103
				Salvesafe H5_R	T_0=30.2 mN/m T_{14}=30.3 mN/m	Revol B., Hisiger S. (2022) No. 2022/104
				Salvesafe H6_R	T_0=30.8 mN/m T_{14}=30.5 mN/m	Revol B., Hisiger S. (2022) No. 2022/105
				Salvesafe H7_R	T_0=31.1 mN/m T_{14}=30.5 mN/m	Revol B., Hisiger S. (2022) No. 2022/106
				Salvesafe H8_R	T_0=31.4 mN/m T_{14}=31.6 mN/m	Revol B., Hisiger S. (2022) No. 2022/107
				Salvesafe H9_R	T_0=30.1 mN/m T_{14}=30.5 mN/m	Revol B., Hisiger S. (2022) No. 2022/108

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Salvesafe H10_R	T_0=30.1 mN/m T_{14}=30.5 mN/m	Revol B., Hisiger S. (2022) No. 2022/109
				Salvesafe H0_F	T_0=28.4 mN/m T_{14}=28.5 mN/m	Revol B., Hisiger S. (2022) No. 2022/088
				Salvesafe H1_F	T_0=27.5 mN/m T_{14}=27.6 mN/m	Revol B., Hisiger S. (2022) No. 2022/089
				Salvesafe H2_F	T_0=28.1 mN/m T_{14}=28.0 mN/m	Revol B., Hisiger S. (2022) No. 2022/090
				Salvesafe H3_F	T_0=28.4 mN/m T_{14}=28.3 mN/m	Revol B., Hisiger S. (2022) No. 2022/091
				Salvesafe H4_F	T_0=28.2 mN/m T_{14}=28.3 mN/m	Revol B., Hisiger S. (2022) No. 2022/092
				Salvesafe H5_F	T_0=28.4 mN/m T_{14}=28.4 mN/m	Revol B., Hisiger S. (2022) No. 2022/093
				Salvesafe H6_F	T_0=27.9 mN/m T_{14}=27.9 mN/m	Revol B., Hisiger S. (2022) No. 2022/094
				Salvesafe H7_F	T_0=28.2 mN/m T_{14}=28.2 mN/m	Revol B., Hisiger S. (2022) No. 2022/095
				Salvesafe H8_F	T_0=28.3 mN/m T_{14}=28.3 mN/m	Revol B., Hisiger S. (2022) No. 2022/096
				Salvesafe H9_F	T_0=28.4 mN/m T_{14}=28.5 mN/m	Revol B., Hisiger S. (2022) No. 2022/097
				Salvesafe H10_F	T_0=28.5 mN/m T_{14}=28.4 mN/m	Revol B., Hisiger S. (2022) No. 2022/098
				Salvesafe H0_R1	T_0=30.3 mN/m	Revol B., Hisiger

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_{14}=30.5 mN/m	S. (2023) No. 2023/103
				Salvesafe H11	T_0=30.4 mN/m T_{14}=30.2 mN/m	Revol B., Hisiger S. (2023) No. 2023/154
				Salvesafe H11_F	T_0=28.5 mN/m T_{14}=28.6 mN/m	Revol B., Hisiger S. (2023) No. 2023/155
3.9.	Viscosity	OECD 114	All products within family (1.98% w/w of Lactic acid) T_0 – initial results T_{14} – after 14 days of accelerated storage	Salvesafe H0	20°C: T_0=493 mPa*s T_{14}=466 mPa*s 40°C: T_0=439 mPa*s T_{14}=400 mPa*s	Revol B., Hisiger S. (2022) No. 2022/077
				Salvesafe H1	20°C: T_0=498 mPa*s T_{14}=481 mPa*s 40°C: T_0=443 mPa*s T_{14}=403 mPa*s	Revol B., Hisiger S. (2022) No. 2022/078
				Salvesafe H2	20°C: T_0=492 mPa*s T_{14}=485 mPa*s 40°C: T_0=451 mPa*s T_{14}=403 mPa*s	Revol B., Hisiger S. (2022) No. 2022/079
				Salvesafe H3	20°C: T_0=489 mPa*s T_{14}=457 mPa*s 40°C: T_0=437 mPa*s T_{14}=396 mPa*s	Revol B., Hisiger S. (2022) No. 2022/080
				Salvesafe H4	20°C:	Revol B., Hisiger

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_0=502 mPa*s T_{14}=477 mPa*s 40°C: T_0=439 mPa*s T_{14}=409 mPa*s	S. (2022) No. 2022/081
				Salvesafe H5	20°C: T_0=500 mPa*s T_{14}=462 mPa*s 40°C: T_0=434 mPa*s T_{14}=401 mPa*s	Revol B., Hisiger S. (2022) No. 2022/082
				Salvesafe H6	20°C: T_0=492 mPa*s T_{14}=472 mPa*s 40°C: T_0=428 mPa*s T_{14}=390 mPa*s	Revol B., Hisiger S. (2022) No. 2022/083
				Salvesafe H7	20°C: T_0=541 mPa*s T_{14}=528 mPa*s 40°C: T_0=473 mPa*s T_{14}=435 mPa*s	Revol B., Hisiger S. (2022) No. 2022/084
				Salvesafe H8	20°C: T_0=508 mPa*s T_{14}=485 mPa*s 40°C: T_0=431 mPa*s T_{14}=407 mPa*s	Revol B., Hisiger S. (2022) No. 2022/085
				Salvesafe H9	20°C: T_0=443 mPa*s T_{14}=417 mPa*s	Revol B., Hisiger S. (2022) No. 2022/086

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					40°C: T_0=398 mPa*s T_{14}=364 mPa*s	
				Salvesafe H10	20°C: T_0=436 mPa*s T_{14}=423 mPa*s 40°C: T_0=384 mPa*s T_{14}=361 mPa*s	Revol B., Hisiger S. (2022) No. 2022/087
				Salvesafe H0_R	20°C: T_0=1015 mPa*s T_{14}=1045 mPa*s 40°C: T_0=987 mPa*s T_{14}=971 mPa*s	Revol B., Hisiger S. (2022) No. 2022/099
				Salvesafe H0_RC	20°C: T_0=1102 mPa*s T_{14}=1085 mPa*s 40°C: T_0=1073 mPa*s T_{14}=1034 mPa*s	Revol B., Hisiger S. (2022) No. 2022/112
				Salvesafe H1_R	20°C: T_0=1042 mPa*s T_{14}=1085 mPa*s 40°C: T_0=1059 mPa*s T_{14}=1018 mPa*s	Revol B., Hisiger S. (2022) No. 2022/100
				Salvesafe H2_R	20°C: T_0=964 mPa*s T_{14}=1012 mPa*s 40°C:	Revol B., Hisiger S. (2022) No. 2022/101

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_0=913 mPa*s T_{14}=875 mPa*s	
				Salvesafe H3_R	20°C: T_0=974 mPa*s T_{14}=1032 mPa*s 40°C: T_0=1013mPa*s T_{14}=1062 mPa*s	Revol B., Hisiger S. (2022) No. 2022/102
				Salvesafe H4_R	20°C: T_0=977 mPa*s T_{14}=1016 mPa*s 40°C: T_0=995 mPa*s T_{14}=965 mPa*s	Revol B., Hisiger S. (2022) No. 2022/103
				Salvesafe H5_R	20°C: T_0=979 mPa*s T_{14}=1031 mPa*s 40°C: T_0=953 mPa*s T_{14}=994 mPa*s	Revol B., Hisiger S. (2022) No. 2022/104
				Salvesafe H6_R	20°C: T_0=966 mPa*s T_{14}=1025 mPa*s 40°C: T_0=932 mPa*s T_{14}=974 mPa*s	Revol B., Hisiger S. (2022) No. 2022/105
				Salvesafe H7_R	20°C: T_0=1006 mPa*s T_{14}=1048 mPa*s 40°C: T_0=1031 mPa*s T_{14}=997 mPa*s	Revol B., Hisiger S. (2022) No. 2022/106

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
				Salvesafe H8_R	20°C: T_0=1167 mPa*s T_{14}=1128 mPa*s 40°C: T_0=1098 mPa*s T_{14}=1052 mPa*s	Revol B., Hisiger S. (2022) No. 2022/107
				Salvesafe H9_R	20°C: T_0=974 mPa*s T_{14}=1028 mPa*s 40°C: T_0=1003 mPa*s T_{14}=1057 mPa*s	Revol B., Hisiger S. (2022) No. 2022/108
				Salvesafe H10_R	20°C: T_0=983 mPa*s T_{14}=1041 mPa*s 40°C: T_0=964 mPa*s T_{14}=1015 mPa*s	Revol B., Hisiger S. (2022) No. 2022/109
				Salvesafe H0_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/088
				Salvesafe H1_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/089
				Salvesafe H2_F	20°C: T_0=< 50 mPa*s	Revol B., Hisiger S. (2022) No.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	2022/090
				Salvesafe H3_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/091
				Salvesafe H4_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/092
				Salvesafe H5_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/093
				Salvesafe H6_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/094
				Salvesafe H7_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/095

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	
				Salvesafe H8_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/096
				Salvesafe H9_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/097
				Salvesafe H10_F	20°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}=< 50 mPa*s	Revol B., Hisiger S. (2022) No. 2022/098
				Salvesafe H0_R1	20°C: T_0= 946 mPa*s T_{14}= 967 mPa*s 40°C: T_0=924 mPa*s T_{14}= 932 mPa*s	Revol B., Hisiger S. (2023) No. 2023/103
				Salvesafe H11	20°C: T_0= 503 mPa*s T_{14}= 485 mPa*s 40°C: T_0=448 mPa*s	Revol B., Hisiger S. (2023) No. 2023/154

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results		Reference
					T_{14}= 407 mPa*s	
				Salvesafe H11_F	20°C: T_0= < 50 mPa*s T_{14}= < 50 mPa*s 40°C: T_0=< 50 mPa*s T_{14}= < 50 mPa*s	Revol B., Hisiger S. (2023) No. 2023/155

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 products are ready-to-use liquids, perfumed and non-perfumed versions, colourless and coloured versions. The main composition of the products is same and the difference only in content of thickening agents, perfumes and dyes. It was shown that perfumes and dye don't impact on physio-chemical properties of the products, however the content of thickening agent only effects the viscosity of the products. The pH of BPF is in range 2.59-2.72. The products are surface active. The density in range of 1.027-1.029. The viscosity at 20°C: for products w/o thickening < 50 mPa*s, for products with thickening agent in range 436-541 and 964-1167 mPa*s depends on type and content of thickening agent. The products are stable for 14 days at 54± 2°C. No changes in the appearance of the tested items occur or content of active substance. Therefore, a provisional shelf-life up to 2 years could be granted. A long-term storage stability test for 24 months is currently on-going and results will be provided when available. The intermediate results after 5 months storage re provided by the applicant. The products showed no changes when stored for 5 months at room temperature in commercial packagings (PET, HDPE, R-PET). Considering the type of formulation of the products these results can be extrapolated to other packaging material. However, ongoing long-term storage stability will be set as a post authorisation data requirement or as a change request according to Technical Agreements for Biocides / Analytical Methods and Physico-chemical Properties (APCP) Version 2.0, February 2020 #4.2.1.3. Shelf-life decision tree: "A shelf life will be granted based on an accelerated storage stability test (variation <10% of AS content). A shelf life up to 2 years could be granted." **Implications for labelling for meta-SPC 1: "**Protect from cold and frost". **Shelf life:** 24 months at room temperature.

3.3 Physical hazards and respective characteristics

Information on the choice of the worst-case composition for physical hazards and respective characteristics (e.g. representative test product) and the justification for why the chosen test product is considered sufficient to cover the whole range of specified variations in the BPF are provided in the confidential annex.

The test products, the corresponding justification and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

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	CLP regulation Differential Scanning Calorimetry (DSC)-Metter	Worst case fam H	The explosives properties are screened based on composition and structural considerations of all co-formulants including the fragrances' ingredients and dye. Explosive properties are not anticipated for the BPF. More detailed information can be found in Conf. Annex to the PAR. BPF contains a large amount of water which is considered as phlegmatizer of explosive properties. In addition, the applicant provided DSC testing data. The sample was observed to undergo an exothermic event from 154°C which had a heat of decomposition of -63 J/g. A second exothermic event was then observed to commence from 305°C which had a heat of decomposition of -226 J/g. The total heat of decomposition is lower than 500 J/g. Therefore, no further testing is needed. The tested product can be considered as a representative product	J-M. François. (2022). Report 2022/381/JMF

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
				within family based on composition (the highest content of active substance and co-formulants).	
4.2.	Flammable gases	Not applicable, all the products are ready to use water-based liquids.			waiver
4.3.	Flammable aerosols	Not applicable, all the products are ready to use water-based liquids.			waiver
4.4.	Oxidising gases	Not applicable, all the products are ready to use water-based liquids.			waiver
4.5.	Gases under pressure	Not applicable, all the products are ready to use water-based liquids.			waiver
4.6.	Flammable liquids	ISO 3679	Worst case parfum Famille H	A test shows that the flash point of the product 99.5°C. The product is not flammable according to CLP criteria. The tested product can be considered as a representative product within family based on composition (the highest content of active substance and co-formulants).	A. Guibet. (2022) Report N°22-08425.001
4.7.	Flammable solids	Not applicable, all products are ready to use water-based liquids.			waiver
4.8.	Self-reactive substances and mixtures	CLP regulation Differential Scanning Calorimetry (DSC)-Metter	Worst case fam H	The self-reactive properties are screened based on composition and structural considerations of all co-formulants including the fragrances' ingredients and dye. Self-reactive properties are not anticipated for the BPF. More detailed information can be found in Conf. Annex to the PAR. BPF contains a large amount of water. In addition, the applicant provided DSC testing data. The sample was observed to undergo an exothermic event from 154°C which had a heat of decomposition of -63 J/g. A second exothermic event was then observed to commence from 305°C which had a heat of decomposition of -226 J/g. The total heat of	J-M. François. (2022). Report 2022/381/JMF

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
				decomposition is lower than 300 J/g. Therefore, no further testing is needed. The tested product can be considered as a representative product within family based on composition (the highest content of active substance and co-formulants).	
4.9.	Pyrophoric liquids	According to the SDSs provided by the suppliers, none of the component of BPF is classified as pyrophoric liquid. All the products in the family are high diluted aqueous solution and the long experience of the applicant in handling the products confirms no concern related to pyrophoric properties of all the products. As well, during the stability studies at a temperature of 54°C over week, the products are not spontaneously ignited when in contact with air.			waiver
4.10.	Pyrophoric solids	Not applicable, all the products are ready to use water-based liquids.			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, all the products are ready to use water-based liquids.			waiver
4.13.	Oxidising liquids	Oxidising properties are not anticipated for the BPF due the structural composition of active substance and co-formulants. More detailed information can be found in Conf. Annex to the PAR.			waiver
4.14.	Oxidising solids	Not applicable, all the products are ready to use water-based liquids.			waiver
4.15.	Organic peroxides	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
4.16.	Corrosive to metals	UN manual of tests and criteria Part III, 37.4 (test C.1)	Product B201 max	Not classified as corrosive to metals. The product shows a negative result for corrosion to metal. After 7 days of testing: Aluminium: max 0.30% (100% liquid) Steel: max 2.6% (100% liquid) The weight loss is below the threshold of 13.5%. The deepest intrusion on steel was measured to be 30 µm. It does not exceed the maximum of 120 µm depth after 7 days of exposure. The tested product can be considered as a representative product within family based on composition (the highest content of active substance and co-formulants).	J. Conderaerts. 2020. Report No. JC 20-380_final_200903
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	DIN 51794	Worst case fam H	The flash point measured is 99.5°C. Moreover, the products are 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 530°C. Therefore, no further testing is needed. The tested product can be considered as a representative product within family based on composition (the highest content of active substance and co-formulants).	C. Cours; K. Wilhelm. (2022) Report No. Report N°R/22/24370
4.17.2.	Relative self-ignition temperature for solids	Not applicable, all the products are ready to use water-based liquids.			waiver
4.17.3.	Dust explosion	Not applicable, all the products are ready to use water-based liquids.			waiver

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
	hazard				

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
Based on the assessment of the representative product, meta-SPC 1 is not classified for the physical hazards.

3.4 Methods for detection and identification

This is no data requirement for an application in accordance with Article 25 of the Regulation (EU) No 528/2012. However, as the method is also being used for storage stability testing, the method has been validated.
The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

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									
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		
Lactic acid, diluted in the linearity range prior to analysis	HPLC	N = 5 Range: 34.11 g/100g – 80.29 g/100g	R^2 = 0.999 Linearity validated in the range 0.131 – 2.499 g/100g	UV spectrum	99.8 – 101.7 %	101.2%	RSD = 0.78%	< 0.02 g/100g	Revol B. (2022). Report No. 2022/136

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method for the determination of Lactic acid 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

Function and field of use

All the products within BPF are ready-to-use water-based disinfectants with 1.98 % w/w Lactic acid. The products are intended to be used as hygienic handwash (professional and non-professional) with a bactericidal, yeasticidal and virucidal efficacy against only enveloped virus in domestic, institutional, industrial area and medical area. These claims are supported by tests EN 13727, EN 13624, EN 14476 and EN 1499 reported in the section 3.5.3 below.

Taking into account no variations of the main co-formulants presented in the BPF, it can be assumed that the efficacy results of this representative product cover the whole BPF. This conclusion is in line with BPC-37 document "*Harmonized approach to determine a worst-case (or a representative) test product to be taken into account for efficacy core assessment for a disinfectant BPF*" where is stated that co-formulants that are present across the entire BPF with a fixed nominal concentration require no bridging/justification. The worst-case test product should contain such co-formulants at their fixed concentration.

In the frame of BPF only the content of thickening agent, perfumes and dye varies. With regards to thickening agent, the applicant has provided additional studies w/o presence of thickening agent to show that it does not impact product efficacy. The perfumes and dye present in low concentrations and not expected to influence efficacy in BPFs. Thus, they are disregarded, and testing is not required. The last is in line with Point 4.2.4 of EN 14885 on Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics.

Therefore, the laboratory studies were conducted with representative product *Hand disinfectant Soap* (with thickening agent) as well with the additional reference product *Hand Disinfectant Soap Foam* (w/o thickening agent).

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.

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	Reference	Number in IUCLID section 6.7/Test report title
PT1 Hand disinfection	Hand disinfectant Soap 1.98% Lactic acid	Bactericide *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10538	EN 13727 (2012+A2:2015 (phase 2, step 1) Tested product concentrations: 80%, 50%, 40%, 25%, 10%, 5%, 1%* Diluent: hard water Contact time: 30 seconds Interfering substance: 3 g/l bovine albumin + 3 g/l sheep erythrocytes (dirty conditions) Test method: dilution-neutralization Test temperature: 20 ± 1°C *Inconsistent with reported concentrations in Test report Page 2	Tested product demonstrated **bactericidal efficacy** (logR > 3 log) at product concentration of **50%** within **30 seconds** contact time under **dirty conditions**. The controls for *P. aeruginosa* were exceeding the requirements due to increased bacterial count of N_0	A. Kramer. (2020) Report No. 201654.V2	Report 201654.V2 Hand disinfectant soap bactericidal activity (EN 13727)
PT1 Hand disinfection	Hand disinfectant Soap Foam 1.98% Lactic acid	Bactericide *Enterococcus hirae* ATCC 10541[2] (Screening)	EN 13727 (2012+A2:2015 (phase 2, step 1) Tested product concentrations: 50%, Diluent: hard water Contact time: 30 seconds Interfering substance: 3 g/l bovine albumin + 3 g/l sheep erythrocytes (dirty conditions) Test method: dilution-neutralization Test temperature: 20 ± 1°C	Tested product demonstrated **bactericidal efficacy** (logR > 3 log) against *E. hirae* at product concentration of **50%** within **30 seconds** contact time under **dirty conditions**.	A. Kramer. (2022). Report No. 220057.V2	Report 220057.V2 Hand disinfectant soap foam bactericidal activity(EN 13727: 2015) - Screening with Enterococcus Hirae
PT1 Hand	Hand disinfectant Soap	Yeasticide	EN 13624 (2013) (phase 2, step 1) Tested product concentrations:	Tested product demonstrated **yeasticidal efficacy** (logR > 2 log) at product concentrations **of 50% and**	A. Kramer. (2021). Report No.	Report 211831.V1 Hand disinfectant soap (Batch

[2] *As more resistance according to test report No. 201654.V2*

disinfection	1.98% Lactic acid	*Candida albicans* ATCC 10231	50%, 25%, 10% Diluent: hard water Contact time: 30 seconds Interfering substance: 3 g/l bovine albumin + 3 g/l sheep erythrocytes (dirty conditions) Test method: dilution-neutralization - Test temperature: 20 ± 1°C	**25%** within **30 seconds** contact time under **dirty conditions**	211831.VI	20750052021) Yeasticidal efficacy (EN 13624)
PT1 Hand disinfection	Hand disinfectant Soap Foam 1.98% Lactic acid	*Candida albicans* ATCC 10231 (Screening)	EN 13624 (2013) (phase 2, step 1) Tested product concentrations: 50%* Diluent: hard water Contact time: 30 seconds Interfering substance: 3 g/l bovine albumin + 3 g/l sheep erythrocytes (dirty conditions) Test method: dilution-neutralization Test temperature: 20 ± 1°C *Inconsistent with the concentrations reported on Test report page 2	Tested product demonstrated **yeasticidal efficacy** (logR > 2 log) at product concentration of **50%** within **30 seconds** contact time under **dirty conditions**.	A. Kramer. (2022). Report No. 220058.V2.	Report 220058.V2 Hand disinfectant soap foam yeasticidal efficacy (EN 13624: 2021) - Screening with Candida albicans
PT1 Hand disinfection	Hand disinfectant Soap 1.98% Lactic acid	*Escherichia coli* K12 NCTC 10538	EN 1499:2013/2017 (phase 2, step 2) Volunteer test Tested product concentrations: 3 ml - 100% (undiluted) Contact time: 30 seconds Contamination fluid: $4.55x10^8$ cfu/ml Test method: dilution neutralization Test temp: 20±1°C Reference: 5 ml soft soap for 60s 15 volunteers	The test item is suitable for the hygienic handwash when hands are kept moist with 3ml (on wetted hands) of test product for a contact time of 30s The overall means of the lg prevalues for RP and PP were at least 5.00 (5.93 and 5.98 respectively) The absolute difference between mean differences RP-PP and PP-RP was 0.35 (Abs = [-1.98–(-2.33)] < 2. The criteria of 5.7.2 were fulfilled. The criteria of 5.7.3. were not fulfilled, since N exceeded the requirements and thus, higher counts was observed in N_{vo} Product was significantly more effective than the reference (rank sum = 0.000	A. Kramer. (2020). Report No.201657.V3	Report 201657.V3 Hand disinfectant soap hygienic hand wash (EN 1499: 2017)

				(1-tailed) significance level p = 0.01)		
PT1 Hand disinfection	Hand disinfectant Soap 1.98% Lactic acid	Modified vacciniavirus Ankara (MVA)	EN 14476:2019-10; Quantitative suspension test (phase 2, step 1) Tested product concentrations: 50%, 10%, 0.1% Diluent: hard water Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) Contact time: 30 seconds Test temperature: 20°C	Tested product demonstrated **3.5 log** virucidal activity against enveloped virus at **50% product** test concentration after exposure time of **30 seconds** under **dirty conditions** and 20°C. All controls were valid according to EN14476 requirements: 1.The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test was -1.50 after 5 min and ≥ 3.83 after 15, 30 and 60 min 2. Comparative virus titration resulted in < 1 log difference (7.33 vs 7.17) 3. Control for suppression of product`s activity was valid (≤0.5; 7.00 vs 6.83)	M. Eggers. (2020). Report No. LI-020-355.	Expert Opinion on the efficacy of hand soap disinfectant against Modifieed Vaccinia virus Ankara (MVA)
PT1 Hand disinfection	Hand disinfectant Soap Foam 1.98% Lactic acid	Modified vacciniavirus Ankara (MVA)	EN 14476:2019-10; Quantitative suspension test (phase 2, step 1) Tested product concentrations: 50%, Diluent: distilled water Interfering substance: 3 g/L BSA + 3.0 ml/l erythrocytes (dirty conditions) Contact time: 30 seconds Test temperature: 20°C	Tested product demonstrated virucidal activity against enveloped virus (**> 4 log**) at **50% product** test concentration after exposure time of **30 seconds** under **dirty conditions** and 20°C. All controls were valid according to EN14476 requirements: 1.The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test was -1.83 after 5 min and ≥ 2.33 after 15, 30 and 60 min 2. Comparative virus titration resulted in < 1 log difference (6.50 vs 6.50) 3. Control for suppression of product`s activity was valid (≤0.5; 6.50 vs 6.17)	M. Eggers. (2022). Report No. LI-022- 049	Expert Opinion on the efficacy of hand disinfectant soap foam against the Modified Vaccinia virus Ankara (MVA) according to DIN EN 14476: 2019-10

Efficacy assessment

Information on the choice of the worst-case compositions for efficacy and the justification for why the chosen test product is considered sufficient to cover the whole range of specified variations in the BPF are provided in the confidential annex.

The test products, the corresponding justification, and the data provided by the applicant are considered sufficient in order to cover the whole range of specified variations applied for.

Conclusion on efficacy

To demonstrate the **bactericidal activity**, quantitative suspension test according to the EN 13727:2012+A2:2015 (method dilution-neutralization) against four reference strains: *Pseudomonas aeruginosa ATCC 15442*, *Enterococcus hirae ATCC 10541*, *Staphylococcus aureus ATCC 6538* and *Escherichia coli K12 NCTC 10538*, has been performed.

Biocidal product activity against bacteria has been evaluated at a 30 sec contact time at dirty conditions (3g/l albumin + 3g/l sheep erythrocytes) and temperature 20 ± 1°C.

At concentration 50% the bactericidal infectivity reduction factor overpass > 3 log for all bacteria species (required > 3.0).

*Therefore, the reference biocidal product **Hand disinfectant Soap** with 1.98% w/w concentration of Lactic acid is a disinfectant with a bactericidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.*

To demonstrate the **bactericidal activity**, quantitative suspension test according to the EN 13727:2015 (method dilution-neutralization) against one reference strain *Enterococcus hirae ATCC 10541* has been performed. This strain considered more resistance according to results with the reference product *Hand disinfectant Soap.*

Biocidal product activity against bacteria has been evaluated at a 30 sec contact time at dirty conditions (3g/l albumin + 3g/l sheep erythrocytes) and temperature 20 ± 1°C.

At concentration 50% the bactericidal infectivity reduction factor overpass > 3 log (required > 3.0).

*Therefore, the additional reference biocidal **Hand disinfectant Soap Foam** product with 1.98% w/w concentration of Lactic acid is a disinfectant with a bactericidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use. The thickening agent doesn't impact efficacy against bacteria.*

Simulation of **practical conditions** to establish whether the biocidal product reduces the release of transient microbial flora on hands was performed according to **EN 1499:2017** (method dilution-neutralization), phase 2, step 2; Hygienic handwash.

The test was performed to find out bactericidal efficacy against *Escherichia coli K12 NCTC 10538* strain according to the following experimental conditions:

Reference procedure	4 ml of soft soap was poured into wetted cupped hands. Hands were washed in accordance with the standard hadwash procedure. After 60 s, this procedure was completed by a 10 s rinse of the hands under running tap water. The overall means values: Prevalue - 5.93 Postvalue – 3.26 Reduction factor – 2.86
Procedure with the tested product	3 ml of the test product was poured into wetted hands. Hands were then washed in accordance with the EN 1499 standard handwash procedure for 30 s. The overall means values: Prevalue – 5.98 Postvalue – 1.15 Reduction factor – 4.84

All acceptance criteria (EN 1499:2017) were met:

1. results of 15 volunteers
2. The overall means of the lg prevalues are above 5.00;
3. The absolute difference of mean differences is less than 2.00;

According to the Wilcoxon-Wilcox statistical test at the required probability level of p=0.01, the difference is considered significant (rank sum=0.00, p=0.000, required p≤0.01).

*Therefore, the reference product **Hand disinfectant Soap** used for hand washing for 30 seconds, under a volume of 3 ml has an biocidal activity according to claimed Standard.*

To demonstrate the **yeasticidal activity**, quantitative suspension test according to the EN 13624:2013 (method dilution-neutralization) against yeast *Candida albicans ATCC 10231* has been performed.

Biocidal product activity against yeast has been evaluated at a 30 sec contact time at dirty conditions (3g/l albumin + 3g/l sheep erythrocytes) and temperature 20 ± 1°C.

At concentration 25% the yeasticidal infectivity reduction factor overpass > 2 log (required> 2.0).

*Therefore, the reference biocidal **Hand disinfectant Soap** product with 1.98% w/w concentration of Lactic acid is a disinfectant with a yeasticidal activity under defined test conditions and exposure 30 sec according to claimed Standard and intended use.*

To demonstrate the **yeasticidal activity**, quantitative suspension test according to the EN 13624:2013 (method dilution-neutralization) against yeast *Candida albicans ATCC 10231* has been performed.

Biocidal product activity against yeast has been evaluated at a 30 sec contact time at dirty conditions (3g/l albumin + 3g/l sheep erythrocytes) and temperature 20 ± 1°C.

At concentration 50% the yeasticidal infectivity reduction factor overpass > 2 log (required > 2.0).

*Therefore, the additional reference biocidal **Hand disinfectant Soap Foam** product with 1.98% w/w concentration of Lactic acid is a disinfectant with a yeasticidal activity under*

defined test conditions and exposure 30 sec according to claimed Standard and intended use. The thickening agent doesn't impact efficacy against yeast.

To demonstrate the **virucidal activity only against enveloped viruses**, quantitative suspension test according to the EN 14476:2019-10 against enveloped viruses *Modified Vaccinia virus Ankara* has been performed.

Biocidal product activity has been evaluated at 30 sec contact time at dirty conditions (3g/l albumin + 3g/l sheep erythrocytes) and temperature 20 ± 1°C.

At concentration 50% the virucidal infectivity reduction factor is 3.5 log (required > 2.0).

*Therefore, the additional reference biocidal product **Hand disinfectant Soap** with 1.98% w/w concentration of Lactic acid is a disinfectant with a virucidal activity only against enveloped viruses under defined test conditions and exposure 30 sec according to claimed Standard and intended use.*

To demonstrate the **virucidal activity only against enveloped viruses**, quantitative suspension test according to the EN 14476:2019-10 against enveloped viruses *Modified Vaccinia virus Ankara* has been performed.

Biocidal product activity has been evaluated at 30 sec contact time at dirty conditions (3g/l albumin + 3g/l sheep erythrocytes) and temperature 20 ± 1°C.

At concentration 50% the virucidal infectivity reduction factor overpass ≥ 4 log (required > 2.0).

*Therefore, the additional reference biocidal product **Hand disinfectant Soap Foam** with 1.98% w/w concentration of Lactic acid is a disinfectant with a virucidal activity only against enveloped viruses under defined test conditions and exposure 30 sec according to claimed Standard and intended use.*

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.

Known limitations

None.

Relevant information if the BPF 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 BPF 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 of BPF, an evaluation related to skin and eyes corrosion / irritation 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 4.1 Summary table of animal studies on skin corrosion/irritation

Summary table of animal studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
OECD Guideline 404, 2015	New-Zealand albino rabbits, 3 males	Test item Fam H, 1.98% w/w Lactic acid 0.5 ml for 3 min, 1 hour and 4 hours	<u>Erythema</u> Animal 1: **0** Animal 2: **0** Animal 3: **0** <u>Oedema</u> Animal 1: **0** Animal 2: **0** Animal 3: **0**	-	Mollá E. et al., 2020 Report No. Tx/20/360

Table 4.2 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	According to the CLP regulation criteria and additivity approach, classification is met with respect to local effects on the skin (irritation) for the individual products of the BPF and thus the BPF itself. The conclusion is made based on RAC opinion for L(+)-Lactic acid, content of individual components, generic cut-off values specified in CLP regulation Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP Annex I, Table 3.2.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%. The Applicant has provided study according to the OECD Test Guidance No. 404. The tested formulation contains 1.98% Lactic acid and surfactants at total concentration above the limit within family. Please refer to the Confidential Annex for detailed

	composition of the tested formulation. The tested formulation can be considered as representative worst case and based on point 1.1.3.5 of CLP regulation Latvian CA is in opinion that tested formulation covers all biocidal products within BPF. According to Table 3.2.2 of the CLP regulation, the substances and mixtures shall be classified as Skin Irrit. 2 if mean score of ≥ 2.3 and ≤ 4.0 for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal is observed. According to the study, the three tested New-Zealand albino male rabbits showed no signs of erythema or oedema. Therefore, the tested product doesn't meet classification criteria. *Additional data* In order to support the good skin tolerance of the products, the Applicant took the initiative to perform the following tests under dermatological control (single application of the investigational product, under semi-occlusive patch on a panel of 11 subjects aged between 18 and 64 years old, with phototype II to IV and with sensitive skin on body. According to the study, the product induced no reaction of irritation and has a very good skin compatibility.
Classification of the product(s) according to CLP	Not relevant

3.6.1.2 Eye irritation

Table 4.16 Summary table of animal studies on serious eye damage and eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
OECD Guideline 405, 2020	New-Zealand albino rabbits	Test item Fam H, 1.98% w/w Lactic acid 0.1 ml for 1 hour, 24, 48 and 72 hours	<u>Cornea</u> Animal 1: **0** Animal 2: **0** Animal 3: **0** <u>Iris</u> Animal 1: **0** Animal 2: **0** Animal 3: **0** <u>Conjonctiva redness</u> Animal 1: **2** after 1 h fully reversible in 72 h Animal 2: **2** after 1 h fully reversible in 72	-	Mollá E. et al., 2020 Report No. Tx/20/361

			h Animal 3: **2** after 1 h fully reversible in 72 h <u>Conjunctival oedema</u> Animal 1: **0** Animal 2: **0** Animal 3: **0**		

Table 4.3 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Do not cause eye damage or eye irritation.
Justification for the value/conclusion	According to the CLP regulation criteria and additivity approach, classification is met with respect to local effects on the eyes (eye damage) for the individual products of the BPF and thus the BPF itself. The conclusion is made based on RAC opinion for L(+) lactic acid, content of individual components, generic cut-off values specified in CLP regulation Annex I, Table 1.1 and generic concentration limits (GCL) specified in CLP regulation Annex I, Table 3.3.3. The sum of the concentrations/GCL of individual components exceeds a concentration limit 1%. The Applicant has provided study according to the OECD Test Guidance No. 405. The tested formulation contains 1.98% Lactic acid and surfactants at total concentration above the limit within family. Please refer to the Confidential Annex for detailed composition of the tested formulation. The tested formulation can be considered as representative worst case and based on point 1.1.3.5 of CLP Latvian CA is in opinion that tested formulation covers all biocidal products within BPF. According to Table 3.3.1 of the CLP regulation, the substances and mixtures shall be classified as Eye Dam 1. if in at least 2 of 3 tested animals, a positive response of: (i) corneal opacity ≥ 3; and/or (ii) iritis > 1,5; calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material. According to Table 3.3.2 of the CLP regulation, the substances and mixtures shall be classified as Eye Irrit 2. if least 2 of 3 tested animals a positive response of: (a) corneal opacity ≥ 1; and/or (b) iritis ≥ 1; and/or (c) conjunctival redness ≥ 2; and/or (d) conjunctival oedema (chemosis) ≥ 2 calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material, and which fully reverses within an observation period of normally 21 days. According to the study 3 albino New Zealand rabbits showed mean individual values 0 for corneal opacity; 0 for iritis; 2 after 1 h fully reversible in 72 h for conjunctival redness and 0 for conjunctival oedema (chemosis). No classification criteria are fulfilled.

Classification of the product(s) according to CLP	Not relevant

3.6.1.3 Respiratory tract irritation

Table 4.4 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 products and according to the classification rules laid down in the CLP regulation, no classification for the respiratory tract irritation is required for any products of the BPF.
Classification of the product(s) according to CLP	Not relevant

3.6.1.4 Skin sensitization

Table 4.19 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
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. The main co-formulants of the BPF are not classified as skin sensitizers. Some ingredients of perfumes are classified as skin sensitizers. However, the concentration of these ingredients in final products is lower than generic concentration limit triggering classification of the products as skin sensitiser (< 1% w/w for H317 and H317 1B components and < 0.1 % for H317 1A components). Therefore, no classification as skin sensitiser according to the CLP regulation is required. Moreover, no special label (i.e. EUH208 "Contains… May produce an allergic reaction') is required for biocidal products as the concentration of these ingredients in final products is lower than concentration limits for elicitation of components of a mixture (< 0.1% w/w for H317 and H317 1B components and < 0.01 % for H317 1A components).
Classification of the product(s) according to CLP	Not relevant

3.6.1.5 Respiratory sensitization

Table 4.5 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizer for the respiratory tract
Justification for the value/conclusion	According to the CLP regulation Section 3.4.3.3, a mixture shall be classified as respiratory sensitiser when at least one ingredient has been classified as respiratory sensitiser and it is present at or above the appropriate generic concentration limit as shown in Table 3.4.5. The main co-formulants and ingredients of the perfumes are not classified as respiratory sensitisers. Therefore, no classification as respiratory sensitiser according to the CLP regulation is required.
Classification of the product(s) according to CLP	Not relevant

3.6.1.6 Acute oral toxicity

Table 4.6 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic by oral route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP regulation, no classification is required for the acute toxicity by oral route as none of the co-formulants are classified as Acute Tox. (oral).
Classification of the product(s) according to CLP	Not relevant

3.6.1.7 Acute inhalation toxicity

Table 4.7 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not toxic by inhalation route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP regulation, no classification is required for the acute inhalation toxicity as none of the co-formulants are classified as Acute Tox. (inhalation).
Classification of the product(s) according to CLP	Not relevant

3.1.6.8 Acute dermal toxicity

Table 4.8 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic by dermal route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP regulation, no classification is required for the acute dermal toxicity as none of the co-formulants are classified as Acute Tox. (dermal).
Classification of the product(s) according to CLP	Not relevant

Information on dermal absorption

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.

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 fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).

Other

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.

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

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

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.

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.

BPF contains Lactic acid as the active substance and 11 co-formulants as substances and 10

perfumes as mixtures. The products within family were 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 all co-formulants and components of perfumes was performed by the Applicant. None of the co-formulants/perfumes component are 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.

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.

Monitoring data

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

Dietary risk assessment

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

Aggregated exposure and risk characterisation

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

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.

3.7 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 BPF.

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

SDSs have been submitted for active substance and each co-formulant. According to SDSs, BPF contains one co-formulant and 5 perfumes classified for environmental hazards (Acute Chronic).

Following to method described in Section 4.1.3.5.5 of CLP regulation, the sum of the concentrations of the components classified for environmental hazards in final product multiplied by their corresponding M-factors is much lower than 25%.

Therefore, BPF is not classified for environmental hazards.

Available studies and endpoints applied in the environmental risk assessment

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

Not relevant.

Substances 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)).

Screening for endocrine disruption relating to non-target organisms

A screening phase for all co-formulants and components of perfumes was performed by the Applicant. None of the co-formulants/perfumes component are 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.

Emission estimation

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

Primary and secondary poisoning

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

Mixture toxicity

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

3.9 Assessment of a combination of biocidal products

Not relevant.

3.10 Comparative assessment

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

3.11 Calculations for exposure assessment

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

3.12 New information on the active substance(s) and substance(s) of concern

No new information on the active substance is available.

3.13 List of studies for the biocidal product family

Author (s)	Year Report date	IUCLID Section No.	IUCLID Document name	Title. Report No.	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H0	Physicochemical Analysis Salvesafe H0 Report N°2022/044 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H0				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H0				
		Section 3.8	Surface tension. SALVESAFE H0				
		Section 3.9	Viscosity. SALVESAFE H0				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H1	Physicochemical Analysis Salvesafe H1 Report N°2022/045 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H1				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H1				
		Section 3.8	Surface tension. SALVESAFE H1				
		Section 3.9	Viscosity. SALVESAFE H1				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H2	Physicochemical Analysis Salvesafe H2 Report N°2022/046 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H2				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H2				
		Section 3.8	Surface tension. SALVESAFE H2				
		Section 3.9	Viscosity. SALVESAFE H2				

Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H3	Physicochemical Analysis Salvesafe H3 Report N°2022/047 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H3				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H3				
		Section 3.8	Surface tension. SALVESAFE H3				
		Section 3.9	Viscosity. SALVESAFE H3				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H4	Physicochemical Analysis Salvesafe H4 Report N°2022/048 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H4				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H4				
		Section 3.8	Surface tension. SALVESAFE H4				
		Section 3.9	Viscosity. SALVESAFE H4				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H5	Physicochemical Analysis Salvesafe H5 Report N°2022/049 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H5				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H5				
		Section 3.8	Surface tension. SALVESAFE H5				
		Section 3.9	Viscosity. SALVESAFE H5				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H6	Physicochemical Analysis Salvesafe H6 Report N°2022/050 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H6				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H6				
		Section 3.8	Surface tension. SALVESAFE H6				

		Section 3.9	Viscosity. SALVESAFE H6				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H7	Physicochemical Analysis Salvesafe H7 Report N°2022/051 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H7				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H7				
		Section 3.8	Surface tension. SALVESAFE H7				
		Section 3.9	Viscosity.SALVESAFE H7				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H8	Physicochemical Analysis Salvesafe H8 Report N°2022/052 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H8				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H8				
		Section 3.8	Surface tension. SALVESAFE H8				
		Section 3.9	Viscosity. SALVESAFE H8				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H9	Physicochemical Analysis Salvesafe H9 Report N°2022/053 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity.SALVESAFE H9				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H9				
		Section 3.8	Surface tension. SALVESAFE H9				
		Section 3.9	Viscosity. SALVESAFE H9				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H10	Physicochemical Analysis Salvesafe H10 Report N°2022/054 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H10				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H10				

		Section 3.8	Surface tension. SALVESAFE H10				
		Section 3.9	Viscosity. SALVESAFE H10				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H0_F	Physicochemical Analysis Salvesafe H0_F Report N°2022/055 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H0_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H0_F				
		Section 3.8	Surface tension. SALVESAFE H0_F				
		Section 3.9	Viscosity. SALVESAFE H0_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H1_F	Physicochemical Analysis Salvesafe H1_F Report N°2022/056 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H1_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H1_F				
		Section 3.8	Surface tension. SALVESAFE H1_F				
		Section 3.9	Viscosity. SALVESAFE H1_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H2_F	Physicochemical Analysis Salvesafe H2_F Report N°2022/057 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H2_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H2_F				
		Section 3.8	Surface tension. SALVESAFE H2_F				
		Section 3.9	Viscosity. SALVESAFE H2_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H3_F	Physicochemical Analysis Salvesafe H3_F Report N°2022/058 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H3_F				

		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H3_F				
		Section 3.8	Surface tension. SALVESAFE H3_F				
		Section 3.9	Viscosity. SALVESAFE H3_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H4_F	Physicochemical Analysis Salvesafe H4_F Report N°2022/059 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H4_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H4_F				
		Section 3.8	Surface tension. SALVESAFE H4_F				
		Section 3.9	Viscosity. SALVESAFE H4_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H5_F	Physicochemical Analysis Salvesafe H5_F Report N°2022/060 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity.SALVESAFE H5_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H5_F				
		Section 3.8	Surface tension. SALVESAFE H5_F				
		Section 3.9	Viscosity. SALVESAFE H5_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H6_F	Physicochemical Analysis Salvesafe H6_F Report N°2022/061 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H6_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H6_F				
		Section 3.8	Surface tension. SALVESAFE H6_F				
		Section 3.9	Viscosity. SALVESAFE H6_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H7_F	Physicochemical Analysis Salvesafe H7_F Report N°2022/062 – Updated	SALVECO	No	Yes

		Section 3.2	Acidity, alkalinity. SALVESAFE H7_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H7_F				
		Section 3.8	Surface tension. SALVESAFE H7_F				
		Section 3.9	Viscosity. SALVESAFE H7_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H8_F	Physicochemical Analysis Salvesafe H8_F Report N°2022/063 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H8_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H8_F				
		Section 3.8	Surface tension. SALVESAFE H8_F				
		Section 3.9	Viscosity. SALVESAFE H8_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H9_F	Physicochemical Analysis Salvesafe H9_F Report N°2022/064 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H9_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H9_F				
		Section 3.8	Surface tension. SALVESAFE H9_F				
		Section 3.9	Viscosity. SALVESAFE H9_F				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H10_F	Physicochemical Analysis Salvesafe H10_F Report N°2022/065 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H10_F				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H10_F				
		Section 3.8	Surface tension. SALVESAFE H10_F				
		Section 3.9	Viscosity. SALVESAFE H10_F				

Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H0_R	Physicochemical Analysis Salvesafe H0_R Report N°2022/066 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H0_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H0_R				
		Section 3.8	Surface tension. SALVESAFE H0_R				
		Section 3.9	Viscosity. SALVESAFE H0_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H1_R	Physicochemical Analysis Salvesafe H1_R Report N°2022/067 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H1_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H1_R				
		Section 3.8	Surface tension. SALVESAFE H1_R				
		Section 3.9	Viscosity. SALVESAFE H1_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H2_R	Physicochemical Analysis Salvesafe H2_R Report N°2022/068 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H2_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H2_R				
		Section 3.8	Surface tension. SALVESAFE H2_R				
		Section 3.9	Viscosity. SALVESAFE H2_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H3_R	Physicochemical Analysis Salvesafe H3_R Report N°2022/069 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H3_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H3_R				
		Section 3.8	Surface tension. SALVESAFE H3_R				

		Section 3.9	Viscosity. SALVESAFE H3_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H4_R	Physicochemical Analysis Salvesafe H4_R Report N°2022/070 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H4_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H4_R				
		Section 3.8	Surface tension. SALVESAFE H4_R				
		Section 3.9	Viscosity. SALVESAFE H4_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H5_R	Physicochemical Analysis Salvesafe H5_R Report N°2022/071 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H5_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H5_R				
		Section 3.8	Surface tension. SALVESAFE H5_R				
		Section 3.9	Viscosity. SALVESAFE H5_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H6_R	Physicochemical Analysis Salvesafe H6_R Report N°2022/072 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H6_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H6_R				
		Section 3.8	Surface tension. SALVESAFE H6_R				
		Section 3.9	Viscosity. SALVESAFE H6_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa).SALVESAFE H7_R	Physicochemical Analysis Salvesafe H7_R Report N°2022/073 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H7_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H7_R				

		Section 3.8	Surface tension. SALVESAFE H7_R				
		Section 3.9	Viscosity. SALVESAFE H7_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa).SALVESAFE H8_R	Physicochemical Analysis Salvesafe H8_R Report N°2022/074 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H8_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H8_R				
		Section 3.8	Surface tension. SALVESAFE H8_R				
		Section 3.9	Viscosity. SALVESAFE H8_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H9_R	Physicochemical Analysis Salvesafe H9_R Report N°2022/075 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H9_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H9_R				
		Section 3.8	Surface tension. SALVESAFE H9_R				
		Section 3.9	Viscosity. SALVESAFE H9_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H10_R	Physicochemical Analysis Salvesafe H10_R Report N°2022/076 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H10_R				
		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H10_R				
		Section 3.8	Surface tension. SALVESAFE H10_R				
		Section 3.9	Viscosity. SALVESAFE H10_R				
Revol B.	2022	Section 3.1	Appearance (at 20°C and 101.3 kPa). SALVESAFE H0_RC	Physicochemical Analysis Salvesafe H0_RC Report N°2022/111 – Updated	SALVECO	No	Yes
		Section 3.2	Acidity, alkalinity. SALVESAFE H0_RC				

		Section 3.3	Relative density (liquids) and bulk, tap density (solids). SALVESAFE H0_RC				
		Section 3.8	Surface tension. SALVESAFE H0_RC				
		Section 3.9	Viscosity. SALVESAFE H0_RC				
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H0	Accelerated storage stability_Salvesafe_H0 Report N°2022/077 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H1	Accelerated storage stability_Salvesafe_H1 Report N°2022/078 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H2	Accelerated storage stability_Salvesafe_H2 Report N°2022/079 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H3	Accelerated storage stability_Salvesafe_H3 Report N°2022/080 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H4	Accelerated storage stability_Salvesafe_H4 Report N°2022/081 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H5	Accelerated storage stability_Salvesafe_H5 Report N°2022/082 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H6	Accelerated storage stability_Salvesafe_H6 Report N°2022/083 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H7	Accelerated storage stability_Salvesafe_H7 Report N°2022/084 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H8	Accelerated storage stability_Salvesafe_H8 Report N°2022/085 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H9	Accelerated storage stability_Salvesafe_H9 Report N°2022/086 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H10	Accelerated storage stability_Salvesafe_H10 Report N°2022/087 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H0_F	Accelerated storage stability_Salvesafe_H0_F Report N°2022/088 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H1_F	Accelerated storage stability_Salvesafe_H1_F Report N°2022/089 – Updated	SALVECO	No	Yes

Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H2_F	Accelerated storage stability_Salvesafe_H2_F Report N°2022/090 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H3_F	Accelerated storage stability_Salvesafe_H3_F Report N°2022/091 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H4_F	Accelerated storage stability_Salvesafe_H4_F Report N°2022/092 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H5_F	Accelerated storage stability_Salvesafe_H5_F Report N°2022/093 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H6_F	Accelerated storage stability_Salvesafe_H6_F Report N°2022/094 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H7_F	Accelerated storage stability_Salvesafe_H7_F Report N°2022/095 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H8_F	Accelerated storage stability_Salvesafe_H8_F Report N°2022/096 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H9_F	Accelerated storage stability_Salvesafe_H9_F Report N°2022/097 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H10_F	Accelerated storage stability_Salvesafe_H10_F Report N°2022/098 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H0_R	Accelerated storage stability_Salvesafe_H0_R Report N°2022/099 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H1_R	Accelerated storage stability_Salvesafe_H1_R Report N°2022/100 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H2_R	Accelerated storage stability_Salvesafe_H2_R Report N°2022/101 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H3_R	Accelerated storage stability_Salvesafe_H3_R Report N°2022/102 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H4_R	Accelerated storage stability_Salvesafe_H4_R Report N°2022/103 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H5_R	Accelerated storage stability_Salvesafe_H5_R Report N°2022/104 – Updated	SALVECO	No	Yes

Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H6_R	Accelerated storage stability_Salvesafe_H6_R Report N°2022/105 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H7_R	Accelerated storage stability_Salvesafe_H7_R Report N°2022/106 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H8_R	Accelerated storage stability_Salvesafe_H8_R Report N°2022/107 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H9_R	Accelerated storage stability_Salvesafe_H9_R Report N°2022/108 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H10_R	Accelerated storage stability_Salvesafe_H10_R Report N°2022/109 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Storage stability SALVESAFE H0_RC	Accelerated storage stability_Salvesafe_H0_RC Report N°2022/112 – Updated	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H0	StabilityReport_Salvesafe_H0_T5 Report N°2022/129	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H1	StabilityReport_Salvesafe_H1_T5 Report N°2022/130	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H2	StabilityReport_Salvesafe_H2_T5 Report N°2022/131	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H3	StabilityReport_Salvesafe_H3_T5 Report N°2022/132	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months).SALVESAFE H4	StabilityReport_Salvesafe_H4_T5 Report N°2022/133	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H5	StabilityReport_Salvesafe_H5_T5 Report N°2022/134	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H6	StabilityReport_Salvesafe_H6_T5 Report N°2022/135	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H7	StabilityReport_Salvesafe_H7_T5 Report N°2022/136	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H8	StabilityReport_Salvesafe_H8_T5 Report N°2022/137	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H9	StabilityReport_Salvesafe_H9_T5 Report N°2022/138	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H10	StabilityReport_Salvesafe_H10_T5 Report N°2022/139	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H0_F	StabilityReport_Salvesafe_H0_F_T5 Report N°2022/140	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H1_F	StabilityReport_Salvesafe_H1_F_T5 Report N°2022/141	SALVECO	No	Yes

Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H2_F	StabilityReport_Salvesafe_H2_F_T5 Report N°2022/142	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H3_F	StabilityReport_Salvesafe_H3_F_T5 Report N°2022/143	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H4_F	StabilityReport_Salvesafe_H4_F_T5 Report N°2022/144	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H5_F	StabilityReport_Salvesafe_H5_F_T5 Report N°2022/145	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H6_F	StabilityReport_Salvesafe_H6_F_T5 Report N°2022/146	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H7_F	StabilityReport_Salvesafe_H7_F_T5 Report N°2022/147	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H8_F	StabilityReport_Salvesafe_H8_F_T5 Report N°2022/148	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H9_F	StabilityReport_Salvesafe_H9_F_T5 Report N°2022/149	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term Storage stability tests (5 months). SALVESAFE H10_F	StabilityReport_Salvesafe_H10_F_T5 Report N°2022/150	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H0_R	StabilityReport_Salvesafe_H0_R_T5 Report N°2022/151	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H1_R	StabilityReport_Salvesafe_H1_R_T5 Report N°2022/152	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H2_R	StabilityReport_Salvesafe_H2_R_T5 Report N°2022/153	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H3_R	StabilityReport_Salvesafe_H3_R_T5 Report N°2022/154	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H4_R	StabilityReport_Salvesafe_H4_R_T5 Report N°2022/155	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H5_R	StabilityReport_Salvesafe_H5_R_T5 Report N°2022/156	SALVECO	No	Yes

Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H6_R	StabilityReport_Salvesafe_H6_R_T5 Report N°2022/157	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H7_R	StabilityReport_Salvesafe_H7_R_T5 Report N°2022/158	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H8_R	StabilityReport_Salvesafe_H8_R_T5 Report N°2022/159	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H9_R	StabilityReport_Salvesafe_H9_R_T5 Report N°2022/160	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H10_R	StabilityReport_Salvesafe_H10_R_T5 Report N°2022/161	SALVECO	No	Yes
Revol B.	2022	Section 3.4.1	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H0_RC	StabilityReport_Salvesafe_H0_RC_T5 Report N°2022/162	SALVECO	No	Yes
J-M. François	2022	Section 4.1	Explosiveness.SALVESAFE H	Differential Scanning Calorimetry (DSC) Report 2022/381/JMF	Dekra	Yes	Yes
A. Guibet	2022	Section 4.6	Flash point. SALVESAFE H	Point éclair Report N°22-08425.001	SGS	Yes	Yes
J. Conderaerts.	2020	Section 4.16	Corrosive to metals. SALVESAFE H FAMILY	Report No. JC 20-380_final_200903	Belgian Welding Institute NPO	Yes	Yes
C. Cours; K. Wilhelm	2022	Section 4.17.1	Auto-ignition temperature (liquids and gases). SALVESAFE H	Température d'auto-inflammation Report N°R/22/24370	Analytice	Yes	Yes
Revol B.	2022	Section 5	Methods of detection.	HPLC Method Validation Report n°2022/136	SALVECO	No	Yes
DR. rer. Med. T. Koburger-Janssen & Prod. Dr. med. A. Kramer	2020	Section 6.7	Efficacy data to support these claims. BACTERICIDAL EFFICACY EN 1499	Hand Disinfectant Soap. Hygienic Handwash (EN1499:2017) Report 201657.V3	Hygiene Nord GmbH	Yes	Yes

DR. rer. Med. T. Koburger-Janssen & Prod. Dr. med. A. Kramer	2020	Section 6.7	Efficacy data to support these claims. BACTERICIDAL EFFICACY EN 13727	Hand disinfectant Soap. Bactericidal activity (EN13727) Report 201654.V2	Hygiene Nord GmbH	Yes	Yes
DR. rer. Med. T. Koburger-Janssen & Prod. Dr. med. A. Kramer	2022	Section 6.7	Efficacy data to support these claims. BACTERICIDAL EFFICACY EN 13727	Hand disinfectant Soap Foam. Bactericidal activity (EN13727:2015) Report 220057.V2	Hygiene Nord GmbH	Yes	Yes
DR. rer. Med. T. Koburger-Janssen & Prod. Dr. med. A. Kramer	2021	Section 6.7	Efficacy data to support these claims. YEASTICIDAL EFFICACY EN 13624	Hand disinfectant Soap (Batch 20750052021) Yesticidal efficacy (EN13624) Report 211831.V1	Hygiene Nord GmbH	Yes	Yes
DR. rer. Med. T. Koburger-Janssen & Prod. Dr. med. A. Kramer	2022	Section 6.7	Efficacy data to support these claims. YEASTICIDAL EFFICACY EN 13624	Hand disinfectant Soap Foam. Yeasticidal efficacy (EN13624:2021) Report 220058.V2	Hygiene Nord GmbH	Yes	Yes
PD Dr. rer. Nat. M. Eggers	2020	Section 6.7	Efficacy data to support these claims. VIRUCIDAL EFFICACY EN 14476+A2	Expert opinion on the efficacy of Hand Soap disinfectant against Modified Vaccinia virus Ankara (MVA) Report N°LI-020-355	Labor Enders	Yes	Yes
PD Dr. rer. Nat. M. Eggers	2022	Section 6.7	Efficacy data to support these claims. VIRUCIDAL EFFICACY EN 14476+A2	Expert opinion on the efficacy of Hand disinfectant Soap Foam against the Modifified Vaccinia Virus Ankara (MVA) according to DIN EN 14476:2019-10 Report N° LI-022-049	Labor Enders	Yes	Yes
E. Mollá	2020	Section 8.1.1	Skin irritation / corrosion. SALVESAFE H (OECD 404)	Acute Skin Irritation/Corrosion test with Fam H (Guideline OCDE 404:2015) Report N° TX/20/360	Insituto Valenciane de Microbiología	Yes	Yes

E. Mollá	2021	Section 8.1.2	Eye irritation. SALVESAFE H (OECD 405)	In vivo Acute eye Irritation/Corrosion test in rabbit model with the product Fam H(OECD 405: 2020 guideline) Report N° TX/20/361	Insituto Valenciane de Microbiología	Yes	Yes
R. Olsavszky, E. A. Nanu, C. Borlescu	2020	Section 8.1.1	Skin irritation / corrosion. SALVESAFE H (OECD 404)	Human patch test under dermatological control Savon mains disinfectant/Desinfecting hand soap Report N° P20 0480/ER 20/139	Eurofins EVIC France Eurofins EVIC Romania	Yes	Yes
Revol B.	2023	Section 3.4.1	Storage stability SALVESAFE H0_R1	Accelerated storage stability_Salvesafe H0_R1 Report N°2023/103 – Updated	SALVECO	Yes	Yes
Revol B.	2023	Section 3.4.1	Storage stability SALVESAFE H11	Accelerated storage stability_Salvesafe H11 Report N°2023/154	SALVECO	Yes	Yes
Revol B.	2023	Section 3.4.1.	Long-term STABILITY REPORT (Report – 5 months) Salvesafe H11	Stability Report_Salvesafe_H11_T5 Report N°2022/157	SALVECO	Yes	Yes
Revol B.	2023	Section 3.4.1	Storage stability SALVESAFE H11_F	Accelerated storage stability_Salvesafe H11_F Report N°2023/155	SALVECO	Yes	Yes

3.14 References

Not relevant

3.15 Confidential information

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