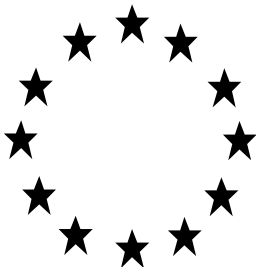
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the competent authority)



SANYTOL LACTIC SA-APP

Product types 2 and 4

Lactic Acid

Case Number in R4BP: BC-FY084371-12

Competent Authority: FR CA

Date: 27/03/2024

Table of Contents

Changes history table

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-APP	FR CA	BC-LA048793-44	09/12/2019	First authorisation – non approved	
SA-APP	FR CA	BC-FY084371-12	27/03/2024	First authorisation	

1 Conclusion

The biocidal products of the family SANYTOL LACTIC SA-APP are product type 2 and 4 containing 0,86 - 0,871% lactic acid and are intended to be used against bacteria, yeasts, fungi and viruses. The products of the family are ready-to-use liquid (meta SPC 1) or impregnated wipes (meta SPC 2) for surface and textiles disinfection for professionals and non-professional users.
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 uses "Soft surface disinfection", "Hard non porous surface disinfection" (meta SPC 1) and "Hard non porous surface disinfection" (meta SPC 2) for professionals and non-professional users, as specified in the Summary of Product Characteristics (SPC).
Nevertheless, product containing the perfume LEMON at the claimed concentration is not considered conform (see confidential annex for details).
The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended uses 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 and satisfy the restriction that concentration has to be limited so that classification of biocidal products is not necessary according to Directive 1999/45/CE or Regulation (EC) No 1272/2008 ;
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 necessary. Detailed information on classification and labelling is provided in section 2.9 of the PAR. The hazard and precautionary statements of the BPF according to Regulation (EC) No 1272/2008 are available in the SPC, in section 3 for each meta-SPC.

The BPF does not contain non-active substances (so called "co-formulant(s)") which are considered as substances of concern.

The BPF does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no significant indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the BPF.

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

[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

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.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have 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 the PAR.

Physical hazards and respective characteristics

A physical hazard was identified in all meta-SPCs. *H290 corrosive to metal cat 1.* More information is available in section 3.3 of the PAR.

Methods for detection and identification

A 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, fungi and enveloped viruses for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

No substances of concern were identified for human health.

The handling of the product for its intended uses does not require personal protective equipment.

The concentration of the perfume LEMON in the products of both meta-SPC has to be strictly below 0.1%. **The product containing the perfume LEMON at the claimed concentration is not considered conform.**

Dietary risk assessment

Not relevant. As lactic acid is listed in Annex I of Regulation (EU) No 528/2012 under Category 4 – Traditionally used substances of natural origin, a dietary risk assessment is not relevant.

Risk assessment for the environment

No substances of concern were identified for the environment.
The products of the SANYTOL LACTIC SA-APP family are not classified for the environment.

2 Information on the biocidal product family

2.1 Product types and types of formulation

Table 2.1 Product types and types of formulation

Product types	*PT2 and PT4 for meta-SPC 1 and 2*
Types of formulation	*AL-any other liquids for meta-SPC 1* *OTHER - Impregnated wipes for meta-SPC 2*

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 number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (by CA)[8]	Comment[9]
[1.1]	*Soft surface disinfection*	*PT2 and PT4*	*Bacteria Yeasts Viruses*	*Spraying*	*RTU*	*Professional Non-professional*	*A*	
[1.2]	*Hard surface disinfection*		*Bacteria Yeasts Fungi Viruses*	*Spraying and wiping Pouring and wiping*	*RTU*		*A*	
[2.1]	*Hard surface disinfection*			*Wiping*	*RTU*		*R*	

[1] Use number (as applied for) to be indicated together with the meta-SPC number, as in the SPC (e.g. 1.2, where "1" is the meta-SPC and "2" is the use number within the meta-SPC)
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for all meta-SPCs for the specific use
[6] Min-max. application rate of the product(s) for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use or meta-SPC is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

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

The application for authorisation as a BPF explicitly identified the maximum risks to human health, animal health, and the environment, and the minimum level of efficacy.

All the products applied for include the same active substance and are similar in composition. Information on the similarity of composition and the identified worst and best case composition are 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]
[1.1]	*PT2 and PT4*	#4	(1)b (2)c
[1.2]	*PT2 and PT4*	#5	(1)b
[2.1]	*PT2 and PT4*	#30	(1)b (2)c

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

The agreed general criteria for deciding on whether the intended uses can be considered as similar were applied, according to the document CA-July19-Doc.4.2-Final entitled "Implementing the concept of biocidal product family".

In accordance with the agreed general criteria, all the intended uses are considered similar uses, in line with the document CG-34-2019-12 AP 15.1 Assessment of similarity in BPF.docx ("Section 2 – Similarity of uses"). The corresponding justifications provided by the applicant are considered acceptable.

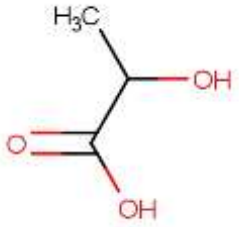
All the intended uses as applied for by the applicant have been assessed. By considering only those uses appropriate for authorisation which bear a consistent set of instructions for use, RMMs etc. (e.g. same RMMs from best to worst case composition), it was ensured that all products of the BPF have 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-SPCs and of the individual products is detailed in sections 2.1 and 7 of the SPC, respectively. Information on the full composition is provided in the confidential annex.

2.5 Identity of the active substance

Main constituent(s)	
Commun 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(s) of the active substance

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

2.7 Candidate for substitution

The active substance lactic acid contained in the BPF SANYTOL LACTIC SA-APP does not meet any substitution criteria listed in Article 10 of Regulation (EU) No.528/2012.

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

The BPF does not contain any active substances having endocrine-disrupting properties.

Based on the available information, there are indications that some of the non-active substances may have endocrine-disrupting properties and these will have to be further investigated.

More detailed information is available in the confidential annex.

2.9 Classification and labelling

Table 2.4 Classification and labelling of the BPF

[Meta SPC 1]	**Classification**	**Labelling**
Hazard Class and Category code		
Hazard Pictograms		
Signal word(s)	Warning	Warning
Hazard statements	H290 corrosive to metal cat 1	H290 corrosive to metal cat 1
Precautionary statements*	P234 Keep only in original packaging. P390 Absorb spillage to prevent material damage. P406 Store in a corrosive resistant container with a resistant inner liner.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements		
Notes	*[Where necessary, add a justification for excluding certain P-statements.]*	

***P-statements that are excluded based on the risk assessment or the intended use of the product(s)[2], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[2] Section 3 of the CA note of Q&A concerning the content of some SPC sections. The document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

Table 2.6 Classification and labelling of the BPF

[Meta SPC 2]	**Classification**	**Labelling**
Hazard Class and Category code		
Hazard Pictograms		
Signal word(s)	Warning	Warning
Hazard statements	H290 corrosive to metal cat 1	H290 corrosive to metal cat 1
Precautionary statements*	P234 Keep only in original packaging. P390 Absorb spillage to prevent material damage. P406 Store in a corrosive resistant container with a resistant inner liner.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements		
Notes	*[Where necessary, add a justification for excluding certain P-statements.]*	

***P-statements that are excluded based on the risk assessment or the intended use of the product(s)[3], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[3] Section 3 of the CA note of Q&A concerning the content of some SPC sections. The document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

2.10 Letter of access

No Letter of Access to the active substance or to the products has been submitted.

2.11 Data submitted in relation to product authorisation

This section is not relevant.

2.12 Similar conditions of use across the Union

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	Range: from 50 mL up to 5000 mL	HDPE	Trigger 0 : TS5 spray med screw 28410 (PP) ~~Trigger 1 : AFA spray rosca 28-410 Verde (2020) (PP)~~ Trigger 2 : TS3 Dexter sanytol spray Verde'19 (PP) Cap (PP)	General public (non-professional) and professional	Yes for HDPE with trigger spray 0 and 2
Bottle	Range: from 500 mL up to 5000 mL	HDPE	Cap (PP)	General public (non-professional) and professional	Yes
Sachets-sampling	Range: from 45 mL up to 1000 mL packed in: Bags (PET-PE)	PET-PE	Sampling film (PET-PE)	General public (non-professional) and professional	Yes
Doypack refill packaging	Range: from 45 mL up to 2000 mL	PET-PE	PE Spout + PE Cap	General public (non-professional) and professional	Yes
Wipes (Meta SPC 2)	Format range: from 3 up to 300 cellulose wipes*.	Multilayer flowpack (PET + PE/EVOH/PE) And	Flowpack	General public (non-professional) and professional	Yes

		Multilayer flowpack (PET + PE)			

* Characteristics of wipes: see confidential annex

3.2 Physical, chemical, and technical properties

One worst case product has been tested for each Meta SPC. The tables below summarize the assessment of the physico chemical properties for the two META SPCs. The Meta SPC range only on:

META SPC 1:

- PERFUME: the variation is very small for both co-formulants (less than 1%).

META SPC 2:

- PERFUME: the variation is very small for both co-formulants (less than 1%).

Information on the choice of the worst case composition for physical, chemical, and technical properties (e.g. representative test product(s)) and the justification for why the chosen test product(s) are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential PAR.

Table 3.2 Physical, chemical, and technical properties

N° BPR	Property	Guideline and Method	Tested product/ batch (AS%/w)	Results	Reference	eCA assessment
3.1.	Appearance at 20 °C and 101.3 kPa	Visual No guideline followed	REW2451 _BL2 (1.075% AS)	White bottle, trigger and neck green, translucid cap. Liquid colourless and transparent. Citric notes followed by floral notes	[redacted] study number EST522, [redacted]	acceptable

N° BPR	Property	Guideline and Method	Tested product/ batch (AS%/w)	Results	Reference	eCA assessment
					[redacted], study number EST523	
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual	REW2451_BL2 (1.075% AS)	Liquid.	[redacted], study number EST522, [redacted], study number EST523	acceptable
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual	REW2451_BL2 (1.075% AS)	Colourless.	[redacted] study number EST522, [redacted], study number EST523	acceptable
3.1.3.	Odour at 20 °C and 101.3 kPa	No guideline followed	REW2451_BL2 (1.075% AS)	Immediate citric notes followed by floral notes	[redacted], study number EST522, [redacted]), study number EST523	acceptable
3.2.	Acidity, alkalinity, and pH value	CIPAC method MT191	REW2451_BL2(1.075% AS)	0.397% as % of HCl (w/w) ≈0.198% as % of H2SO4 (w/w) pH= 2.78 (at 23.7°C)	[redacted], study number EST522 [redacted], study number EST523	acceptable

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/ batch (AS%/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>3.3.</td><td>Relative density / bulk density</td><td>CIPAC MT 186</td><td>REW2451_BL2(1.075% AS)</td><td>1.0025</td><td>[redacted], study number EST522

[redacted] study number EST523</td><td>acceptable</td></tr>
<tr><td>3.4.1.1.</td><td>Storage stability test – accelerated storage</td><td>CIPAC method MT 46.3

Active substance determination: Method BPL-MA-057 validated method in 2.2.4</td><td>REW2451_BL2(1.075% AS)</td><td>Storage of Sanytol Deo Textil at 54°C ± 2°C for 2 weeks in a 500Ml HDPE trigger bottle (spray trigger 0)
<table>
<tr><th>Test</th><th>T=0</th><th>T=2 weeks</th></tr>
<tr><td>Active ingredient</td><td>0.86 %</td><td>0.88 % (+2.3%)</td></tr>
<tr><td>Relative density</td><td>1.0025</td><td>1.0026</td></tr>
<tr><td>pH</td><td>2.78</td><td>2.86</td></tr>
<tr><td>Acidity as HCl</td><td>0.397%</td><td>0.419%</td></tr>
<tr><td>Viscosity</td><td>4.66 cp (20°C)
4.25 cp (40°C)</td><td>4.65 cp (20°C)
4.24 cp (40°C)</td></tr>
<tr><td>Weight change</td><td colspan="2">Loss: 0.51 g
Change: 0.09%</td></tr>
<tr><td>Appearance, physical state, colour and odour</td><td>White bottle, trigger and neck green, translucid cap. Liquid colourless. Immediate citric notes followed by floral notes.</td><td>White bottle, trigger and neck green, translucid cap. Liquid colourless. Less intense citric notes followed by floral notes.</td></tr>
<tr><td>Spray characterization</td><td>Dmin 18cm;
Dmax 24.5cm</td><td>Dmin 18.4cm;
Dmax 25.5cm</td></tr>
</table></td><td>[redacted], study number EST522</td><td>Acceptable. The results of this study can be extrapolated to the other trigger spray claim as not interaction between the packaging and the product has been observed and the material of the trigger sprays are identical.</td></tr>
</table>

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/ batch (AS%/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Dmin – Dmax After spraying 3 times at 30 cm distance</td><td></td><td></td></tr>
<tr><td>Amount delivered (g per spray) After 5 spray dosages</td><td>1.014 g</td><td>1.208 g</td></tr>
<tr><td>Stability of packaging</td><td>No craks, holes, etc. No leaks No blocks were observed</td><td>No craks, holes, etc. No leaks Width change: 2.70 cm No blocks were observed</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>3.4.1.2.</td><td>Storage stability test – long-term storage at ambient temperature</td><td>CIPAC method MT 46.3

Active substance determination: Method BPL-MA-057 validated method in 2.2.4</td><td>REW2451_BL2(1.075% AS)</td><td>Results after 12, 24 and 36 months storage at 20°C in its commercial packaging (500Ml trigger bottle – spray trigger 0) are presented below:
<table>
<tr><th>Test</th><th>T=0</th><th>T=12 months</th><th>T=24 months</th><th>T= 36 months</th></tr>
<tr><td>Lactic acid content</td><td>0.86%</td><td>Mean : 0.85% (-1%)</td><td>Mean : 0.87%(+1%)</td><td>Mean : 0.86%</td></tr>
<tr><td>Density (g/cm3)</td><td>1.0025</td><td>1.0026</td><td>1.0025</td><td>1.0026</td></tr>
<tr><td>Ph</td><td>2.78</td><td>2.84</td><td>2.87</td><td>2.80</td></tr>
<tr><td>Acidity</td><td>0.40%</td><td>0.44%</td><td>0.43%</td><td>0.432%</td></tr>
<tr><td>Viscosity</td><td>4.66 cp (20°C) 4.25 cp (40°C)</td><td>4.73 cp (20°C) 3.85 cp (40°C)</td><td>4.72 cp (20°C) 4.04 cp (40°C)</td><td>5.02 cp (20° C) 4.02 cp (40°C)</td></tr>
</table>
</td><td>[redacted], study number EST523</td><td>Acceptable. The long term storage should have been performed on each trigger spray. Nevertheless, based on the composition of the product, no interaction between the material of the trigger spray and the product is expected. Therefore, the stability of the trigger tested can be extrapolated to other trigger spray tested.

Moreover, the</td></tr>
</table>

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/ batch (AS%/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Surface Tension (Mn/m)</td><td>25.4</td><td>25.7</td><td>25.8</td><td>25.8</td></tr>
<tr><td>Appearance</td><td colspan="4">Transparent liquid with floral and citric aroma notes</td></tr>
<tr><td>Weight change</td><td>-</td><td>-0.09%</td><td>-0.16%</td><td>-0.26%</td></tr>
<tr><td>Stability of packaging</td><td colspan="4">No anomalies detected (no nozzle blockage detected)</td></tr>
<tr><td>Spray pattern (Dmax, Dmin) After spraying 3 times at 30 cm distance</td><td>27cm
22cm</td><td>22cm
20cm</td><td>25cm
20.5cm</td><td>23cm
20cm</td></tr>
<tr><td>Amount delivered (g per spray) After 5 spray dosages</td><td>1.26</td><td>1.29</td><td>1.32</td><td>1.33</td></tr>
</table>
</td><td></td><td>applicant claimed also a bag in PET-PE for meta SPC 1. Based on the composition of the product, the data obtained in HDPE packaging can be extrapolated to the bag PET-PE.</td></tr>
<tr><td>3.4.1.3.</td><td>Storage stability test – low temperature stability</td><td>CIPAC method MT 39.3</td><td>REW2451_BL2(1.075% AS)</td><td>Storage was performed in the commercial packaging material. The low temperature stability testing showed that no precipitation and no phase separation was observed at the storage for up to 1 week at 0 ºC for the test item since no</td><td>[redacted]
Study number: Mo6439</td><td>acceptable</td></tr>
</table>

N° BPR	Property	Guideline and Method	Tested product/ batch (AS%/w)	Results	Reference	eCA assessment
	test for liquids			precipitation and no separation into layers occurred.		
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	The study does not need to be conducted as the active substance is known not to undergo photolysis.		acceptable
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	REW2451_BL2(1.075% AS)	Taking into account the results of the storage and Low temperature stability tests, it can be concluded that there is no effect on content of the active substance and technical characteristics of the biocidal product due to the temperature. The assessment of humidity effects is not required due to the high water content of the formulation.		acceptable
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	REW2451_BL2(1.075% AS)	No reactivity has been shown towards the container materials.	[redacted], study number EST522	Given the composition of biocidal product composition, no reactivity with container material is expected

N° BPR	Property	Guideline and Method	Tested product/ batch (AS%/w)	Results	Reference	eCA assessment
3.5.1.	Wettability	-	-	The study does not need to be conducted as the data is only required for solids preparations which are to be dispersed in water.		acceptable
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	-	The study does not need to be conducted since these data are only required for wettable powders, aqueous suspensions concentrates, water dispersible granules, water dispersible powders and suspensions.		acceptable
3.5.3.	Wet sieve analysis and dry sieve test	-	-	The study does not need to be conducted since these data are only required for solid preparations which are to be dispersed in water.		acceptable
3.5.4.	Emulsifiability, re-emulsifiability, and emulsion stability	-	-	The study does not need to be conducted as these data are only required for suspo-emulsions.		acceptable
3.5.5.	Disintegration time	-	-	The study does not need to be conducted as this data is only required for tablets.		acceptable
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	-	The study does not need to be conducted since these data are only required for powder biocidal products and granules.		acceptable
3.5.7.	Persistent foaming	-	-	The study does not need to be conducted as this data is only required for products which are diluted, suspended or dispersed in a tank of water inside of an application equipment.		acceptable
3.5.8.	Flowability/pourability/dustability	-	-	The study does not need to be conducted as the data is only required for granular formulations applied through application equipment.		acceptable
3.5.9.	Burning rate — smoke generators	-	-	The study does not need to be conducted as this data is only required for preparations applied as a smoke		acceptable

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/ batch (AS%/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td>3.5.10.</td><td>Burning completeness — smoke generators</td><td>-</td><td>-</td><td>The study does not need to be conducted as this data is only required for preparations applied as a smoke.</td><td></td><td>acceptable</td></tr>
<tr><td>3.5.11.</td><td>Composition of smoke — smoke generators</td><td>-</td><td>-</td><td>The study does not need to be conducted as this data is only required for preparations applied as a smoke.</td><td></td><td>acceptable</td></tr>
<tr><td>3.5.12.</td><td>Spraying pattern — aerosols / spray</td><td>Internal mehod BPL-MA-016 Spray characterisation. Internal method</td><td>Study number VCT05818Q: REW2451_BL2(1.075 % AS)

Study number MCT17718Q: REW 2338 AMPHO

Study number RO22-042_V01: REW 2338 AMPHO</td><td>
<table>
<tr><th></th><th>Trigger 0= TS5 SPRAY MED SCREW 28410</th><th>Trigger 1= AFA SPRAY ROSCA 28-410 VERDE (2020)</th><th>Trigger 2 TS3 DEXTER SANYTOL SPRAY VERDE ‘19</th></tr>
<tr><td>PRIMING (strokes max)</td><td>10</td><td>9</td><td>10</td></tr>
<tr><td>DOSE (mL)</td><td>1,2 +/- 0,3</td><td>1,35 +/- 0,2</td><td>1,2 +/- 0,3</td></tr>
<tr><td>Spray pattern Ø – shape (mm)</td><td>170mm +/- 30mm from 20cm</td><td>40º+/-15º from 25cm (180mm +/- 40mm from 25cm)</td><td>200mm +/-30mm from 25cm</td></tr>
<tr><td>Venting</td><td>No permanent deform</td><td>No permanent deform</td><td>No permanent deform</td></tr>
<tr><td>Leakage</td><td>none</td><td>none</td><td>none</td></tr>
<tr><td>Clogging</td><td>none</td><td>none</td><td>none</td></tr>
</table>
<u>Trigger 0:</u>
<table>
<tr><th>Characteristic</th><th>Target</th><th>New</th><th>6th week</th><th>12th week</th></tr>
<tr><td>Priming</td><td>10 strokes max</td><td>4</td><td>-</td><td>-</td></tr>
<tr><td>Dose</td><td>1.2 ml ± 0.3</td><td>1.3</td><td>1.3</td><td>1.3</td></tr>
<tr><td>Spray pattern Ø</td><td>170±30 mm from cm 20</td><td>170</td><td>170</td><td>170</td></tr>
<tr><td>Venting</td><td>no permanent deformation</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Leakage</td><td>none</td><td>-</td><td>-</td><td>-</td></tr>
</table>
</td><td>study number VCT05818Q

study number MCT17718Q

study number RO22-042_V01</td><td>A justification statement provided by the applicant indicated that 3 type of trigger spray are claimed with different characteristics.

For trigger 0 and 2, the results provided are acceptable. However regarding the trigger 1, the spray pattern was not provided in the study but only provided by technical data from industry.</td></tr>
</table>

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/ batch (AS%/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Clogging</td><td>none</td><td>-</td><td>-</td><td>-</td></tr>
</table>
Particle size determination:
<table>
<tr><th colspan="2">Drop mean Ø [µm]</th></tr>
<tr><td>D (v, 0,1)</td><td>33</td></tr>
<tr><td>D (v, 0.5)</td><td>127</td></tr>
<tr><td>D (v, 0.9)</td><td>334</td></tr>
</table>
<table>
<tr><th colspan="2">Drop size Volume [%]</th></tr>
<tr><td>< 10 µm</td><td>1</td></tr>
</table>
<u>Trigger 1</u>
Particle size determination:
<table>
<tr><th colspan="7">Particle size distribution Opus SONA with REW2338_AMPHO</th></tr>
<tr><th></th><th>Average</th><th>St. deviation</th><th>Max</th><th>Min</th><th>Range</th><th></th></tr>
<tr><td>Dv(10%)</td><td>58,27</td><td>52,96</td><td>2,93</td><td>58,27</td><td>49,71</td><td>8,56</td></tr>
<tr><td>Dv(50%)</td><td>155,90</td><td>133,73</td><td>13,90</td><td>155,90</td><td>113,50</td><td>42,4</td></tr>
<tr><td>Dv(90%)</td><td>563,30</td><td>499,14</td><td>63,58</td><td>563,30</td><td>395,70</td><td>167,6</td></tr>
<tr><td>D[4][3]</td><td>238,40</td><td>208,84</td><td>23,26</td><td>238,40</td><td>172,60</td><td>65,8</td></tr>
<tr><td>% volume < 10 µm</td><td>0,19</td><td>0,24</td><td>0,04</td><td>0,32</td><td>0,19</td><td>0,133</td></tr>
<tr><td>10 µm < % volume < 100 µm</td><td>29,84</td><td>36,07</td><td>3,91</td><td>42,31</td><td>29,84</td><td>12,47</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/ batch (AS%/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>% volume > 100 µm</td><td>69,97</td><td>64,02</td><td>3,86</td><td>69,97</td><td>57,42</td><td>12,55</td></tr>
<tr><td>% volume < 40 µm</td><td>3,34</td><td>4,46</td><td>0,88</td><td>5,62</td><td>3,20</td><td>2,42</td></tr>
</table>
<u>Trigger 2</u>
<table>
<tr><th>Characteristic</th><th>Target</th><th>New</th><th>6th week</th><th>12th week</th></tr>
<tr><td>Priming</td><td>10 strokes max</td><td>3</td><td>-</td><td>-</td></tr>
<tr><td>Dose</td><td>1.2 ml ± 0.3</td><td>1.2</td><td>1.2</td><td>1.2</td></tr>
<tr><td>Spray pattern Ø</td><td>200±30mm from cm 20</td><td>170-D</td><td>170-D</td><td>170-D</td></tr>
<tr><td>Venting</td><td>no permanent deformation</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Leakage</td><td>none</td><td>-</td><td>-</td><td>-</td></tr>
</table>
Particle size determination:
<table>
<tr><td>Drop mean Ø [µm]</td><td></td></tr>
<tr><td>D (v,0.1)</td><td>56</td></tr>
<tr><td>D (v,0.5)</td><td>155</td></tr>
<tr><td>D (v,0.9)</td><td>517</td></tr>
</table>
<table>
<tr><td>Drop size Volume [%]</td><td></td></tr>
<tr><td>< 10 µm</td><td>0.8</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>3.6.1.</td><td>Physical compatibility</td><td>-</td><td>-</td><td>The study does not need to be conducted as the products is not going to be used in combination with any other products.</td><td></td><td>acceptable</td></tr>
<tr><td>3.6.2.</td><td>Chemical compatibility</td><td>-</td><td>-</td><td>The study does not need to be conducted as the products is not going to be used in combination with any other products.</td><td></td><td>acceptable</td></tr>
</table>

N° BPR	Property	Guideline and Method	Tested product/ batch (AS%/w)	Results	Reference	eCA assessment
3.7.	Degree of dissolution and dilution stability	-	-	The study does not need to be conducted as this data is only required for tablets and soluble bags.		acceptable
3.8.	Surface tension	OECD Guideline 115	REW2451_ BL2(1.075 % AS)	25.4 mN/m at T:23.4 ºC (neat liquid) The product is surface active.	[redacted] Study number: EST560	acceptable
3.9.	Viscosity	internal method BPL-MA-013 with a BrookField LV rotational viscosimeter – adapted from OECD 114	REW2451_ BL2(1.075 % AS)	20°C: 4.66 cp 40°C: 4.25 cp	[redacted], study number EST522	acceptable

Table 3.3 Conclusion on physical, chemical and technical properties

Conclusion on physical, chemical, and technical properties
The products SANYTOL LACTIC SA-APP of META SPC 1 are AL (any other liquid) formulations. All studies have been performed in accordance with the current requirements and the results are considered as acceptable. The appearance of the product is a colourless liquid with a characteristic odour of citric notes followed by floral notes. There is no effect of high temperature on the stability of the formulation, since after 2 weeks at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 3 years at room temperature when stored in a HDPE trigger bottle (commercial packaging material). However, as the spray characteristics of the trigger spray 1 is not supported by a study report, this one is not considered acceptable. The products are stable at 0°C. Their technical characteristics are acceptable for AL formulations.

Table 3.4 Physical, chemical, and technical properties

META SPC 2: STD WIPES

According to the document *CA-Nov16-Doc.4.3 – Final- Handling "carriers"* in the authorisation of biocidal products issued by the European Commission, META SPC2 products should be classified as Type A. Product stability tests for biocidal products of type A should be carried out with the product as it is supplied to the user.
Tests for all other physical-chemical properties may be performed with the substance/mixture before it is applied to the carrier component.

Formula used in stability report is nearly identical to the products under META SPC 2.

A technical justification (justification 230119_TJ10_Reference formula stability META 1 and 2) has been provided.

N° BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA assessment
3.1.	Appearance at 20 °C and 101.3 kPa	Visual No guideline followed	REW2338_AMPHO(1.075% AS)	All elements are solid. Package with green tones with pink letters in white background. Odour: Fresh citric with clear grapefruit note	[redacted], Study number: EST520 [redacted] Study number: EST521	acceptable
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual	REW2338_AMPHO(1.075% AS)	Solid impregnated.	[redacted] Study number: EST520 [redacted] Study number: EST521	acceptable
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual	REW2338_AMPHO(1.075% AS)	White.	[redacted], Study number: EST520	acceptable

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>[redacted] Study number: EST521</td><td></td></tr>
<tr><td>3.1.3.</td><td>Odour at 20 °C and 101.3 kPa</td><td>No guideline followed</td><td>REW2338_AMPHO(1.075% AS)

Liquid used for impregnation</td><td>Fresh and citric</td><td>[redacted], Study number: EST520

[redacted], Study number: EST521</td><td>acceptable</td></tr>
<tr><td>3.2.</td><td>Acidity, alkalinity, and pH value</td><td>CIPAC method MT191</td><td>REW2338_AMPHO(1.075% AS)

Liquid used for impregnation</td><td>Acidity : 0.367% $_{HCl}$

pH (impregnation liquid)= 2.97 at 23.7 ºC</td><td>[redacted] Study number: EST520
[redacted] Study number: EST521</td><td>acceptable</td></tr>
<tr><td>3.3.</td><td>Relative density / bulk density</td><td>CIPAC MT 186</td><td>REW2338_AMPHO(1.075% AS)

Liquid used for impregnation</td><td>1.0029 ±0.0000</td><td>[redacted], Study number: EST520
[redacted] Study number: EST521</td><td>acceptable</td></tr>
<tr><td>3.4.1.1.</td><td>Storage stability test – accelerated storage</td><td>CIPAC method MT 46.3

Active substance determination: method BPL-MA-054 validated method in 2.2.4</td><td>REW2338_AMPHO(1.075% AS)</td><td>Storage of Sanytol wipes Grapefruit (ref REW24338_AMPHO) at 40°C ± 2°C for 8 weeks. Packaging tested: PET + PE/EVOH/PE

<table>
<tr><th>Test</th><th>T=0</th><th>T=8 weeks</th></tr>
<tr><td>Active ingredient</td><td>0.89 %</td><td>0.91%</td></tr>
<tr><td>Relative density</td><td>1.0029</td><td>1.0033</td></tr>
<tr><td>pH</td><td>2.97</td><td>3.02</td></tr>
<tr><td>Acidity</td><td>0.367%$_{HCl}$</td><td>0.437%$_{HCl}$</td></tr>
<tr><td>Viscosity</td><td>5.35 cp</td><td>5.35 cp</td></tr>
</table></td><td>[redacted] Study number: EST520</td><td>Acceptable Biocidal product is stable for 8 weeks at 40°C.

Two packaging are claimed, but only one packaging was tested.

As the</td></tr>
</table>

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>(20°C)
4.50 cp
(40°C)</td><td>(20°C)
4.62 cp
(40°C)</td></tr>
<tr><td>Weight change</td><td colspan="2">Loss: 9.93 g
Change: 4.15%</td></tr>
<tr><td>Appearance, physical state, colour and odour</td><td>Wipes: solid, impregnated, white, fresh citric with clear grapefruit note odour</td><td>Wipes: solid, impregnated, white, fresh citric with clear grapefruit note odour</td></tr>
<tr><td>Stability of packaging</td><td>No anomalies detected</td><td>No changed observed after storage</td></tr>
</table>
</td><td></td><td>permeability is the critical point of the wipes packaging, the accelerated storage stability should have been on each packaging claimed.
see packaging compatibility part below for this part of the assessment</td></tr>
<tr><td>3.4.1.2.</td><td>Storage stability test – long-term storage at ambient temperature</td><td>CIPAC method MT 46.3

Active substance determination: method BPL-MA-054 validated method in 2.2.4</td><td>REW2338_AMPHO(1.075% AS)</td><td>Storage of Sanytol wipes Grapefruit (ref REW24338_AMPHO) at RT for 36 months. Packaging tested: PET + PE/EVOH/PE
<table>
<tr><th>Test</th><th>T=0</th><th>T=12 months</th><th>T=24 months</th><th>T= 36 months</th></tr>
<tr><td>Lactic acid content</td><td>0.89% ±0.01%</td><td>0.91% ±0.03%</td><td>0.97% ±0.02% (+9%)</td><td>1.02% ±0.01% (+14.5%)</td></tr>
<tr><td>Density (g/cm^3)</td><td>1.0029</td><td>1.0031</td><td>1.0035</td><td>1.0047</td></tr>
<tr><td>pH</td><td>2.97 ±0.00</td><td>3.09 ±0.01</td><td>3.06 ±0.00</td><td>3.00 ±0.00</td></tr>
<tr><td>Acidity</td><td>0.367 ±0.001</td><td>0.416 ±0.006</td><td>0.459 ±0.002</td><td>0.484 ±0.001</td></tr>
<tr><td>Viscosity</td><td>5.35 ±1.84 cp (20°C)
4.50 ±1.59 cp (40°C)</td><td>5.27 ±0.15 cp (20°C)
4.33 ±0.09 cp (40°C)</td><td>5.34±0.14 cp (20°C)
4.59±0.18 cp (40°C)</td><td>5.70 ±0.16 cp (20°C)
4.74 ±0.47 cp (40°C)</td></tr>
</table>
</td><td>[redacted] study number: EST521</td><td>The content of active substance increase with the time, it seems that the packaging is not totally barrier. As the increase is higher 10% after 36 months and as the concentration of active substance above 1% leads to a tox classification, the shelf life is set at 24 months.</td></tr>
</table>

<table>
<tr><th>N° BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Surface tension</td><td>24.4 ±0.1 mN/m</td><td>25.4 ±0.0 mN/m</td><td>25.4 ±0.0 mN/m</td><td>26.7 ±0.1 mN/m</td></tr>
<tr><td>Appearance</td><td>Solid

Fresh and citric odour with clear grapefruit notes</td><td>Solid

Odour slightly less intense than control sample</td><td>Solid

Odour slightly less intense than control sample</td><td>Solid

Less intense fragrance than de control sample but the note is maintained</td></tr>
<tr><td>Weight change</td><td>-</td><td>-3.17% ± 0.34%</td><td>-6.40% ± 0.33%</td><td>-10.99% ± 3.22%</td></tr>
<tr><td>Homogeneity of the content mixture/wipe</td><td>Min: 8.05 g
Max: 12.00 g</td><td>Min: 8.04 g
Max: 11.8 g</td><td>Min: 7.48 g
Max: 11.54 g</td><td>Min: 7.44 g
Max: 10.13 g</td></tr>
<tr><td>Stability of packaging</td><td colspan="4">No crack or defects in the exterior or in the inside of the package
All samples found in sound conditions</td></tr>
</table>

The weight loss observed in the weight change assay is due to slight evaporation of the formula’s solvents and is considered acceptable in this type of packaging after 3 years of storage. There is no impact in the quality of the product as the wipes are perfectly wet and usable. Moreover, this weight loss justifies the</td><td></td><td></td></tr>
</table>

N° BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA assessment
				increment in the active ingredient concentration. The stability of the active ingredient is acceptable as it has been demonstrated in this study and in the parallel stability study conducted with the impregnation liquid only.		
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	CIPAC method MT 39.3	REW2338_AMPHO(1.075% AS) Liquid used for impregnation	The study does not need to be conducted as the biocidal product is a solid. However, the wipes are impregnated with a liquid. The test was performed with the liquid used for impregnation. Results and observations in the appearance test showed that there were no significant differences in terms of physical state, colour and odour between T=0 and T=7 days for each test item. On the other hand, and after 7 days of low temperate storage, the formula REW2338_AMPHO_GRAPE1 present a thin layer of white powder at the bottom of the glass cylinder. However, it was not possible to determine the volume of the layer due to its thinness. The liquid phase was considered homogeneous and did not present phase separation at final time and after 24 hours at room temperature.	Study number: EST736	acceptable
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	The study does not need to be conducted due to the packaging characteristics of the biocidal products. As the packaging is opaque, light effects are predicted negative. Moreover, the active substance is known not to undergo photolysis.		Not acceptable. The opacity of a packaging does not imply that the packaging is barrier to light. However as the active substance is not light sensitive, no mitigation measured is necessary.

N° BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA assessment
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Taking into-- account the results of the storage stability test we can conclude that there is no effect on content of the active substance and technical characteristics of the biocidal product due to the temperature. The assessment of effects of humidity is considered not required due to the high water content of the formulation.		Acceptable, the active substance is stable at temperature.
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	REW2338_AMPHO(1.075% AS)	No reactivity has been shown towards the container materials. as the water permeability is similar for both packaging (4.8-4.9 g/m²/24h), the compatibility of both packagings are similar.	[redacted], study number: EST521	Two packaging are claimed, but only one packaging was tested. As the permeability is the critical point of the wipes packaging, the storage stability should have been on each packaging claimed. However, eCA agree with applicant justification that, based on the technical data provided and justification based on composition,

N° BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA assessment
						compatibility is similar between both packagings.
3.5.1.	Wettability	-	-	The study does not need to be conducted as the data is only required for solids preparations which are to be dispersed in water.		acceptable
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	-	The study does not need to be conducted since these data are only required for wettable powders, aqueous suspensions concentrates, water dispersible granules, water dispersible powders and suspensions.		acceptable
3.5.3.	Wet sieve analysis and dry sieve test	-	-	The study does not need to be conducted since these data are only required for solid preparations which are to be dispersed in water.		acceptable
3.5.4.	Emulsifiability, re-emulsifiability, and emulsion stability	-	-	The study does not need to be conducted as these datas are only required for suspo-emulsions.		acceptable
3.5.5.	Disintegration time	-	-	The study does not need to be conducted as this data is only required for tablets.		acceptable
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	-	The study does not need to be conducted since these data are only required for powder biocidal products and granules.		acceptable
3.5.7.	Persistent foaming	-	-	The study does not need to be conducted as this data is only required for products which are diluted, suspended or dispersed in a tank of water inside of an application equipment.		acceptable
3.5.8.	Flowability/pourability/dust	-	-	The study does not need to be conducted as the data is only required for granular formulations applied through application		acceptable

N° BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA assessment
	ability			equipment.		
3.5.9.	Burning rate — smoke generators	-	-	The study does not need to be conducted as this data is only required for preparations applied as a smoke.		acceptable
3.5.10.	Burning completeness — smoke generators	-	-	The study does not need to be conducted as this data is only required for preparations applied as a smoke.		acceptable
3.5.11.	Composition of smoke — smoke generators	-	-	The study does not need to be conducted as this data is only required for preparations applied as a smoke.		acceptable
3.5.12.	Spraying pattern - spray	-	-	The study does not need to be conducted as the product is not going to be applied as a spray.		acceptable
3.6.1.	Physical compatibility	-	-	The study does not need to be conducted as the products is not going to be used in combination with any other products.		acceptable
3.6.2.	Chemical compatibility	-	-	The study does not need to be conducted as the products is not going to be used in combination with any other products.		acceptable
3.7.	Degree of dissolution and dilution stability	-	-	The study does not need to be conducted as this data is only required for tablets and soluble bags.		acceptable
3.8.	Surface tension	OECD Guideline 115	REW2338_AMPHO(1.075% AS) Liquid used for impregnation	24.4 mN/m at T:23.6 ºC (neat liquid) The product is surface active.	[redacted] Study number: EST560	acceptable
3.9.	Viscosity	internal method BPL-MA-013 with a BrookField LV rotational viscosimeter	REW2338_AMPHO(1.075% AS) Liquid used for impregnation	20°C: 5.35 ±1.84 cp 40°C: 4.50 ±1.59 cp	[redacted], Study number: EST520 [redacted], study number: EST521	acceptable

N° BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	eCA assessment
		– adapted from OECD 114				

Table 3.5 Conclusion on physical, chemical and technical properties

Conclusion on physical, chemical, and technical properties
The products SANYTOL LACTIC SA-APP of META SPC 2 are impregnated wipes. All studies on REW2338_AMPHO have been performed in accordance with the current requirements and the results are considered as acceptable. The appearance of the product is a white impregnated wipes with a fresh citric and grapefruit odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C; neither the active ingredient content nor the technical properties were changed. A mitigation measure should be added on the label : store the product at temperature below 40°C. The long term stability storage shows after 36 months an increase of the active substance above 1% in the impregnated solution. This increase is due to the evaporation of formulation's solvent. This (>1%) content would imply a tox classification (see tox part) and therefore the shelf life should be set at 24 months. Moreover, the shelf life study has been performed with the packaging PET + PE/EVOH/PE. Another packaging is claimed for the meta SPC 2, PET+PE which has not been tested. No interaction between the packaging and the product is expected. However, the critical point in that case is the permeability of the packaging. Based on the technical data sheet of the packaging claimed the permeability of both packaging is similar (4.8 g/m2/24h and 4.9 g/m2/24h). In consequence the results of the shelf life can be extrapolated to PET +PE packaging. Their technical characteristics are acceptable for impregnated wipes.

3.3 Physical hazards and respective characteristics

META SPC1: MU/LH/DEO TEXTILE
META SPC2: STD WIPES: (The classification for Type A carriers is used for the impregnation solution)

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

Table 3.6 Physical hazards and respective characteristics

N° BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	reference	eCA assessment
4.1.	Explosives	DSC Analysis inert High Pressure DSC crucible Heating rate of 5ºK/min the sample was heated up to 400ºC.	REW2338_AMPHO. 0,86% (v/v) lactic acid	No exothermic decomposition higher than 300mJ/g was observed. According to the theoretical and experimental analysis, it can be concluded that the classification procedure for explosive or self-reactive properties of our formulation can be safely waived. (see conf PAR)	Document : DR_8_JT14_ Waiver Explosives Properties	acceptable
4.2.	Flammable gases	-	N.A.	According to the classification of all ingredients present in this biocidal product family under the Regulation 1272/2008 (CLP), which do not classify as flammable gases, it is not necessary to test the biocidal product family for flammable gases properties.	_	acceptable
4.3.	Flammable aerosols	-	N.A.	The study does not need to be conducted as the product is a liquid.	_	acceptable
4.4.	Oxidising gases	-	N.A.	The study does not need to be conducted as the product is a liquid.	_	acceptable
4.5.	Gases under pressure	-	N.A.	The study does not need to be conducted as the product is liquid.	_	acceptable

N° BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	reference	eCA assessment
4.6.	Flammable liquids	-	N.A.	The products do not contain any flammable components in amounts that are significant enough to have any impact on the flammability of the final products.	_	acceptable
4.7.	Flammable solids	-	N.A.	For META SPC 1, the study does not need to be conducted as the product is a liquid. For META SPC 2 the study does not need to be conducted since the products do not contain any flammable components in amounts that are significant enough to have any impact in flammability to the final products.	_	acceptable
4.8.	Self-reactive substances and mixtures	DSC Analysis inert High Pressure DSC crucible Heating rate of 5ºK/min the sample was heated up to 400ºC.	REW2338_AMPHO. 0,86% (v/v) lactic acid	No exothermic decomposition higher than 300mJ/g was observed. According to the theoretical and experimental analysis, it can be concluded that the classification procedure for explosive or self-reactive properties of our formulation can be safely waived.	Document : DR_8_JT14_ Waiver Explosives Properties	acceptable
4.9.	Pyrophoric liquids	-	N.A.	Based on experience on handling or manufacture, the products are known to be stable at room temperature for prolonged times.	_	acceptable
4.10.	Pyrophoric solids	-	N.A.	For META SPC 1, not applicable, the product is a liquid. For META SPC 2, based on experience on handling or manufacture, the products are known to be stable at room temperature for prolonged times.	_	acceptable

N° BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	reference	eCA assessment
4.11.	Self-heating substances and mixtures	-	N.A.	Based on the CLP criteria for this classification, this endpoint does not need to be applied to this product as it forms a stable mixture. Further the active substance does not contain metals in the chemical structure. The result for this test is predicted negative based on manufacturing processes of the components and handling experience.	_	Acceptable, no further data required as the product is a liquid
4.12.	Substances and mixtures which in contact with water emit flammable gases	-	N.A.	The products are aqueous solutions that are known not to emit flammable gases.	_	acceptable
4.13.	Oxidising liquids	O.2	REW238LR_LEUC1 (0,86% AS)	The 1:1 mixture of the test item and cellulose did not reach a pressure of 2070 kPa and therefore no further testing is required. Not classified as an oxidising liquid of UN Class 5.1	Report S30160143 18R1/2023	acceptable
4.14.	Oxidising solids	-	N.A.	For META SCP 1, the study does not need to be conducted because the product is a liquid. For META SPC 2, the study does not need to be conducted because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.	_	acceptable
4.15.	Organic	-	N.A.	Based on the non-existence of peroxide	_	acceptable

N° BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	reference	eCA assessment
	peroxides			structure -O-O- in any of the single substances in the products, it is not necessary to perform any study for organic peroxides.		
4.16.	Corrosive to metals	UN specification Section 37.4.1.1. Plate size: 20x50 mm Aluminium tested: 7075-T6 Steel tested: EN 10025 S235JR	REW 2451_BL2 and REW2338_AMPHO. 0,86% (v/v) lactic acid	A test has been provided. Results are presented in a table before the conclusion on the physical hazards. Based on measured results of each sample tested after exposure to the product, it appears that products do not show massive corrosion after 7 days at 55°C. However, based on pictures of each sample tested after exposure, picking corrosion phenomenon appears on aluminium plates for products Sanytol DEO Textil, REW 2451_BL2 and for aluminium and steed for REW2338_AMPHO. See the tables below with detail results.		Biocidal products in BPF are classified H290.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	EEC/440/2008 ASTM E659	REW238LR_LEUC1 (0,86% AS)	Measured as > 600°C	Report S30160143 18R1/2023	acceptable
4.17.2.	Relative self-ignition temperature for solids	-	N.A.	The study does not need to be conducted as the product is liquid.	_	acceptable
4.17.3.	Dust explosion hazard	-	N.A.	Not applicable to liquid formulations	_	acceptable

Results on corrosive to metals properties:

<table>
<tr><td rowspan="3">Exposure media</td><td rowspan="3">Exposure type</td><td colspan="5">Mass loss (%)</td></tr>
<tr><td colspan="4">Results*</td><td>Requirements</td></tr>
<tr><td colspan="2">Steel</td><td colspan="2">Aluminium</td><td rowspan="7">≤13,5%
(Mass loss results lower than this value mean that products cannot be considered corrosive for metals after 7 days of test at +55°C)</td></tr>
<tr><td rowspan="3">Sanytol Deo Textil (A).
REW2451_BL2</td><td>Total immersion</td><td colspan="2">5.3</td><td>3.8</td><td>4.4**</td></tr>
<tr><td>Partial immersion</td><td>3.3</td><td>3.4**</td><td>2.8</td><td>3.3**</td></tr>
<tr><td>Gas phase</td><td>0.1</td><td>0.3**</td><td colspan="2">n.d.</td></tr>
<tr><td rowspan="3">REW2338_AMPHO</td><td>Total immersion</td><td colspan="2">2.0</td><td colspan="2">8.6</td></tr>
<tr><td>Partial immersion</td><td colspan="2">4.1</td><td colspan="2">3.8</td></tr>
<tr><td>Gas phase</td><td colspan="2">n.d.</td><td colspan="2">n.d.</td></tr>
</table>

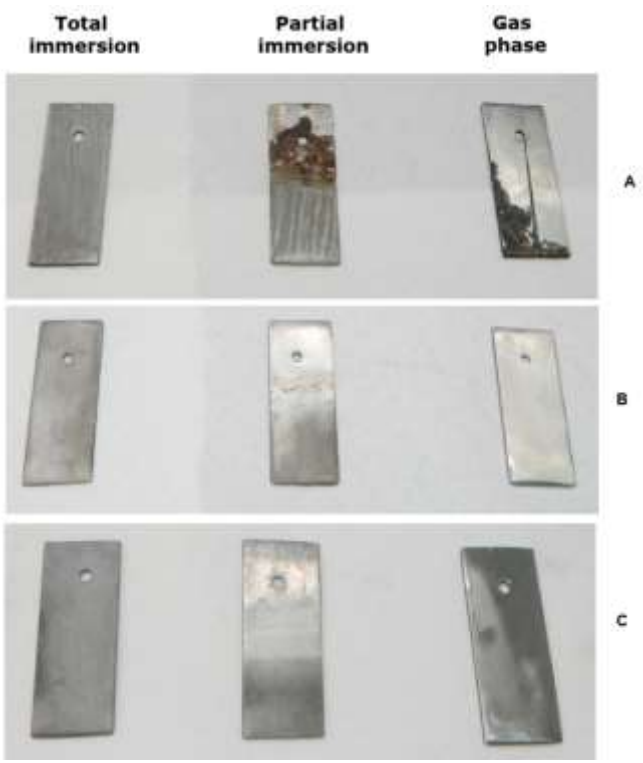
n.d.: not clearly detected because of the low mass difference

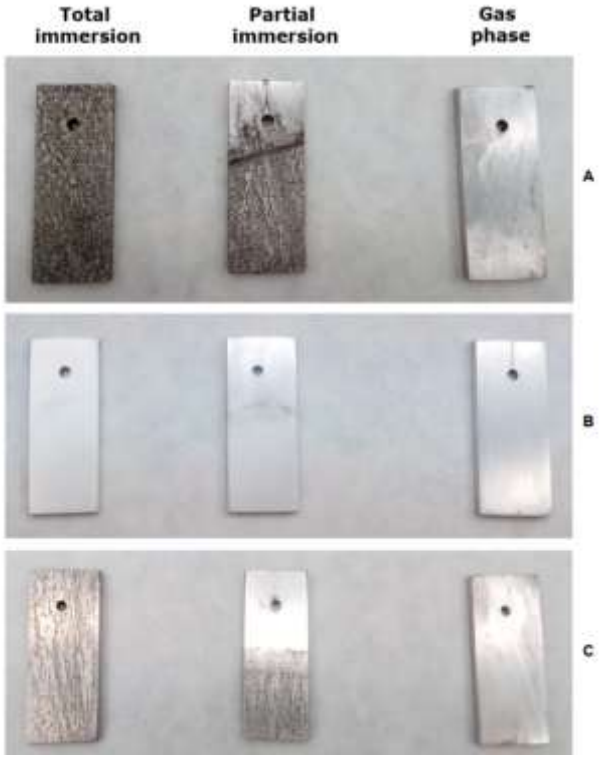
*: Results obtained after rinsing with water and cleaning with brush at the end of the corrosion test.

**: Results showed the percentage of mass loss after chemical etching of the surface corrosion products.

Exposure media	Exposure type	Localised corrosion	
		Results*	Requirements

		Aluminium	steel	
Sanytol Deo Textil (A). REW2451_BL2	Total immersion	0.14 mm	Not measured	≤120 µm (7 days at 55°C)
	Partial immersion	0.15 mm	Not measured	
REW2338_AMPHO	Total immersion	0.33 mm	0.19 mm	
	Partial immersion	0.27 mm	0.22 mm	

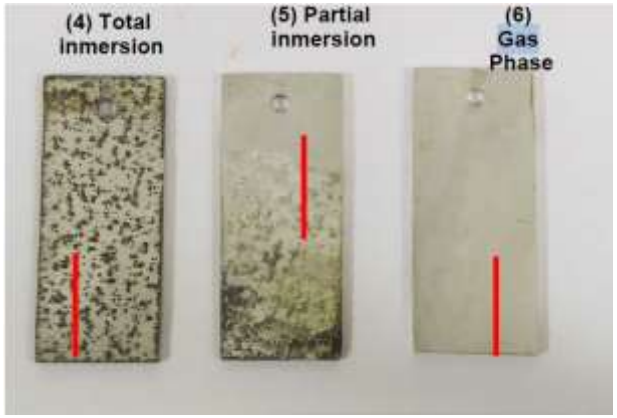


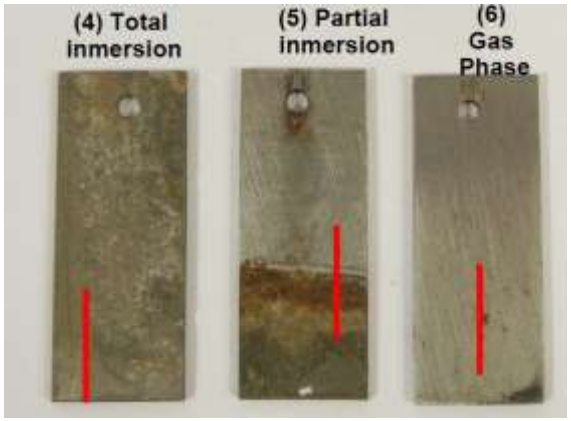


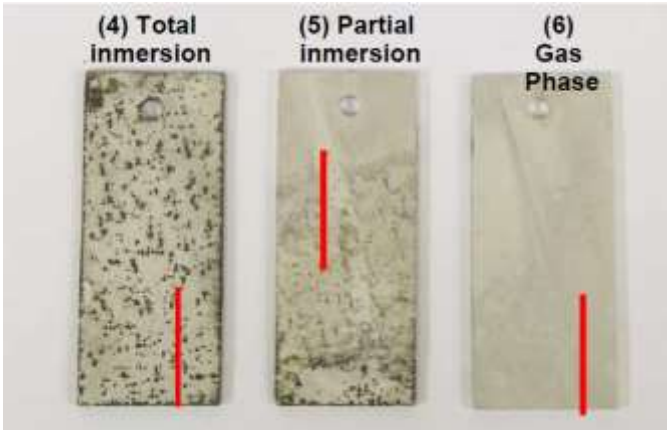
Carbon steel plates (left) and aluminium plates (right) after test with the liquids A, B, C.

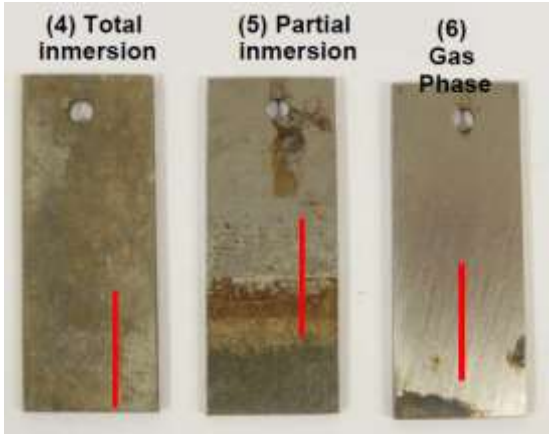
It should be noted that different composition within each meta SPC imply compounds that, according to the compositions provided in their MSDS, do not contain halogens. Thus, they can be considered equivalent for metal corrosion and products tested cover their respective meta SPC.

REW2338_AMPHO:









Aluminium plates after test with REW2338_AMPHO liquid. Both sides. Cuts for metallographic preparation are indicated (left) and Steel plates

after test with REW2338_AMPHO liquid. Both sides. Cuts for metallographic preparation are indicated (right).
Example of pitting measurement:

Table 3.7 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The products of Meta SPC 1 and Meta SPC 2, are not explosive, self-reactive properties. They are not classified as flammable. Based on the test results , the product are classified corrosive to metal cat 1 (H290)

3.4 Methods for detection and identification

Information on the choice of the worst-case composition for methods for detection and identification (e.g. representative test product(s)) and the justification for why the chosen test products are considered sufficient to cover the whole range of specified variations (use/composition) in the BPF are provided in the confidential PAR and 230119_TJ10_Reference formula stability META 1 and 2.
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 3.8 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the methods*:* Meta SPC 1: formulation Sanytol DEO textile standard, ref: REW2451_BL2 An aliquot of 600 mL of sample was diluted with NaOH 0.05N to 10 mL, filtered with a 0.20 µm filter and left a minimum of 45 min at room temperature. Analysis is done by LC-UV at 210 nm with a C18 column. Quantification is done by external standard using a calibration curve. Meta SPC 2: formulation Sanytol wipes grapefruit internal reference: REW2338_AMPHO This method has two main steps: extraction of the solution from the wipe, and the analysis of the LA of this solution. The impregnation solution is extracted using a 60 mL syringe. Afterwards, 600 mg of extracted sample are weighed and diluted with NaOH 0.05N to 10 ml, filtered with a 0.2 µm filter and left a minimum of 45 minutes at room temperature (20-25 ºC). Analysis is performed using HPLC-UV at 210 nm with a C18 column. Quantification is done by external standard using a calibration curve.											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Lactic acid 0.86% META SPC 1: DEO TEXTILE/ MU/LH	R^2>0.99 5 point cal curve (40-1250 µg/mL 60% - 140%)	solutions analyzed: -Solvent blank (NaOH) -Formulation blank REW2451_BL2 without lactic acid) No interferences observed.	64 %-128 %	N=12	64% 100 % 128 %	97.7% (n=3) 97.3% (n=6) 97.6% (n=3)	1.0 % 0.6 % 0.3 %	100% Precision at 98.5% (n=6): RSD=0.57 %	6	N.A.	Report No EST517,

Lactic acid 0.86% META SPC 2: STD WIPES	R^2>0.999 5 point cal curve (40-1250 µg/mL	The method is specific. No interferences that could interfere with LA analysis were observed.	80 %-125 %	N=12	80% 100 % 125 %	102.9% (n= 3) 104.6% (n= 6) 100.9% (n= 3)	2.50% 1.26% 2.60%	0.69% 0.86% 1.08%	3 6 3	N.A.	Report No EST518

Table 3.9 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical methods (reference study number= EST517 and EST518) for the determination of lactic acid are available. Specificity, linearity, accuracy and precisions were checked and found acceptable. Therefore, the analytical methods provided are fully validated for the determination of the active substance, lactic acid. No SoCs are present in the formulation. Relevant residues in food of plant and animal origin and in the environmental compartments arising from the application of lactic acid are not expected. Therefore, residue analytical methods for lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.

3.5 Assessment of efficacy against target organisms

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

Main group 01: Disinfectants.
Product Type 02: Disinfectants and algaecides not intended for direct application to humans or animals.
Product Type 04: Food and feed area.

The products of SANYTOL LACTIC SA-APP family are ready-to-use products used for hard surfaces and textiles disinfection by non-professionals.

The product family has 2 META SPC:

- META SPC 1 (PT2&PT4): liguid disinfectant for soft surfaces by spraying against bacteria and yeasts, and hard surfaces by spraying/pouring and wiping, against bacteria, yeasts, fungi and enveloped viruses.
- META SPC 2 (PT2 & PT4): impregnated wipes for hard surfaces disinfection, by wiping, against bacteria, yeasts, fungi and enveloped viruses.

Surfaces to be disinfected include those found in industrial, domestic and institutional areas, excluding situations where disinfection is medically indicated.

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

The dissociation degree of Lactic acid in solution depends on pH value. In contact of undissociated form of Lactic acid with biological materials, such as micro-organisms, the Lactic acid is able to pass the cells membrane. At a relatively low pH, the Lactic acid inhibits the pathogens through the penetration of the undissociated form across the membrane, which interferes with the metabolic functions of the pathogen. The decrease in the intracellular pH causes dissipation of the membrane and leads to membrane disruption. Therefore, the mode of action for this product is inhibiting of cells growth and biomass producing and finally cells are destroyed.
.

3.5.3 Efficacy data

META SPC 1

Table 3.10 Efficacy data

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference**	**Number in IUCLID section 6.7/Test report title**
PT 2-4 *Use #1,2 and 3*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae* *Escherichia coli*	EN 1276: 2010;Erratum 2011 Phase 2 Step 1 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 80%, 50% and 1%	Passed concentration: 80% and 50% (v/v) (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/18/274	IUCLID 6.7-01 Bactericidal Activity Test in suspension with the product REW2338_AMPHO in dirty conditions (UNE-EN 1276:2010; Erratum 2011)
PT 2-4 *Use # 1,2 and 3*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Candida albicans*	NF EN 1650: 2019 Phase 2 Step 1 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 80%, 50% and 0.1%	Passed concentration: 80% (≥ 4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/22/B0405	IUCLID 6.7-02 Quantitative suspension test for the evaluation of the bactericidal activity of antiseptics and chemical disinfectants used in food, industrial, domestic, and institutional areas. Test method requirenments (phase

						2, stage 1), with the producto REW2338_AMPHO with deviations from the standard. (NF EN 1276:2019 Standard)
PT 2-4 *Use # 2 and 3*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Aspergillus brasiliensis*	EN 1650:2019 Standard Phase 2 Step 1 Contact time: 60 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 80%, 50% and 0.1%	Passed concentration: 80% and 50% (≥ 4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/21/B0504	IUCLID 6.7-18 Fungicidal activity against Aspergillus brasilensis with the product REW2338_AMPHO with deviations from the standard (NF EN 1650:2019 standard)
PT 2 *Use # 1*	DEO REW2338 Lactic acid 0,86+/-0,09%	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae* *Escherichia coli* *Candida albicans*	EN13697:2015 (adapted porous surfaces- cotton carrier) Phase 2 Step 2 Contact time: 15 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100%, 50% and 10%	Passed concentration: Bactericide concentration:100 % and 50% (≥ 4 log unit reduction). Yeasticidal concentration: 100 and 50% (≥ 3 log unit reduction) The validity criteria of the test method are fulfilled.	[redacted] Study nº L18/0768.2	IUCLID 6.7-03 Bactericidal and Yeasticidal activity of DEO REW 2338 in the quantitative surface test following to DIN EN 13697:2015 (Phase 2, Step 2)
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid	*Shigella flexneri* *Listeria monocytogenes*	EN 1276: 2019 Standard Phase 2 Step 1	Passed concentration: 80% and 50% (≥ 5 log	[redacted]	IUCLID 6.7-04 Quantitative

and 3 *Additional strains*	0,86+/-0,086%	*Clostridium difficile* *Campylobacter jejuni* *Salmonella enterica*	Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 80%, 50% and 0.1%	unit reduction). The validity criteria of the test method are fulfilled.	Study nº D/21/B0371	suspension test for the evaluation of the bactericidal activity of antiseptics and chemical disinfectants used in food, industrial, domestic, and institutional areas. Test method requirenments (phase 2, stage 1), with the producto REW2338_AMPHO with deviations from the standard. (NF EN 1276:2019 Standard)
PT 2-4 *Use # 2 and 3* *Additional strains*	REW2338_AMPHO Lactic acid 0,86+/-0,09%	*Microsporum canis* *Trichosporon asahii* *Trichosporon cutaneum*	EN 1650:2019 Standard Phase 2 Step 1 Contact time: 30 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 80%, 50% and 0.1%	Passed concentration: 80% and 50%.(≥ 4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/21/B0677	IUCLID 6.7-05 Fungicidal activity against *Microsporum canis*, Trichosporon asahii and *Trichosporon cutaneum* with the producto REW2338_AMPHO, with deviation from the standard. (nf en 1650:2019 Standard)
PT 2-4 *Use # 1, 2 and 3*	REW2338_AMPHO Lactic acid 0,86+/-0,09%	Vaccinia Poxvirus (ATCC VR-1508) Modified vaccinia virus Ankara (MVA)	EN14476:2013 + A2:2019 Phase 2 Step 1 Contact time: 2 minutes Contact temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine serum	Passed concentration: Virucidal concentration against enveloped virus: 80% and 50% (>4 log unit reduction) The validity criteria of the test method	[redacted] Study nº D/22/V0003	IUCLID 6.7-06 Virucidal test against Vaccinia virus, strain modified Vaccinia Ankara (MVA) with the product "REW2338_AMPHO" with deviations to the Standard (NF EN 14476: 2013 + A2:

			albumin) Concentrations tested: 80%, 50% and 1%	are fulfilled.		2019 Standard)
PT 2-4 *Use # 2 and 3*	REW2338_AMPHO	SARS-COV-2	EN 14476:2013 + A2: 2019 Standard Phase 2 Step 1 Contact time: 5 minutes Contact temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L BSA + 3mL/L sheep erythrocytes) Concentrations tested: 80%, 50% and 0.1%	Passed concentration: Virucidal concentration against enveloped virus: 80% and 50% (>4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] 1156/01/EN14476 -163/19	IUCLID 6.7-09 Evaluation based on european standard EN 14476+A2 (July 2019(methodology of virucidal activity of hard surface disinfectant toward SARS-COV-2-Coronavirus in dirty conditions
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa*	EN13697:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 80%, 50% and 1%	Passed concentration: Bactericidal concentration: 100% and 50% ≥ 5 log unit reduction The validity criteria of the test method are fulfilled.	[redacted] Study nº D/18/199	IUCLID 6.7-10 Bactericidal activity on non-porous surfaces with the product REW2338_AMPHO (UNE-EN 13697:2015)
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Candida albicans*	EN13697:2015 + A1: 2019 Standard Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty	Passed concentration: Yeasticidal concentration: 100% and 50% (≥ 4 log unit reduction). The validity criteria	[redacted] Study nº D/22/B0406	IUCLID 6.7-11 Yeasticidal activity on non-porous surfaces (phase 2, step 2), under dirty conditions with the product REW2338_AMPHO. (NF EN 13697: 2015 +

			conditions (3 g/L bovine albumin) Concentrations tested: 100%, 50% and 1%	of the test method are fulfilled.		A1: 2019 Standard)
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Listeria monocytogenes* *Salmonella enterica*	EN 13697: 2015 + A1: 2019 Standard Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100%	Passed concentration: Bactericidal concentration: 100%, 50% (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/22/B0224	IUCLID 6.7-12 Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 2), for additional bacteria, with the product REW2338_AMPHO. (Based on NF EN 13697: 2015 + A1: 2019 Standard)
PT 2-4 *Use # 2 and 3*	REW2338_AMPHO_EUC Lactic acid 0,86+/-0,09%	Vaccinia Poxvirus (ATCC VR-1508) Modified vaccinia virus Ankara (MVA)	EN 16777:2018 Phase 2, step 2 Contact time: 2 minutes Temperature: 18-25 ºC ±1 ºC Soiling: dirty conditions (3 g/L BSA) Concentrations tested: 100%, 50% and 10%	Passed concentration: Virucidal concentration against enveloped virus: 100% (>4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº L21/0779aMV.3	See IUCLID section 6.7-13 Evaluation of the effectiveness of REW2338_AMPHO_EUC based on EN 16777:2018 (3.0 g/l BSA) Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area –

						Test method and requirements (phase 2/step 2)
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli K12* *Pseudomonas aeruginosa* *Candida albicans*	EN16615:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100%	Passed concentration: Bactericidal concentration: 100% (≥ 5 log unit reduction). Yeasticidal concentration: 100% (≥ 4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/21/B0680 & D/22/B0407	See IUCLID section 6.7-16 Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2), with the product REW2338_AMPHO, with deviations from the Standard. (UNE-EN 16615: 2015 Standard).
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Aspergillus brasilensis*	EN16615:2015 Phase 2 Step 2 Contact time: 15 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	Passed concentration: Fungicidal concentration: 100% (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/22/B0002	See IUCLID section 6.7-17 Quantitative test method for the evaluation of fungicidal activity on non-porous surfaces with mechanical action using wipes in the medical area (4-fields of assay) (phase 2, step 2) against Aspergillus brasiliensis, with the product REW2338_AMPHO, with deviations from the standard. (based

						on UNE-EN 16615: 2015 Standard)
PT 2-4 *Use # 1*	REW2338_AMPHO_EUC Lactic acid 0,86+/- 0,09%	Vaccinia Poxvirus (ATCC VR-1508) Modified vaccinia virus Ankara (MVA)	EN 16777:2018 Phase 2, step 2 Cotton carrier Contact time: 5 minutes Temperature: 18-25 ºC ±1 ºC Soiling: dirty conditions (3 g/L BSA) Concentrations tested: 100%, 50% and 10%	Passed concentration: Virucidal concentration against enveloped virus: 100% (>4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº L21/00841MV.10	See IUCLID section 6.7-19 Evaluation of the effectiveness of REW2338_AMPHO_EUC based on EN 16777:2018 (3.0 g/l BSA) Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area – Test method and requirements (phase 2/step 2)
PT 2-4 *Use # 2 and 3* *Additional strain*	REW2338-AMPHO Lactic acid 0,86+/- 0,09%	Influenza A virus H1N1pdm09, strain A/California/7/2009	EN 14476:2013+A2:2019 Phase 2 Step 1 Contact time: 2 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L BSA) Concentrations tested: 80%, 50% and 0.1%	Passed concentration: Activity against Influenza A virus H1N1: 80% and 50% (>4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/23/V0050.	IUCLID 6.7-22 Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1), against Influenza A (H1N1) pdm09 with the product "REW2338_AMPHO", with deviations from the Standard (based on EN 14476: 2013 + A2: 2019

						Standard)
PT 2-4 *Use # 2 and 3* *Additional strain*	REW2338-AMPHO Lactic acid 0,86+/- 0,09%	Coronavirus 229E (ATCC VR-740)	EN 14476:2013+A2:2019 Phase 2 Step 1 Contact time: 2 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L BSA) Concentrations tested: 80%, 50% and 0.1%	Passed concentration: Activity against coronavirus 229E: 80% and 50% (>4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/23/V0052.	IUCLID 6.7-23 Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1), against Coronavirus 229E with the product "REW2338_AMPHO", with deviations from the Standard (based on EN 14476: 2013 + A2: 2019 Standard)
PT 2-4 *Use # 2 and 3* *Additional strain*	REW2338_AMPHO Lactic acid 0,86+/- 0,09%	Influenza A virus H1N1pdm09, strain A/California/7/2009	EN 16777:2019 Phase 2, step 2 Contact time: 2 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L BSA) Concentrations tested: 100%, 50% and 10%	Passed concentration: Virucidal concentration against enveloped virus: 100% (>4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/23/V0051.	See IUCLID section 6.7-24 Quantitative non-porous surfaces test of chemical disinfectants for the evaluation of virucidal activity, without mechanical action in the medical area (phase 2/step 2), against Influenza A (H1N1)pdm09 cepa A/California/7/2009 (H1N1) virus, with the product "REW2338_AMPHO" with deviations to the Standard (based on EN 16777: 2019 Standard)
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid 0,86+/- 0,09%	Coronavirus 229E (ATCC VR-740)	EN 16777:2019 Phase 2, step 2 Contact time: 2 minutes	Passed concentration: Virucidal concentration	[redacted] Study nº	See IUCLID section 6.7-25 Quantitative non-

and 3 *Additional strain*			Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L BSA) Concentrations tested: 100%, 50% and 10%	against enveloped virus: 100% (>4 log unit reduction). The validity criteria of the test method are fulfilled.	D/23/V0053.	porous surface virucidal activity test without mechanical action (phase 2, step 2), against Coronavirus 229E, with the product "REW2338_AMPHO", with deviations from the Standard (EN 16777: 2019 Standard)
PT 2-4 *Use # 2 and 3* *Additional strains*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Listeria monocytogenes* *Salmonella enterica*	EN16615:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	Passed concentration: Bactericidal concentration: 100% (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/23/B0093	See IUCLID section 6.7-27 Quantitative test for the evaluation of bactericidal activity against Listeria monocytogenes and Salmonella enterica, on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2) with the product "REW2338_AMPHO", with deviations from Standard. (Based on EN 16615: 2015 Standard)
PT 2-4 *Use # 2 and 3* *Additional strains*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Trichosporon cutaneum* *Microsporum canis*	EN16615:2015 Phase 2 Step 2 Contact time: 15 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty	Passed concentration: Fungicidal concentration: 100% (≥ 4 log unit reduction).	[redacted] Study nº D/23/B0094	See IUCLID section 6.7-28 Quantitative test method for the evaluation of fungicidal activity against Trichosporon

			conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	The validity criteria of the test method are fulfilled.		cutaneum and Microsporum canis, on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2) with the product "REW2338_AMPHO", with deviations from the Standard.(Based on EN 16615: 2015 Standard)
PT 2-4 *Use # 2*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Aspergillus brasilensis*	EN 13697: 2015 + A1: 2019 Standard Phase 2 Step 2 Contact time: 30 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100%, 50% and 0.1%	Passed concentration: Fungicidal concentration: 100%, 50% (≥ 3 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/22/B0224	IUCLID 6.7-30 Fungicidal activity against Aspergillus brasiliensis on non-porous surfaces (phase 2, step 2), under dirty conditions with the product REW2338_AMPHO, with deviations from the standard (NF EN 13697: 2015 + A1: 2019 Standard)
PT 2-4 *Use # 2* *Additional strains*	REW2338_AMPHO Lactic acid 0,86+/-0,086%	*Trichosporon cutaneum* *Microsporum canis*	EN 13697: 2015 + A1: 2019 Standard Phase 2 Step 2 Contact time: 30 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations	Passed concentration: Fungicidal concentration: 100%, 50% (≥ 3 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/22/B0225	IUCLID 6.7-31 Quantitative fungicidal activity test on non-porous surface (phase 2, step 2), against Microsporum canis and Trichosporon cutaneum, with the product REW2338_AMPHO. (Based on NF EN

			tested: 100%, 50% and 0.1%			13697: 2015 + A1: 2019 Standard)

META SPC 2

Table 3.11 Efficacy data

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference**	**Number in IUCLID section 6.7/Test report title**
PT 2-4 *Use # 3*	REW2338_AMPHO Lactic acid 0,86%	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa* *Escherichia coli* *Candida albicans*	EN16615:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100%	Pass concentration: Bactericidal and yeasticidal concentration: 100% (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled	[redacted] Study nº L18/0223.1 and L18/0223.2	See IUCLID section 6.7-20 Bactericidal and yeasticidal activity of REW238_AMPHO in the quantitative 4-field-test according to DIN EN 16615:2015 (Phase 2, Step 2)
PT 2-4 *Use*	REW2338_AMPHO Lactic acid 0,86%	*Aspergillus brasilensis*	EN16615:2015 Phase 2 Step 2 Contact time: 15 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty	Pass concentration: Fungicidal concentration: 100% ≥ 4 log unit reduction	[redacted] Study nº D/21/B0709	See IUCLID section 6.7-21 Quantitative test method for the evaluation of fungicidal activity on non-porous surfaces with

			conditions (3 g/L bovine albumin) Concentrations tested: 100%	The validity criteria of the test method are fulfilled		mechanical action using wipes in the medical area (4-fields of assay) (phase 2, step 2) against Aspergillus brasiliensis, with the product REW2338_AMPHO, with deviations from the standard. (based on UNE-EN 16615: 2015 Standard)
PT 2-4 *Use #3* *Additional strains*	REW2338_AMPHO fi=2.5 Lactic acid 0,86+/-0,086%	*Listeria monocytogenes* *Salmonella enterica*	EN16615:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	Passed concentration: Bactericidal concentration: 100% (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/23/B0087	See IUCLID section 6.7-26 Quantitative test for the evaluation of bactericidal activity against Listeria monocytogenes and Salmonella enterica, on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2) with the product "REW2338_AMPHO fi=2.5", with deviations from Standard. (Based on EN 16615: 2015 Standard)
PT 2-4 *Use #3* *Additional strains*	REW2338_AMPHO fi=2.5 Lactic acid 0,86+/-0,086%	*Microsporum canis*, *Trichosporon cutaneum*	EN16615:2015 Phase 2 Step 2 Contact time: 15 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	Passed concentration: Fungicidal concentration: 100% (≥ 4 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº D/23/B0088	See IUCLID section 6.7-29 Quantitative test method for the evaluation of fungicidal activity against Trichosporon cutaneum and Microsporum canis, on non-porous surfaces with mechanical action

						using wipes in the medical area (phase 2, step 2) with the product "REW2338_AMPHO fi=2,5", with deviations from the Standard. (Based on EN 16615: 2015 Standard)
PT 2-4 *Use number 1 and 3*	REW2338_AMPHO (FRESH SAMPLE) Lactic acid 0,86+/-0,086%	*Staphylococcus aureus*	EN16615:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	Passed concentration: Bactericidal concentration: 100% (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº B0623.1 Supportive study	See IUCLID section 6.7-39 EVALUATION OF BACTERICIDAL DISINFECTANT EFFICACY
PT 2-4 *Use number 1 and 3*	REW2338_AMPHO (AGED SAMPLE T=48 MONTH) Lactic acid 0,86+/-0,086%	*Staphylococcus aureus*	EN16615:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	Passed concentration: Bactericidal concentration: 100% (≥ 5 log unit reduction). The validity criteria of the test method are fulfilled.	[redacted] Study nº B0623.2 Supportive study	See IUCLID section 6.7-40 EVALUATION OF BACTERICIDAL DISINFECTANT EFFICACY
PT 2-4 *Use number 1 and 3*	REW2338_AMPHO CONC 14.6% Lactic acid 0,86+/-0,086%	*Staphylococcus aureus*	EN16615:2015 Phase 2 Step 2 Contact time: 5 minutes Temperature: 20 ºC ±1 ºC	Passed concentration: Bactericidal concentration: 100% (≥ 5 log unit	[redacted] Study nº B0623.3 Supportive study	See IUCLID section 6.7-41 EVALUATION OF BACTERICIDAL DISINFECTANT

			Soiling: dirty conditions (3 g/L bovine albumin) Concentrations tested: 100% and 0.1%	reduction). The validity criteria of the test method are fulfilled.		EFFICACY

3.5.4 Efficacy assessment

Laboratory studies were conducted with SANYTOL LACTIC SA APP product family according to the Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C). The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

- **META SPC 1:**

META-SPC1 contains products at 0,86 % w/w Lactic acid pure, with range of variations for perfumes. It is assumed that perfumes have no impact on efficacy.
Laboratory studies were conducted with two representative products REW2338 AMPHO and REW2338_AMPHO_EUC, which only contain variations of perfumes.
The formula DEO REW2338 used in soft surface efficacy tests is not part of the product family SANYTOL LACTIC SA APP and includes a surface modifier. Bridging studies according to EN 1276 have been performed by the applicant in order to demonstrate that the representative product REW2338 AMPHO (without surface modifier) and the product DEO REW2338 (with surface modifier) show similar lever of efficacy, and then the efficacy studies performed with 3 representative products cover the whole Meta SPC1 (see confidential PAR).

META SPC 1: Use # 1 textile disinfection (PT2 and 4) – Spraying (without mechanical action)

Due to the lack of specific efficacy test related to the application of disinfectant products on soft surfaces, the applicant proposed an adaptation of EN13697, considering to use a soft surface as a carrier instead of a stainless-steel disk surface. The best soft surface candidate as carrier for testing, able to cover efficacy an all other textiles is cotton. Indeed, cotton is one of the most commonly used textiles and is the one showing the maximum adherence capacity for microorganisms and the most suitable properties to promote the growth of the microorganisms when the favourable growth conditions are present (Hsieh and Merry 1986; Bajpaj et al., 2011; Shorter, 1924; Schuster et al., 2006; Szostak-Kotowa J., 2004; Teufel and Redl, 2006). Furthermore, standard methods in the field of textile disinfection (ASTM 2274, 2406, VAH 16-17, EN16616) have considered traditionally only cotton as carrier surface to cover the scope of the test. eCA agreed with this argumentation.

Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276) at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentrations of 80 and 50 % v/v.
Bactericidal activity is demonstrated in phase 2, step 2 test (EN 13697 - adapted porous surfaces with a cotton carrier), at 20 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 100 and 50 % v/v.

Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 80% v/v.
Yeasticidal activity is demonstrated in phase 2, step 2 test (EN 13697- adapted porous surfaces and adapted with a cotton carrier), at 20 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 100 and 50 % v/v.

Virucidal activity is demonstrated against enveloped virus, in phase 2, step 1 test (EN 14476) at 20 °C, with a contact time of 2 minutes, in dirty conditions (3g/L BSA). In these

conditions, virucidal activity is shown at the in-use concentration of 80 and 50 % v/v.
Virucidal activity is demonstrated against enveloped virus, in phase 2, step 2 test (EN 16777 – adapted porous surfaces with a cotton carrier) at 20 °C, with a contact time of 5 minutes, in dirty conditions (3g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 100 % v/v.

No P2S2 tests on adapted porous surface (cotton) has been provided on additional bacterial and virucidal strains.

META SPC 1: Use # 2 Hard surface disinfection – Spraying/pouring and wiping

Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276) at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentrations of 80 and 50 % v/v.
Bactericidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 100 and 50% v/v.
With mechanical action, bactericidal activity is demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.
Activity against additional bactericidal strains *Salmonella enterica* and *Listeria monocytogenes* have been also shown in both phase 2, steps 1 and 2 tests (EN 1276 and EN 16615/EN 13697), in the same conditions with and without mechanical action.

Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 100 and 50% v/v.
Yeasticidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 100 and 50% v/v.
With mechanical action, yeasticidal activity is demonstrated in phase 2, step 2 test (EN 16615), at 20°C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 100 % v/v.

Fungicidal activity is demonstrated in phase 2, step 1 test (EN 1650), at 20°C, with a contact time of 60 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, fungicidal activity is shown at the in-use concentration of 80 and 50% v/v.
Fungicidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 30 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, fungicidal activity is shown at the in-use concentration of 100 and 50% v/v.
With mechanical action, fungicidal activity is demonstrated in phase 2, step 2 test (EN 16615) at 20°C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, fungicidal activity is shown at the in-use concentration of 100 % v/v. As contact time is different between P2S1 test and P2S2 tests, the worst-case (60 min) should normally be taken into account. However, as a mechanical action is claimed and since the suspension test is not able to simulate this action, eCA agreed that for with the mechanical action, the contact time can be reduced to 15 min.
Activity against additional fungicidal strains *Microsporum canis* and *Trichosporon cutaneum* have been also shown shown in both phase 2, steps 1 and 2 tests (EN 1650 and EN 16615/EN 13697) in the same conditions with and without mechanical action.

Virucidal activity is demonstrated against enveloped virus, in phase 2, step 1 test (EN 14476) at 20 °C, with a contact time of 2 minutes, in dirty conditions (3g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 80 and 50 % v/v.

Virucidal activity is demonstrated against enveloped virus, in phase 2, step 2 test (EN 16777) at 20 °C, with a contact time of 2 minutes, in dirty conditions (3g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 100 % v/v.
Activity against additional virucidal strains H1N1 and Human coronavirus 229E have been also shown in both phase 2, steps 1 and 2 tests (EN 14476 and EN 16777) in the same conditions.
P2S1 tests (EN14476 with 5 min contact time) have been provided on additional virucidal strain SARS-COV2, but no P2S2 test (EN 16777) has been submitted.

Justifications provided by the applicant on the relevance of additional strains claimed and mentioned in the SPC:

- Salmonella and Listeria: These bacteria are related with food poisoning.
  Salmonella enterica is the second most commonly reported gastrointestinal infection, and an important cause of food-borne outbreaks in the EU/EEA.
  Listeriosis is a serious infection usually caused by eating food contaminated with *L. monocytogenes*. An estimated 1,600 people get listeriosis each year, and about 260 dies and the severity and increasing trend in numbers of cases during the preceding years is still worrying.

- *Trichosporon cutaneum* and *Microsporum canis*: Regarding the additional fungi claimed, aproximately 50 species of the genus Trichosporon have been characterized, 16 of which are associated with diseases in humans. In the last few years, cases of onychomycosis associated with infections caused by Trichosporon spp. have increased.
  Moreover, *M. canis* is a dermatophyte that causes numerous forms of disease. The greatest risk factor for acquiring infection is contact with damaged cells on skin, hair, and nails. *M. canis* can infect all mammals.
- Human coronavirus 229E, SARS-CoV-2 and H1N1: Respiratory viruses are the most frequent causative agents of disease in humans, with significant impact on morbidity and mortality worldwide, mainly in children. Approximately one-fifth of all childhood deaths worldwide are related to acute respiratory infections. SARS coronavirus (SARS-CoV) and influenza viruses have emerged in recent years as threats to public health.

Additional strains where both P2S1 and P2S2 tests have been provided, are mentioned in the SPC as information for the users at the section 5.1.

META SPC 2- STD WIPES

META-SPC2 contains products at 0,86 % w/w Lactic acid pure, with a range of variations in perfumes, used as pre-impregnated wipes. It is assumed that perfumes have no impact on efficacy. Laboratory studies were conducted with two representative products REW2338_AMPHO and REW2338_AMPHO_EUC, covering the whole META SPC2 claims.

META SPC 2: Use # 3 Hard surface disinfection – Wiping

Detailed composition of products in Meta SPC2, used as pre-impregnated wipes is identical to Meta SPC1. Therefore regarding phase 2 step 1 tests, read across with Meta SPC1 is acceptable and efficacy studies performed with representative products REW2338_AMPHO and REW2338_AMPHO_EUC covers the whole META SPC 2. See table of experimental data and conclusions for Meta SPC1 P2S1 tests.

Efficacy data package has been completed with additional phase 2 step 2 tests (EN16615) for bacteria, yeasts and fungi, performed with the commercial impregnated wipes included in Meta SPC2.

Bactericidal and yeasticidal activities are demonstrated in phase 2, step 2 test (EN 16615) at 20ºC, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal and yeasticidal activities is shown at the in-use concentration of 100% v/v.
Activity against additional bactericidal strains *Salmonella enterica* and *Listeria monocytogenes* have been also shown in phase 2, steps 2 test (EN 16615) in the same conditions.

Fungicidal activity is demonstrated in phase 2, step 2 test (EN 16615) at 20ºC, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, activity against fungi is shown at the in-use concentration of 100% v/v.

Activity against additional fungicidal strains *Microsporum canis* and *Trichosporon cutaneum* have been also shown in phase 2, step 2 test (EN 16615) in the same conditions.

Based on Meta SPC1 tests results, virucidal activity is demonstrated against enveloped virus, in phase 2, step 2 test (EN 16777) at 20 °C, with a contact time of 2 minutes, in dirty conditions (3g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 100 % v/v.
Activity against additional virucidal strains H1N1 and Human coronavirus 229E have been also shown in both phase 2, steps 1 and 2 tests (EN 14476 and EN 16777) in the same conditions, but no P2S2 test (EN 16777) has been submitted on the strain SARS-COV2 based on Meta SPC1 tests results.

Justifications provided by the applicant on the relevance of additional strains claimed and mentioned in the SPC are detailed in Meta SPC1 part. Additional strains where both P2S1 and P2S2 tests have been provided, are mentioned in the SPC as information for the users at the section 5.1.

The long term stability storage assessed in physical properties part shows after 36 months an increase of the active substance above 1% in the impregnated solution. This increase is due to the evaporation of formulation's solvent. This (>1%) content would imply a tox classification (see tox part) and therefore the shelf life should be set at 24 months. Efficacy studies with aged products are therefore supportive studies.

3.5.5 Conclusion on efficacy

Conclusion on the efficacy of the product
SANYTOL LACTIC SA APP product family has shown a sufficient efficacy in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C): META SPC 1: -Textiles disinfection (PT2 & PT4) by spraying at room temperature (dirty conditions) with a contact time of 15 min against bacteria, yeasts and enveloped virus.

No appropriate P2S2 tests (cotton carriers) have been submitted for additional strains claimed : *Salmonella enterica*, *Listeria monocytogenes*, H1N1, Coronavirus 22E and SARS-COV2.

-Hard surfaces disinfection (PT2 & PT4) by spraying/pouring (and wiping) at room temperature (dirty conditions):
with a contact time of 5 min (with and without mechanical action) against bacteria, yeasts and enveloped virus,
with a contact time of 15 min with mechanical action and 60 min without mechanical action against fungi.
Activity against additional strains have been also shown against Salmonella, Listeria, *Microsporum canis*, *Trichosporon cutaneum,* H1N1 and Human coronavirus.

META SPC 2:
Hard surfaces disinfection (PT2 & PT4) by wiping at room temperature (dirty conditions) with a contact time of 5 min against bacteria, yeasts and enveloped virus, 15 min against fungi.
Activity against additional strains have been also shown against Salmonella, Listeria, *Microsporum canis*, *Trichosporon cutaneum,* H1N1 and Human coronavirus.

3.5.6 Occurrence of resistance and resistance management

No resistance phenomenon has been reported with lactic acid in the scientific literature.

No incidence of resistance to Lactic acid has been recorded until now. (Source: Assessment Report. L (+) Lactic Product types 2, 3 and 4. June 2017. RMS, Germany)

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

3.5.7 Known limitations

None.

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

Biocidal products from SANYTOL LACTIC SA-APP family are not intended to be authorised for the use with other biocidal products.

3.7 Risk assessment for human health

According to Article 25 and Article 20 (1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the biocidal product family fulfills all conditions for a simplified authorisation procedure.

3.7.1 Assessment of effects on human health

For the SANYTOL LACTIC SA-APP biocidal product family, classification for skin irritation, sensitisation and acute toxicity effects has been determined by using the calculation method laid down in the CLP Regulation 1272/2008/EC, based on the available data on each component.
An in vitro study is available for eye corrosion and irritation.
For products of Meta-SPC 2, results from the long-term stability storage indicate an increase of the content of active substance in the solution, due to the evaporation of the formulation's solvent. This variation of the active content being >10% after 3 years, a justification for the acceptability of this increase on the risk assessment should be provided.
As this variation has an impact on human health classification and the acceptability of the criteria of Article 25 of the Regulation, the shelf life has be set at 24 months.

See APCP section and Confidential annex for further details.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not classified as skin corrosive or irritant.
Justification for the value/conclusion	The active substance and one ingredient are classified for skin corrosion. Using the additivity approach, the result of the calculation with the content of the active substance and the ingredient is below the threshold of 5% for skin corrosion and 1% for skin irritation. Please refer to the Confidential Annex for further details.
Classification of the product(s) according to CLP	No classification is required.

Eye irritation

Summary table of in vitro studies on serious eye damage and eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not classified as eye corrosive or irritant
Justification for the value/conclusion	The active substance and several ingredients are classified for serious eye damage. Using the additivity approach, the result of the calculation is above the threshold of 1% for eye irritation. An *in vitro* eye irritation test has been conducted on the product REW2338 AMPHO. This tested formulation has a similar composition as the formulations in the SANYTOL LACTIC SA-APP dossier, with the only difference being the active substance. The tested formulation contains L-(+)-lactic acid (CAS: 79-33-4) as active substance, while the formulations in the SANYTOL LACTIC SA-APP products contain lactic acid

	(CAS: 50-21-5). Therefore, the test conducted applies to the SANYTOL LACTIC SA-APP family. According to the results from the eye irritation test (OECD TG 438) Meta SPC 1 & 2 products have shown not to require classification for eye hazard. Please refer to the Confidential Annex for further details.
Classification of the product(s) according to CLP	No classification is required.

Summary table of in vitro studies on eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
Isolated Chicken Eye Test Method OECD 438 GLP: yes Reliability: 1	Test item REW2338_AMPHO 30 µL to 3 enucleated chicken eyes	Positive control = 3 eyes in the same manner with Benzalkomium Chloride 5% Negative control = physiological saline Application time: 10 seconds Rinse with 10 mL of physiological saline Damages assessed by determination of corneal swelling, corneal opacity and fluorescein retention at 45 minutes before the treatment and 30, 75, 120, 180 and 240 minutes post-dose.	**Test item:** Corneal opacity: 0.0 = class I Fluorescein retention: 1.3 = Class II Corneal swelling: 1% = Class I ➔ Combination = 2 x I, 1 x II → No category **Positive control:** ➔ Combination = 1 x III, 2 x IV → Corrosive/ Severe irritant **Negative control:** ➔ Combination = 3 × I → No Category **Conclusion:** The test item does not require classification for eye irritation and serious eye damage.	No major deviation	[redacted] Study number ICE-PH-21-01049 IUCLID section 8.1.2-02

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin
Justification for the value/conclusion	Each product of the family SANYTOL LACTIC SA-APP contains one different perfume. All perfumes contain ingredients classified for skin sensitization, but their concentration in the products is below the generic concentration limit for classification (0.1% for category 1A and 1% for category 1 and category 1B). All but one perfumes contain ingredients classified for skin sensitization below the EUH 208 limit (0.01% for category 1A and 0.1% for category 1 and category 1B). The perfume LEMON contains one ingredient, (E)-3-methyl-5-phenylpent-2-enenitrile, which is classified Skin Sens. Cat 1A – H317 and is present in the product at a concentration above 0.01%. This induces the additional labelling information EUH208 "Contains (E)-3-methyl-5-phenylpent-2-enenitrile. May produce an allergic reaction" This labelling has to be applied for the entire meta-SPC (meta-SPC 1 and 2), included for products of the meta-SPC without the perfume LEMON. To avoid unnecessary labelling, the content of the perfume LEMON in each meta-SPC has to be lowered below 0.1%, which would lower the content of the ingredient (E)-3-methyl-5-phenylpent-2-enenitrile below the limit of 0.01% for EUH208 labelling. Considering this, the products containing the perfume LEMON are not conform.
Classification of the product according to CLP	No classification is required. The additional labelling information EUH208 – "Contains (E)-3-methyl-5-phenylpent-2-enenitrile. May produce an allergic reaction" is required for some products

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via oral route
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product
Classification of the product according to CLP	No classification required

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

No substances of concern regarding human health were identified in the products of the biocidal product family SANYTOL LACTIC SA-APP, 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), Annex A).

3.7.3 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

3.7.4 Exposure assessment and risk characterisation for human health

The handling of the BPF as part of its intended use does not require any personal protective equipment (PPE).

The BPF fulfils the conditions for a simplified authorisation according to the Article 25 of the Regulation.

3.7.5 Dietary risk assessment

For L+ lactic acid data the following evaluation was provided in the Assessment Report, 2007:
"L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e.g. via anaerobic catabolism of glycogen and glucose) production by gastro intestinal microorganisms and uptake via food. The production of L(+) lactic acid as an intermediary metabolite in a 70 kg resting man is estimated to be in the range of 117-230 g/d but can be much higher during exercise. the mean daily per capita intake of L(+) lactic acid and D(-)Lactic acid from milk and milk products has been estimated to be approximately 1 g in Switzeland (Walther, 2006). The estimated overall intake via food in the EU and the USA is estimated to be 1.65-2.76 g/person/day.
L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (Quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008)."

Moreover, "Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended

uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD have been set".

By definition, PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected for LACTIC SA-APP Family PT 2 uses.

As PT4, LACTIC SA-APP Family is intended to be used for surface disinfection in households/private areas and professional sectors. According to the Competent Authority Report from L(+) lactic acid PTs 02, 03 & 04, residues in food from the intended PT4 use are expected to be low compared to naturally occurring levels in food. Therefore, the intended use does not significantly contribute to consumer exposure to lactic acid.

3.7.5.1 Information of non-biocidal use of the active substance and residue definitions

Table 3.12 Summary table of other (non-biocidal) uses

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Food	Lactic Acid (E 270) – Food additive	*Quantum satis* (Regulation (EU) 1129/2011)
2.	Veterinary	Lactic Acid - All food producing species	No MRL required (Regulation (EC) No 37/2010)
3.	Cosmetic	Lactic Acid – Used as buffering humectant or skin conditioning	Up to a maximum level of 2.5% and a pH ≥ 5 (SCCBFP, 2000)

[1] e.g., plant protection products, veterinary use, food or feed additives

[2] e.g., MRLs. Use footnotes for references.

3.7.5.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

Not relevant

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

Not relevant

3.7.5.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

Not relevant

3.7.5.5 Maximum residue limits or equivalent

Not relevant

Table 3.13 Maximum residue limits or equivalent

Not relevant

3.8 Risk assessment for animal health

Not relevant.

3.9 Risk assessment for the environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the products of the family fulfil all conditions for a simplified authorisation procedure.

3.9.1 Classification

The classification of the products have been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008 and the products are not classified.

Moreover, there is no need for risk mitigation measure to protect the environment.

3.9.2 Substance(s) of concern

The products of the SANYTOL LACTIC SA-APP family do not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017).

3.9.3 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substance(s), refer to the respective section of the confidential annex.

3.10 Assessment of a combination of biocidal products

Biocidal products from SANYTOL LACTIC SA-APP family are not intended to be authorised for the use with other biocidal products.

3.11 Comparative assessment

Not relevant, none of the active substance are candidate for substitution or exclusion.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Not relevant.

4.1.2 Dietary assessment

Not relevant

4.1.3 Environment

Not relevant.

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

No new information on the active substance is available.

4.3 List of studies for the biocidal product family

Table 4.1 List of studies for the biocidal product family

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
[redacted]	2021	IUCLID section 6.7-13	Evaluation of the effectiveness of REW2338_AMPHO_EUC based on EN 16777:2018 (3.0 g/l BSA) on cotton carriers	L21/0779aMV.3	Study report	[redacted]	No	Yes
[redacted]	2021	IUCLID section 6.7-19	Evaluation of the effectiveness of REW2338_AMPHO_EUC based on EN 16777:2018 (3.0 g/l BSA) on cotton carriers	L21/00841MV.10	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID 6.7-32	EVALUATION OF DISINFECTANT EFFICACY REW 2338_AMPHO. EN 1276, November 2019 – Chemical and antiseptic disinfectants - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2/step1)	B0423.7	Study report	[redacted]	No	Yes

	2023	IUCLID 6.7-33	EVALUATION OF DISINFECTANT EFFICACY REW 2338_AMPHO_POLYQUART. EN 1276, November 2019 – Chemical and antiseptic disinfectants - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2/step1)	B0423.8	Study report		No	Yes
	2023	IUCLID section 6.7-39	Nº Report: B0623.1 EVALUATION OF BACTERICIDAL DISINFECTANT EFFICACY	B0623.1	Study report		No	Yes
	2023	IUCLID section 6.7-40	Nº Report: B0623.2 EVALUATION OF BACTERICIDAL DISINFECTANT EFFICACY	B0623.2	Study report		No	Yes
	2023	IUCLID section 6.7-41	Nº Report: B0623.3 EVALUATION OF BACTERICIDAL DISINFECTANT EFFICACY	B0623.3	Study report		No	Yes
	2021	IUCLID section 6.7-09	Evaluation based on european standard EN 14476+A2 (July 2019(methodology of virucidal activity of hard surface disinfectant toward SARS-COV-2- Coronavirus in dirty conditions	1156/01/EN14476-163/19	Study report		Yes	Yes

[redacted]	2018	IUCLID section 6.7-01	Bactericidal Activity Test in suspension with the product REW2338_AMPHO in dirty conditions (UNE-EN 1276:2010; Erratum 2011)	D/18/274	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-23	Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1), against Coronavirus 229E with the product “REW2338_AMPHO” with deviations from the Standard (Based on EN 14476: 2013 + A2: 2019 Standard)	D/23/V0052	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-22	Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1), against Influenza A (H1N1) pdm09 with the product “REW2338_AMPHO”, with deviations from the Standard (based on EN 14476: 2013 + A2: 2019 Standard)	D/23/V0050	Study report	[redacted]	No	Yes
[redacted]	2021	IUCLID section 6.7-30	Fungicidal activity against Aspergillus brasiliensis on non-porous surfaces (phase 2, step 2), under dirty conditions with the product REW2338_AMPHO, with deviations from the standard (NF EN 13697: 2015 + A1: 2019 Standard)	D/21/B0679	Study report	[redacted]	No	Yes

[redacted]	2021	IUCLID section 6.7-31	Quantitative fungicidal activity test on non-porous surface (phase 2, step 2), against Microsporum canis and Trichosporon cutaneum, with the product REW2338_AMPHO. (Based on NF EN 13697: 2015 + A1: 2019 Standard)	D/22/B0225	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-25	Quantitative non-porous surface virucidal activity test without mechanical action (phase 2, step 2), against Coronavirus 229E, with the product "REW2338_AMPHO", with deviations from the Standard (EN 16777: 2019 Standard)	D/23/V0053	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-24	Quantitative non-porous surfaces test of chemical disinfectants for the evaluation of virucidal activity, without mechanical action in the medical area (phase 2/step 2), against Influenza A (H1N1)pdm09 cepa A/California/7/2009 (H1N1) virus, with the product "REW2338_AMPHO" with deviations to the Standard (based on EN 16777: 2019 Standard)	D/23/V0051	Study report	[redacted]	No	Yes

[redacted]	2023	IUCLID section 6.7-34	Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas (Phase 2, step 1), with the product “REW2338_AMPHO”. (EN 1650: 2019 Standard)	D/23/B0182	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-36	Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1), against Aspergillus brasiliensis, with the product “REW2338_AMPHO”, with deviations from the Standard. (EN 1650: 2019 Standard)	D/23/B0183	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-35	Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas (Phase 2, step 1), with the product “REW2338_AMPHO_POLYQUART”.	D/23/B0186	Study report	[redacted]	No	Yes

			(EN 1650: 2019 Standard)					
[redacted]	2023	IUCLID section 6.7-37	Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1), against Aspergillus brasiliensis, with the product "REW2338_AMPHO_POLYQUART", with deviations from the Standard. (EN 1650: 2019 Standard)	D/23/B0187	Study report	[redacted]	No	Yes
[redacted]	2021	IUCLID section 6.7-21	Quantitative test method for the evaluation of fungicidal activity on non-porous surfaces with mechanical action using wipes in the medical area (4-fields of assay) (phase 2, step 2) against Aspergillus brasiliensis, with the product REW2338_AMPHO, with deviations from the standard. (based on UNE-EN 16615: 2015 Standard)	D/21/B0709	Study report	[redacted]	No	Yes
[redacted]	2022	IUCLID section 6.7-02	Quantitative suspension test for the evaluation of yeasticidal activity of chemical disinfectants and antiseptics	D/22/B0405	Study report	[redacted]	No	Yes

			used in food, industrial, domestic, and institutional areas (Phase 2, step 1), with the product REW2338_AMPHO. (NF EN 1650: 2019 Standard)					
	2021	IUCLID section 6.7-16	Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2), with the product REW2338_AMPHO, with deviations from the Standard. (UNE-EN 16615: 2015 Standard).	D/21/B0680	Study report		No	Yes
	2022	IUCLID section 6.7-16	Quantitative test method for the evaluation of yeasticidal activity on non-porous surfaces with mechanical action using wipes in the medical area (4-field test) (phase 2, step 2), with the product REW2338_AMPHO, with deviations from standard. (UNE-EN 16615: 2015 Standard).	D/22/B0407	Study report		No	Yes
	2022	IUCLID section 6.7-06	Virucidal test against Vaccinia virus, strain modified Vaccinia Ankara (MVA) with the product "REW2338_AMPHO" with deviations to the Standard (NF EN 14476: 2013 + A2: 2019	D/22/V0003	Study report		No	Yes

			Standard)					
[redacted]	2018	IUCLID section 6.7-10	Bactericdial activity on non-porous surfaces with the product REW2338_AMPHO (UNE-EN 13697:2015)	D/18/199	Study report	[redacted]	No	Yes
[redacted]	2022	IUCLID section 6.7-11	Yeasticidal activity on non-porous surfaces (phase 2, step 2), under dirty conditions with the product REW2338_AMPHO. (NF EN 13697: 2015 + A1: 2019 Standard)	D/22/B0406	Study report	[redacted]	No	Yes
[redacted]	2021	IUCLID section 6.7-04	Quantitative suspension test for the evaluation of the bactericidal activity of antiseptics and chemical disinfectants used in food, industrial, domestic, and institutional areas. Test method requirenments (phase 2, stage 1), with the producto REW2338_AMPHO with deviations from the standard. (NF EN 1276:2019 Standard)	D/21/B0371	Study report	[redacted]	No	Yes
[redacted]	2021	IUCLID section 6.7-05	Fungicidal activity against Microsporum canis, Trichosporon asahii and Trichosporon cutaneum with the producto REW2338_AMPHO, with deviation from the standard.	D/21/B0677	Study report	[redacted]	No	Yes

			(nf en 1650:2019 Standard)					
[redacted]	2021	IUCLID section 6.7-18	Fungicidal activity against Aspergillus brasilensis with the product REW2338_AMPHO with deviations fro mthe standard (NF EN 1650:2019 standard)	D/21/B0504	Study report	[redacted]	No	Yes
[redacted]	2021	IUCLID section 6.7-11	Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 2), for additional bacteria, with the product REW2338_AMPHO. (Based on NF EN 13697: 2015 + A1: 2019 Standard)	D/21/B0224	Study report	[redacted]	No	Yes
[redacted]	2022	IUCLID section 6.7-17	Quantitative test method for the evaluation of fungicidal activity on non-porous surfaces with mechanical action using wipes in the medical area (4-fields of assay) (phase 2, step 2) against Aspergillus brasiliensis, with the product REW2338_AMPHO, with deviations from the standard. (based on UNE-EN 16615: 2015 Standard)	D/22/B0002	Study report	[redacted]	No	Yes

[redacted]	2023	IUCLID section 6.7-27	Quantitative test for the evaluation of bactericidal activity against Listeria monocytogenes and Salmonella enterica, on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2) with the product “REW2338_AMPHO”, with deviations from Standard. (Based on EN 16615: 2015 Standard)	D/23/B0093	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-28	Quantitative test method for the evaluation of fungicidal activity against Trichosporon cutaneum and Microsporum canis, on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2) with the product “REW2338_AMPHO”, with deviations from the Standard. (Based on EN 16615: 2015 Standard)	D/23/B0094	Study report	[redacted]	No	Yes
[redacted]	2023	IUCLID section 6.7-26	Quantitative test for the evaluation of bactericidal activity against Listeria monocytogenes and Salmonella enterica, on non-porous surfaces with mechanical action using wipes in the medical area (phase 2,	D/23/B0087	Study report	[redacted]	No	Yes

			step 2) with the product "REW2338_AMPHO fi=2,5", with deviations from Standard. (Based on EN 16615: 2015 Standard)					
[redacted]	2023	IUCLID section 6.7-29	Quantitative test method for the evaluation of fungicidal activity against Trichosporon cutaneum and Microsporum canis, on non-porous surfaces with mechanical action using wipes in the medical area (phase 2, step 2) with the product "REW2338_AMPHO fi=2,5", with deviations from the Standard. (Based on EN 16615: 2015 Standard)	D/23/B0088	Study report	[redacted]	No	Yes
[redacted]	2021	IUCLID section 6.7-03	Bactericidal and Yeasticidal activity of DEO REW 2338 in the quantitatie surface test following to DIN EN 13697:2015 (Phase 2, Step 2)	L18/0768.2	Study report		GLP information not provided	Yes
[redacted]	2018	IUCLID section 6.7-20	Bactericidal nad yeasticidal activity of REW238_AMPHO in the quantitative 4-field-test according to DIN EN 16615:2015 (Phase 2, Step 2)	L18/0223.1	Study report		GLP information not provided	Yes

4.4 References

4.4.1 References other than list of studies for the BPF

- *Not relevant*

4.4.2 Guidance documents

- *Not relevant*

4.4.3 Legal texts

- *Not relevant*

4.5 Confidential information

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