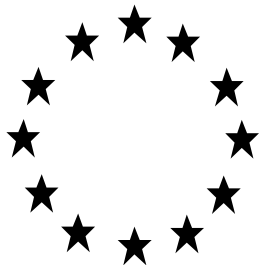
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



COLGATE-PALMOLIVE_LACTIC ACID_PT2

Product type 02

L(+) lactic acid as included in the Union list of approved active substances

Case Number in R4BP: BC-HK051319-37

Evaluating Competent Authority: FR

Date: 11 March 2022

Table of Contents

1 CONCLUSION

1.1 Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The biocidal product family, COLGATE-PALMOLIVE_LACTIC ACID_PT2, is based on 1.5 to 4 % of L (+) lactic acid, is a product type 2 intended for surface disinfection. The products of this biocidal family are in the form of liquids, to be applied for the disinfection against bacteria by non-professional users.
Two uses are claimed for all products of the BPF:

- Use #1: disinfection of hard surfaces (domestic surfaces other than kitchen)
- Use #2: Toilet bowl surfaces disinfection.

The BPF COLGATE-PALMOLIVE_LACTIC ACID_PT2 is composed of four Meta-SPC:

- Meta-SPC 1–2 : application by pouring on sponge and then spreading on the surface
- Meta-SPC 3 – application by spraying
- Meta-SPC 4 – application by spraying
- Meta-SPC 5 – application with impregnated wipes

Conclusions of the assessments of each section are given below:

Physico-chemical properties

The physico-chemical properties of the biocidal product family COLGATE-PALMOLIVE LACTIC ACID PT2 have been described and considered acceptable in the conditions of use detailed in the SPC.

The analytical method for the determination of the active substance, L (+) lactic acid in the biocidal product family is fully validated.

For self-reactive properties, DSC tests of representative products of all Meta SPCs should be provided in post-authorisation within 6 months to confirm the non-classification in this hazard class.

Meta SPC 1-2:

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material.
The products of Meta SPC 1-2 must not be stored above 40°C. The products should be protected from light.

Meta SPC 3:
The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material.
The products of Meta SPC 3 are classified as corrosive to metal H290 Met Corr. I.

Meta SPC 4:

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material. The products should be protected from light.

Meta SPC 5:

The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in commercial packaging material.
The products of Meta SPC 5 must not be stored above 30°C.
The products of Meta SPC 5 are classified as corrosive to metal H290 Met Corr. I.

Efficacy

COLGATE-PALMOLIVE_LACTIC_ACID_PT2 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) for PT2 uses against bacteria:

META SPC 1-2: By spreading on porous and non-porous hard surfaces
META SPC 3: By spraying on porous and non-porous hard surfaces
META SPC 4: By spraying on porous and non-porous hard surfaces
META SPC 5: By wiping on hard non-porous surfaces
Regarding the claim against bacterial spores, the efficacy is not demonstrated.

Human health

Meta SPC1-2 (Uses#1 and #2)

Meta SPC 1-2 is classified Skin Irrit. 2 and Eye Dam. 1.

For products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in bottle (named BDC for Bucket Dilutable Cleaner by applicant) (Meta SPC 1-2), the risk during hard surface disinfection is acceptable considering the qualitative risk assessment for local effects with the following risk mitigation measures (RMM):

- Wash hands after use
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- Avoid contact with eyes
- Avoid splashes and spills during pouring

and:

- The bottles sized above 1L and up to 2L must be adapted with a handle.
- The packaging must be adapted with a child proof closure.

Meta SPC 3 & 4 (Uses#1 and #2)

Meta SPC 3 and 4 are classified Skin Irrit. 2 and Eye Dam. 1.

For products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in trigger spray (Meta SPC 3 & 4), the risk during hard surface disinfection (domestic surfaces and toilet bowl) is not acceptable considering the qualitative risk assessment for local effects.

Meta SPC 5 (Uses#1 and #2)

Meta SPC 5 is classified Skin Irrit. 2 and Eye Dam. 1.

For products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged impregnated wipes (Meta SPC 5), the risk during hard surface disinfection is acceptable considering the systemic and local effects with the following risk mitigation measures (RMM):

- Wash hands after use
- Avoid contact with eyes
- Keep out of reach of children and non-target animals/pets

For Meta SPC 1-2 and 5, the risk is considered acceptable for the secondary exposure of the general public with the application of risk mitigation measures listed below:

- Do not touch the surface until the surface is rinsed and dry.
- Children should not be present during disinfection and until the surface is rinsed and dry.

Dietary risk assessment

By definition, PT02 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feeding stuffs. Thus no evaluation has been conducted with regard to risk for consumer under indirect exposure via food.

Environment

Uses of the BPF does not pose a risk to environmental compartments.

b) Presentation of the biocidal product/biocidal product family including classification and labelling

Classification of product family (meta SPC 1-2)	
Hazard category	Skin Irrit. 2 Eye Dam. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage

Classification of product family (meta SPC 5)	
Hazard category	Skin Irrit. 2 Eye Dam. 1 Met Corr. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage H290: May be corrosive to metals

The description of the structure of the family is available in the SPC.
The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance lactic acid contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is (are) not considered (a) candidate(s) for substitution. Therefore, a comparative assessment of the biocidal product family is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

Meta SPC	Field of use	Composition	Application rate and uses	Conclusions
1-2	Hard surface disinfection domestic surfaces other than kitchen Toilet bowl surfaces disinfection	1.5-2.8% Lactic acid (pure)	Indoor Non-professionals Pouring and spreading (with rinsing afterwards) Contact time: 15min	Acceptable with RMM*
3	Hard surface disinfection domestic surfaces other than kitchen Toilet bowl surfaces disinfection	3.2% lactic acid (pure)	Indoor Non-professionals Spraying (with rinsing afterwards) Contact time: 5min	Not acceptable: Unacceptable risks for local effects
4	Hard surface disinfection domestic surfaces other than kitchen Toilet bowl surfaces disinfection	2.4% lactic acid (pure)		Not acceptable: Unacceptable risks for local effects
5	Hard surface disinfection domestic surfaces other than kitchen Toilet bowl surfaces disinfection	3.504 – 4% Lactic acid (pure)	Indoor Non-professionals Wiping (with rinsing afterwards) Contact time: 5min	Acceptable with RMM*

*Please refer to the general and specific directions of use for more details.

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s) in the biocidal product family are met.
The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family COLGATE-PALMOLIVE_LACTIC_ACID_PT2 is sufficiently effective;
2. the biocidal product family COLGATE-PALMOLIVE_LACTIC_ACID_PT2 has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
   - the fate and distribution of the biocidal product in the environment,
   - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
   - the impact of the biocidal product on non-target organisms,
   - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use(s) described in the SPC, may be authorised.

1.2 BPC opinion on the Union authorisation of the biocidal product/biocidal product family

As the conditions of Article 19(1) are met it is proposed that biocidal product family shall be authorised[1], for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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[1] This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[2]	**Country (if relevant)**
COLGATE-PALMOLIVE_LACTIC ACID_PT2	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Colgate-Palmolive Sp. Z.o.o
	Address	Wybrzeże Gdyńskie 6D 01-531 Warszawa Poland
Pre-submission phase started on		
Pre-submission phase concluded on		
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Colgate-Palmolive Industrial S.A.S
Address of manufacturer	60 Avenue du Vermandois 60200 Compiègne, France
Location of manufacturing sites	60 Avenue du Vermandois 60200 Compiègne, France

Name of manufacturer	Colgate Palmolive (Hellas) SAIC
Address of manufacturer	89 Athinon 18541 Piraeus, Greece
Location of manufacturing sites	89 Athinon 18541 Piraeus, Greece

[2] Please fill in here the identifying product name from R4BP 3.

Name of manufacturer	Colgate Palmolive Srl Italy
Address of manufacturer	Viale Palmolive, 18 00042 Anzio, Italy
Location of manufacturing sites	Viale Palmolive, 18 00042 Anzio, Italy

Name of manufacturer	EURO WIPES
Address of manufacturer	2 Rue du Grand Champ 28400 Nogent-le-Rotrou, France
Location of manufacturing sites	2 Rue du Grand Champ 28400 Nogent-le-Rotrou, France

Name of manufacturer	Hangzhou Guoguang Touring Commodity Co., Ltd
Address of manufacturer	No.8 Yunshun Road, Jingshan Town, Yuhang District, Hangzhou,Zhejiang Province,China.
Location of manufacturing sites	No.8 Yunshun Road, Jingshan Town, Yuhang District, Hangzhou,Zhejiang Province,China.

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

Active substance	L(+) lactic acid
Name of manufacturer	Purac Biochem bv (included in art.95 as RP participant)
Address of manufacturer	Purac Biochem bv Arkelsedijk 46 NL-4200 AA Gorinchem The Netherlands
Location of manufacturing sites	Purac Biochem bv Arkelsedijk 46 NL-4200 AA Gorinchem The Netherlands

Active substance	L(+) lactic acid
Name of manufacturer	Purac Bioquimica SA (included in art.95 by "art.95 submission")
Address of manufacturer	Purac Bioquimica SA Gran Vial 19-25 08160 Montmeló (Barcelona) Spain
Location of manufacturing sites	Gran Vial 19-25 08160 Montmeló (Barcelona) Spain

Active substance	L(+) lactic acid
Name of manufacturer	Jungbunzlauer International S.A. (included in art.95 by "art.95 submission")
Address of manufacturer	St. Alban-Vorstadt 90 - P.O. Box – CH-4002 Basel Switzerland
Location of manufacturing sites	Jungbunzlauer S.A. Z.I. et Portuaire B.P. 32. FR-67390 Marckolsheim. France

The detail of the composition of the active substance premix (aqueous solution of lactic acid) is provided in the confidential annex.

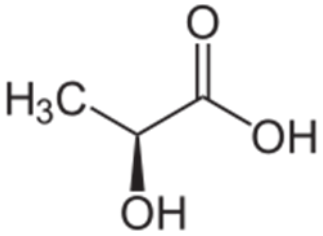
2.1.2 Product (family) composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	L(+) lactic acid
IUPAC or EC name	(S)-2-Hydroxypropanoic acid
EC number	201-196-2
CAS number	79-33-4
Index number in Annex VI of CLP	607-743-00-5
Minimum purity / content	≥ 95.5% w/w (dry weight)
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance(s) contained in the biocidal products is not a candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family[2]

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance*	79-33-4	201-196-2	1.5	4
		Technical active substance**			1.57	4.19
Content in the BP of the mixture including the pure AS					1.875	5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	0	3
Propan-2-ol		Solvent	67-63-0	200-661-7	0	0.1

*Based on the content of active substance in the mixture used for the formulation of the biocidal products (80% w/w).
**Based on the minimum purity of lactic acid (CAS 79-33-4): 95.5% w/w.

2.1.2.4 Information on technical equivalence

The sources of the active substance from Purac Biochem bv and Purac Biochemica SA are the same as those evaluated for inclusion in the Union list of approved active substances.

The source of the active substance from Jungbunzlauer International S.A. is considered technically equivalent compared to the reference source (Decision number: TAP-D-1403137-31-00/F).

2.1.2.5 Information on the substance(s) of concern

Two co-formulants included in the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family were identified as substance of concern for human health/environment.

Please see section 2.2.6.1 and the confidential annex for further details.
To be noted that some substances that have European IOELVs which are not relevant for the general public have been only flagged and indicated as candidate to SoC by IOELV but not identified as SoC.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product family

The biocidal product contains the active substance "Lactic Acid", which is not considered to have endocrine disrupting properties.
None of the co-formulants contained in the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family are regulatory identified as endocrine disruptors or have significant ED properties.

However, that are indications that some co-formulants have ED properties and they should be further assessed in the frame of REACH Regulation.

2.1.2.7 Type of formulation

AL : Any other liquid

PART II - SECOND INFORMATION LEVEL - META SPC 1-2.

2.1.3 Meta SPC 1-2 administrative information

2.1.3.1 Meta SPC identifier

Identification	META SPC 1-2 PT2 BDC

2.1.3.2 Suffix to the authorisation number

2.1.3.3 Product type(s)

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2.1.4 Meta SPC 1-2 composition

2.1.4.1 Qualitative and quantitative information on the composition of the meta SPC 1-2

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.5	2.8
		Technical active substance			1.57	2.93
Content in the BP of the mixture including the pure AS					1.875	3.5
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3	3

2.1.4.2 Type(s) of formulation of the meta SPC 1-2

AL : Any other liquid

2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1-2

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1

Classification	
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage
Precautionary statements	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P264 Wash … thoroughly after handling. ~~P280: Wear protective gloves/ protective clothing/eye protection/face protection/ hearing protection/…~~ P302 + P352 IF ON SKIN: Wash with plenty of water/… P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/… P321 Specific treatment (see … on this label).P332 + P313 If skin irritation occurs: Get medical advice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse.
Note	P280: Not required for non-professionals

2.1.6 Authorised use(s) of the META SPC 1-2

2.1.6.1 Use description

Table 1. Use # 1 – Hard surface disinfection domestic surfaces

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria
Field of use	Indoor Household – Bathroom porous and non-porous hard surfaces other than kitchen.
Application method(s)	Manual application Pour the neat product on sponge and spread on the surface (without pre-cleaning). Rinsing is required.
Application rate(s) and frequency	Ready to use. 18 g of product per m² on a sponge.

	Contact time: 15 minutes Room temperature Frequency: Daily
Category(ies) of users	Non-professionals
Pack sizes and packaging material	PET bottle 650, 750, 1000, 1250, 1300, 1500 and PE bottle 2000 mL

2.1.6.1.1 Use-specific instructions for use

- 1/2 cap of product on a sponge corresponding to 18 g of product per m²

2.1.6.1.2 Use-specific risk mitigation measures

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

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

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

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2.1.6.2 Use description

Table 2. Use # 2 – Toilet bowl surfaces disinfection

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria
Field of use	Indoor Household toilets - Disinfection for Toilets bowls surfaces – porous and non-porous hard surface disinfection
Application method(s)	Manual application Pour the neat product on sponge and then spread on the surface to disinfect (without pre-cleaning). Rinsing is required.

Application rate(s) and frequency	Ready to use. 18 g of product per m² on a sponge. Contact time: 15 minutes Room temperature Frequency: daily
Category(ies) of users	Non professionals
Pack sizes and packaging material	PET bottle 650, 750, 1000, 1250, 1300, 1500 and PE bottle 2000 mL

2.1.6.2.1 Use-specific instructions for use

- 1/2 cap of product on a sponge corresponding to 18 g of product per m².

2.1.6.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

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2.1.7 General directions for use of the meta SPC 1-2

2.1.7.1 Instructions for use

- Comply with the instructions for use.
- Inform the registration holder if the treatment is ineffective.
- Ensure complete wetting on the surfaces, leave for appropriate contact time
- Clean the cap after dosing.
- Let the surface dry after rinsing.

2.1.7.2 Risk mitigation measures

- Wash hands after use.
- Avoid contact with eyes.
- Avoid splashes and spills during pouring.
- Wash thoroughly the sponge with a great amount of water.
- Do not touch the surface until the surface is rinsed and dry.

- Children and pets should not be present during disinfection and until the surface is rinsed and dry.
- The bottles sized above 1L and up to 2L must be adapted with a handle.
- The packaging must be adapted with a child proof closure.

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.
  Call 112/ambulance for medical assistance.
  Information to Healthcare personnel/doctor:
  The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

- Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.

If medical advice is needed, have product container or label at hand

2.1.7.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations

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

- Shelf life: 2 years
- Do not store above 40°C
- Protect from light
- Keep out of reach of children and non-target animals/pets

2.1.8 Other information

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PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1-2

2.1.9 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	B029-1342-0015 Ajax APC Antibacterial Blue @ 1.3% LA (ref B029-1342-0015) Ajax Antibakteriell Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh Ajax Απολυμαντικό Clean Fresh Ajax Optimal 7 Antibactérien Fraîcheur Océan Ajax Multi-surfaces Antibactérien Fraîcheur Océan Ajax Antibacterial Ocean Fresh Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh Ajax Απολυμαντικό Clean Fresh Ajax Disinfettante Clean Fresh Ajax Antibacteriano Ultra Frescura Ajax Antibacteriano Ajax Antibacterial Blue Ajax Désinfectant / Ajax Desinfecterend Ajax Désinfectant Clean Fresh / Ajax Desinfecterend Clean Fresh; Ajax Désinfectant Fraîcheur Océan / Ajax Desinfecterend Oceaan Frisheid Ajax Antibactérien / Ajax Antibacterieel Ajax Desinfectant Ajax Desinfectant Clean Fresh Ajax Desinfectant Oceaan Frisheid				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.5
		Technical active substance			1.57
Content in the BP of the mixture including the pure AS					1.875
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

Trade name(s)	B029-1342-0014 Ajax APC Antibacterial Blue @ 2.6% LA (B029-1342-0014) Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh + (Plus) Ajax Απολυμαντικό Clean Fresh + (Plus) Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh + (Plus) Ajax Απολυμαντικό Clean Fresh + (Plus) Ajax Disinfettante Clean Fresh + (Plus) Ajax Antibacteriano Ultra Frescura + (Plus) Ajax Antibacteriano + (Plus) Ajax Antibacteriano Ultra Frescura Ajax Antibacterial Blue Plus					
Authorisation number						
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.8
		Technical active substance			2.93
Content in the BP of the mixture including the pure AS					3.5
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

Trade name(s)	B029-4339-0011 Ajax APC Liquid Blue @ 1.3% LA (ref B029-4339-0011) Ajax Απολυμαντικό Χωρίς Χλώριο Ocean Fresh Ajax Απολυμαντικό Ocean Fresh Ajax Maison Pure Ajax Απολυμαντικό Ocean Fresh Ajax Disinfettante Ocean Fresh Ajax Antibacteriano Frescura do Oceano Ajax Antibacteriano Frescura del Océano Ajax Antibacterial Pure Home				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic	Pure active substance	79-33-4	201-196-2	1.5

	acid	Technical active substance			1.57
Content in the BP of the mixture including the pure AS					1.875
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

Trade name(s)	B029-4339-0010 Ajax APC Liquid Blue @ 2.6% LA (B029-4339-0010) Ajax Απολυμαντικό Χωρίς Χλώριο Ocean Fresh + (Plus) Ajax Απολυμαντικό Ocean Fresh + (Plus) Ajax Blu Ajax Disinfettante Ocean Fresh + (Plus) Ajax Pure Home Ajax Antibacteriano Ajax Antibacteriano Frescura do Oceano + (Plus) Ajax Antibacteriano Frescura del Océano + (Plus) Ajax Antibacterial Pure Home Plus				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.8
		Technical active substance			2.93
Content in the BP of the mixture including the pure AS					3.5
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

Trade name(s)	B029-7583-0003 Ajax Healthy Home & Happy Blossom @ 1.3% LA (B029-7583-0003)

	Ajax Reines Zuhause Salbei & Apfelblüten Ajax Maison Pure Salbei & Apfelblüten Ajax Pure Home Salbei & Apfelblüten Ajax Essential Purity Salbei & Apfelblüten Ajax Pureté Essentielle Salbei & Apfelblüten Ajax Pure Home Sage & Apple Blossom Ajax Maison Pure Sage & Apple Blossom Ajax Essential Purity Sage & Apple Blossom Ajax Pureté Essentielle Sage & Apple Blossom Ajax Healthy Home Sage & Apple Blossom Ajax Απολυμαντικό Pure Home Sage & Apple Blossom Ajax Pure Home Μήλο & Φασκόμηλο Ajax Pure Home Άνθη Μηλιάς & Φασκόμηλο Ajax Pure Home Φασκόμηλο & Μήλο Ajax Maison Pure Sauge et notes de Fleurs de Pommier Ajax Pure Home Sauge & notes de Fleur de Pommier Ajax Essential Purity Sauge & notes de Fleur de Pommier Ajax Pureté Essentielle Sauge & notes de Fleur de Pommier Ajax Maison Pure Sauge & Fraîcheur Fleurs de Pommier Ajax Pure Home Salvia e Mela Fiorita Ajax Purezza di Casa Salvia e Mela Fiorita Ajax Purezza di Casa Salvia e Fior di Mela Ajax Pure Home Salvia e Fior di Mela Ajax Casa Sana Salvia e Mela Fiorita Ajax Healthy Home Salvia e Mela Fiorita Ajax Healthy Home Salvia e Fior di Mela Ajax Casa Sana Salvia e Fior di Mela Ajax Pure Home Szałwia i Kwiat Jabłoni Ajax Maison Pure Szałwia i Kwiat Jabłoni Ajax Essential Purity Szałwia i Kwiat Jabłoni Ajax Pureté Essentielle Szałwia i Kwiat Jabłoni Ajax Pure Home Salva & Flor de Macieira Ajax Hogar Limpio y Saludable con Flor de Manzana Ajax Maison Pure Sauge & Fleur de Pommier / Ajax Reines Zuhause Salbei & Apfelblüten Ajax Maison Pure Sauge & Fleur de Pommier / Ajax Pure Home Salbei & Apfelblüten Ajax Essential Purity Sauge & Fleur de Pommier / Ajax Essential Purity Salbei & Apfelblüten Ajax Pureté Essentielle Sauge & Fleur de Pommier / Ajax Pureté Essentielle Salbei & Apfelblüten Ajax Pure Home Sauge & Fleurs de Pommier / Ajax Pure Home Salie & Appelbloesem Ajax Pure Home Fleurs de Pommier / Ajax Pure Home Appelbloesem Ajax Pure Home Fraîcheur Fleurs de Pommier / Ajax Pure Home Appelbloesem Frisheid Ajax Pure Home Fraîcheur Fleurs de Pommier Antibactérien /

	Ajax Pure Home Appelbloesem Frisheid Ajax Pure Home Fraîcheur Fleurs de Pommier / Ajax Pure Home Appelbloesem Frisheid Antibacterieel Ajax Pure Home Salie & Appelbloesem Ajax Pure Home Appelbloesem Ajax Pure Home Appelbloesem Frisheid Ajax Pure Home Appelbloesem Frisheid Antibacterieel				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.5
		Technical active substance			1.57
Content in the BP of the mixture including the pure AS					1.875
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

Trade name(s)	B029-7583-0002 Ajax Healthy Home & Happy Blossom @ 2.6% LA (B029-7583-0002) Ajax Healthy Home Sage & Apple Blossom + (Plus) Ajax Απολυμαντικό Pure Home Sage & Apple Blossom + (Plus) Ajax Pure Home Μήλο & Φασκόμηλο + (Plus) Ajax Pure Home Άνθη Μηλιάς & Φασκόμηλο + (Plus) Ajax Pure Home Φασκόμηλο & Μήλο + (Plus) Ajax Healthy Home Sage & Apple Blossom + (Plus) Ajax Απολυμαντικό Pure Home Sage & Apple Blossom + (Plus) Ajax Healthy Home Allegria Floreale Ajax Healthy Home Fioritura Allegra Ajax Casa Sana Fioritura Allegra Ajax Casa Sana Fiore Allegro Ajax Casa Sana Allegria Floreale Ajax Healthy Home Fiore Allegro. Ajax Pure Home Salva & Flor de Macieira + (Plus) Ajax Hogar Limpio y Saludable con Flor de Manzana + (Plus) Ajax Pure Home Sage & Apple Blossom Plus
Authorisation number	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.8
		Technical active substance			2.93
Content in the BP of the mixture including the pure AS					3.5
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

Trade name(s)	B029-7582-0000 Ajax Healthy Home Sage & Elder Flower @ 1.3% LA (B029-7583-0000) Ajax Reines Zuhause Salbei & Holunderblüten Ajax Maison Pure Salbei & Holunderblüten Ajax Pure Home Salbei & Holunderblüten Ajax Essential Purity Salbei & Holunderblüten Ajax Pureté Essentielle Salbei & Holunderblüten Ajax Pure Home Sage & Elderflower Ajax Maison Pure Sage & Elderflower Ajax Essential Purity Sage & Elderflower Ajax Pureté Essentielle Sage & Elderflower Ajax Healthy Home Sage & Elderflower Ajax Απολυμαντικό Pure Home Sage & Elderflower Ajax Pure Home Φασκόμηλο & Κουφοξυλιά Ajax Pure Home Κουφοξυλιά & Φασκόμηλο; Ajax Maison Pure Sauge et Fleur de Sureau Ajax Pure Home Sauge & Fleur de Sureau Ajax Essential Purity Sauge & Fleur de Sureau Ajax Pureté Essentielle Sauge & Fleur de Sureau Ajax Maison Pure Sauge & Fraîcheur Fleurs de Sureau Ajax Pure Home Άνθη Ακτέας & Φασκόμηλο Ajax Healthy Home Salvia e Fiore di Sambuco Ajax Casa Sana Salvia e Fiore di Sambuco Ajax Pure Home Salvia e Fiore di Sambuco Ajax Purezza di Casa Salvia e Fiore di Sambuco Ajax Pure Home Szałwia i Kwiat Czarnego Bzu Ajax Maison Pure Szałwia i Kwiat Czarnego Bzu Ajax Essential Purity Szałwia i Kwiat Czarnego Bzu Ajax Pureté Essentielle Szałwia i Kwiat Czarnego Bzu Ajax Pure Home Sage & ElderflowerAjax Pure Home Sage & Elderflower

	Ajax Pure Home Salva & Flor de Sabugueiro Ajax Hogar Limpio y Saludable con Flor de Saúco Ajax Maison Pure Sauge & Fleur de Sureau / Ajax Reines Zuhause Salbei & Holunderblüten Ajax Pure Home Sauge & Fleur de Sureau / Ajax Pure Home Salbei & Holunderblüten Ajax Essential Purity Sauge & Fleur de Sureau / Ajax Essential Purity Salbei & Holunderblüten Ajax Pureté Essentielle Sauge & Fleur de Sureau / Ajax Pureté Essentielle Salbei & Holunderblüten Ajax Pure Home Sage & Elder Flower Ajax Pure Home Sauge & Fleur de Sureau / Ajax Pure Home Salie & Vlierbloesem Ajax Pure Home Fleur de Sureau / Ajax Pure Home Vlierbloesem Ajax Pure Home Fraîcheur Fleur de Sureau / Ajax Pure Home Vlierbloesem Frisheid Ajax Pure Home Fraîcheur Fleur de Sureau Antibactérien / Ajax Pure Home Vlierbloesem Frisheid Antibacterieel Ajax Pure Home Salie & Vlierbloesem Ajax Pure Home Vlierbloesem Ajax Pure Home Vlierbloesem Frisheid Ajax Pure Home Vlierbloesem Frisheid Antibacterieel				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	1.5
		Technical active substance			1.57
Content in the BP of the mixture including the pure AS					1.875
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

Trade name(s)	B029-7582-0001 Ajax Healthy Home Sage & Elder Flower @ 2.6% LA (B029-7582-0001) Ajax Pure Home Sage & Elderflower + (Plus) Ajax Healthy Home Sage & Elderflower + (Plus) Ajax Απολυμαντικό Pure Home Sage & Elderflower + (Plus) Ajax Pure Home Φασκόμηλο & Κουφοξυλιά + (Plus)

	Ajax Pure Home Κουφοξυλιά & Φασκόμηλο+ (Plus) Ajax Pure Home Sage & Elderflower + (Plus) Ajax Healthy Home Sage & Elderflower + (Plus) Ajax Απολυμαντικό Pure Home Sage & Elderflower + (Plus) Ajax Healthy Home Salvia e Fiore di Sambuco + (Plus) Ajax Casa Sana Salvia e fiore di Sambuco + (Plus) Ajax Pure Home Salva & Flor de Sabugueiro + (Plus) Ajax Hogar Limpio y Saludable con Flor de Saúco + (Plus) Ajax Pure Home Sage & Elder Flower Plus				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	2.8
		Technical active substance			2.93
Content in the BP of the mixture including the pure AS					3.5
Decan-1-ol, ethoxylated (>2.5 moles EO)		Emulsifier	26183-52-8	500-046-6	3

PART II - SECOND INFORMATION LEVEL - META SPC 5

2.1.10 Meta SPC 5 administrative information

2.1.10.1 Meta SPC identifier

Identification	meta SPC5 PT2 WIPES

2.1.10.2 Suffix to the authorisation number

2.1.10.3 Product type(s)

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2.1.11 Meta SPC 5 composition

2.1.11.1 Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	3.504	4
		Technical active substance			3.67	4.19
Content in the BP of the mixture including the pure AS					4.38	5
Propan-2-ol		Solvent	67-63-0	200-661-7	0.1	0.1

2.1.11.2 Type(s) of formulation of the meta SPC 5

AL - Any other liquid

2.1.12 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Skin Irrit. 2 Eye Dam. 1 Met Corr. 1
Hazard statement	H315: Causes skin irritation H318: Causes serious eye damage H290: May be corrosive to metals
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H318: Causes serious eye damage H290: May be corrosive to metals

Classification	
Precautionary statements	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P264 Wash … thoroughly after handling. ~~P280: Wear protective gloves/ protective clothing/eye protection/face protection/ hearing protection/…~~P302 + P352 IF ON SKIN: Wash with plenty of water/… P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/… P321 Specific treatment (see … on this label). P332 + P313 If skin irritation occurs: Get medical advice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse. P234: Keep only in original container. P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/… container with a resistant inner liner.
Note	P280: Not required for non-professionals

2.1.13 Authorised use(s) of the META SPC 5

2.1.13.1 Use description

Table 3. Use # 1 – Hard surface disinfection – domestic surfaces other than kitchen

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria
Field of use	Indoor Household – Bathroom and non-porous hard surfaces other than kitchen.
Application method(s)	Wiping Without pre-cleaning Rinsing required
Application rate(s) and frequency	Ready to use Contact time: 5 minutes Room temperature Frequency: daily

Category(ies) of users	Non professionals
Pack sizes and packaging material	laminated PE/PET resealable flow-pack with pre-cut on opening coupled with a plastic closure with 25, 35, 40, 50, 60 wipes

2.1.13.1.1 Use-specific instructions for use

- For multipack wipes, close the package after opening

2.1.13.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.13.2 Use description

Table 4. Use # 2 – Toilet bowl surfaces disinfection

Product Type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria
Field of use	Indoor Household toilets - Disinfection for Toilets bowls surfaces – Non porous hard surfaces
Application method(s)	Wiping Without pre-cleaning Rinsing required
Application rate(s) and frequency	Ready to use Contact time: 5 minutes Frequency: daily
Category(ies) of users	Non professionals

Pack sizes and packaging material	laminated PE/PET resealable flow-pack with pre-cut on opening coupled with a plastic closure 25, 35, 40, 50, 60 wipes

2.1.13.2.1 Use-specific instructions for use

-

2.1.13.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.14 General directions for use of the meta SPC 5

2.1.14.1 Instructions for use

- Comply with the instructions for use.
- Inform the registration holder if the treatment is ineffective.
- Apply on non porous surfaces
- Ensure complete wetting on the surfaces, leave for appropriate contact time
- For multipack wipes, close the package after opening.
- Let the surface dry after rinsing.

2.1.14.2 Risk mitigation measures

- Wash hands after use.
- Avoid contact with eyes.
- Do not touch the surface until the surface is rinsed and dry.
- Children and pets should not be present during disinfection and until the surface is rinsed and dry.

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

- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

- IF IN EYES: Immediately rinse with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing for at least 15 minutes.
Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

- Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.

If medical advice is needed, have product container or label at hand

2.1.14.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations

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

- Shelf life: 1 year
- Do not store above 30°C
- Keep out of reach of children and non-target animals/pets

2.1.15 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

2.1.16 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	B023-1874-0010 Ajax Optimal 7 Wipes Bathroom and Toilet @ 3.5% (ref B023-1874-0010) Ajax Power Bathroom Ajax Power Antilimescale

	Ajax Bathroom & WC Ajax Expert Μπάνιο & Λεκάνη Πανάκια Ajax Μπάνιο & Λεκάνη Ajax Plant Based Μπάνιο & WC Απολυμαντικό Ajax Optimal 7 Salle de bain & WC Antibactérien Ajax Salle de bain & WC Antibactérien Ajax Power Anti-calcaire Ajax Lingettes Antibactériennes Salle de Bain & WC Ajax Lingettes Désinfectantes Salle de Bain & WC Ajax Ultra 7 Antibakterielle Reinigungstücher Bad & WC Ajax Antibakterielle Reinigungstücher Bad & WC Ajax Power Antibakterielle Reinigungstücher Bad & WC Ajax Μπάνιο & Λεκάνη Ajax Πανάκια Μπάνιο & Λεκάνη Ajax Salviettine Bagno e WC Salviette Ajax Plant Based Bagno Ajax Łazienka i WC Toalhitas Ajax Casa de Banho Frescura Pura Ajax Plant Based Casa de Banho & Ação Antibacteriana Ajax Baños Ajax antibakterielle Reinigungstücher Bad & WC / Ajax lingettes nettoyantes antibactériennes Bain & WC Ajax Antibacterial Wipes Pure Freshness Ajax Antibacterial Wipes Bathroom Ajax Antibacterial Wipes Bathroom & WC Ajax Lingettes Antibactériennes Salle de Bain / Ajax Antibacteriële Doekjes Badkamer Ajax Lingettes Antibactériennes Salle de Bain & WC / Ajax Antibacteriële Doekjes Badkamer & WC Ajax Lingettes Désinfectantes Salle de Bain / Ajax Desinfecterende Doekjes Badkamer Ajax Lingettes Désinfectantes Salle de Bain & WC/ Ajax Desinfecterende Doekjes Badkamer & WC Ajax Antibacterial Wipes Bathroom Ajax Antibacterial Wipes Bathroom & WC Ajax Antibacteriële Doekjes Badkamer Ajax Antibacteriële Doekjes Badkamer & WC Ajax Desinfecterende Doekjes Badkamer Ajax Desinfecterende Doekjes Badkamer & WC				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	3.50
		Technical active substance			3.67

Content in the BP of the mixture including the pure AS					4.38
Propan-2-ol		Solvent	67-63-0	200-661-7	0.1

Trade name(s)	B023-1874-0011 Ajax Optimal 7 Wipes Bathroom and Toilet @ 4% (ref B023-1874-0011) Ajax Expert Μπάνιο & Λεκάνη + (Plus) Ajax Μπάνιο & Λεκάνη + (Plus) Πανάκια Ajax Μπάνιο & Λεκάνη + (Plus) Ajax Πανάκια Μπάνιο & Λεκάνη + (Plus) Ajax Plant Based Μπάνιο & WC Απολυμαντικό Ajax Μπάνιο & Λεκάνη + (Plus) Ajax Expert Μπάνιο & Λεκάνη + (Plus) Ajax Salviettine Bagno e WC + (Plus) Salviette Ajax Plant Base Bagno Toalhitas Ajax Casa de Banho Frescura Pura + (Plus) Ajax Plant Based Casa de Banho & Ação Antibacteriana Ajax Baños + (Plus) Ajax antibakterielle Reinigungstücher Bad & WC / Ajax lingettes nettoyantes antibactériennes Bain & WC Ajax Antibacterial Wipes Pure Freshness Plus

Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	4
		Technical active substance			4.19
Content in the BP of the mixture including the pure AS					5
Propan-2-ol		Solvent	67-63-0	200-661-7	0.1

Trade name(s)	B023-1873-0006 Ajax Optimal 7 Wipes Multisurfaces @ 3.5% (ref B023-1873-0006) Ajax Ultra 7 Antibakterielle Reinigungstücher Ajax Antibakterielle Reinigungstücher Ajax Power Antibakterielle Reinigungstücher Ajax Power Multipurpose Ajax Multipurpose Ajax Multisurface

	Ajax Expert Για Όλες τις Επιφάνειες Ajax Πανάκια Για Όλες τις Επιφάνειες Πανάκια Ajax Για Όλες τις Επιφάνειες Ajax Plant Based για Όλες τις Επιφάνειες & Απολυμαντικό Ajax Optimal 7 Surfaces Grasses Antibactérien Ajax Surfaces Grasses Ajax Power Ajax Multisurfaces Ajax Lingettes Antibactériennes Multi-Surfaces Ajax Lingettes Désinfectantes Multi-Surfaces Ajax Ultra 7 Antibakterielle Reinigungstücher Ajax Antibakterielle Reinigungstücher Ajax Power Antibakterielle Reinigungstücher Ajax Για Όλες τις Επιφάνειες Ajax Salviettine Multiuso Salviette Ajax Plant Based Multiuso Toalhitas Ajax Multiusos Frescura Intensa Ajax Plant Based Multiusos & Ação Antibacteriana Ajax Toallitas Multiusos Ajax antibakterielle Allzweck-Tücher / Ajax lingettes nettoyantes antibactériennes Multi-Usages Ajax Antibacterial Wipes Intense Freshness Ajax Antibacterial Wipes Multisurface Ajax Lingettes Antibactériennes Multi-Surfaces / Ajax Antibacteriële Doekjes Multi-Oppervlakken Ajax Lingettes Désinfectantes Multi-Surfaces / Ajax Desinfecterende Doekjes Multi-Oppervlakken Ajax Antibacteriële Doekjes Multi-Oppervlakken Ajax Desinfecterende Doekjes Multi-Oppervlakken
Authorisation number	

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	3.50
		Technical active substance			3.67
Content in the BP of the mixture including the pure AS					4.38
Propan-2-ol		Solvent	67-63-0	200-661-7	0.1

Trade name(s)	B023-1873-0005 Ajax Optimal 7 Wipes Multisurfaces @ 4% (ref B023-1873-0005)

	Ajax Για Όλες τις Επιφάνειες + (Plus) Ajax Expert Για Όλες τις Επιφάνειες + (Plus) Ajax Πανάκια Για Όλες τις Επιφάνειες + (Plus); Πανάκια Ajax Για Όλες τις Επιφάνειες + (Plus) Ajax Plant Based για Όλες τις Επιφάνειες & Απολυμαντικό Ajax Salviettine Multiuso; Ajax Optimal 7 Salviettine Multiuso+; Ajax Salviettine Multiuso+ Salviette Ajax Plant Base Multisup Toalhitas Ajax Multiusos Frescura Intensa + (Plus) Ajax Plant Based Multiusos & Ação Antibacteriana Ajax Toallitas Multiusos + (Plus) Ajax antibakterielle Allzweck-Tücher / Ajax lingettes nettoyantes antibactériennes Multi-Usages Ajax Antibacterial Wipes Intense Freshness Plus				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
L-(+)-lactic acid	(2S)-2-Hydroxypropanoic acid	Pure active substance	79-33-4	201-196-2	4
		Technical active substance			4.19
Content in the BP of the mixture including the pure AS					5
Propan-2-ol		Solvent	67-63-0	200-661-7	0.1

2.1.38 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottle META SPC 1-2	650, 750, 1000mL	PET bottle + Paper labels and Shrink Sleeve (in plastic) *	Screw Cap / HDPE	General public	yes
Bottle META SPC 1-2	1250, 1300, 1500, 2000 mL	PE bottle with handle +paper labels	Screw cap / PP	General public	yes

SPRAY META SPC 3 , 4	500, 600, 750 and 1000 mL (Bottle filling volumes: 450, 480, 490, 500, 550, 580, 590, 600, 700, 730, 740, 750, 950, 980, 990,1000 mL)	PET or PE bottle + Shrink Sleeve (PET), Paper and Plastic Labels	Spray Trigger about 85% PP or Refill Screw cap 100% PP Type: Standard Foam (Ref number 10187463 / 10199103 / 10198735), or Pre-Compress Upside-down M3B Mesh Foam (Ref number 10180950)	General public	yes
WIPES META SPC 5	25, 35, 40, 50, 60 bamboo or viscose wipes	laminated PE/PET film resealable flow-pack with 25, 35, 40, 50, 60 wipes with pre-cut on opening coupled with a plastic closure 	PP pressure-sensitive label	General public	yes

2.1.39 Documentation

2.1.39.1 Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product family were submitted by the applicant.
Data submitted on the biocidal product family are listed in the Annex 3.1.
See the list of studies for the biocidal product in the confidential annex (section 8)

2.1.39.2 Access to documentation

A letter of access to the data of the CAR of L(+)Lactic Acid (PT2 and PT4) has been submitted by Purac Biochem (owners of studies on L(+)Lactic Acid) and allows Colgate-Palmolive Sp. Z.o.o.) to refer to active substance data.

2.1.39.3 Similar conditions of use

[Please indicate here the outcome of the consultation during the pre-submission phase.]

2.2 Assessment of the biocidal product (family)

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

Table 4. Use #1 - Disinfectant for domestic hard surfaces excluding kitchen surfaces

Product Type	**PT2**
Where relevant, an exact description of the authorised use	**Porous and non-porous Hard surface disinfection – Bathroom and other surfaces out of kitchen**
Target organism (including development stage)	BDC(bottle) and SPRAY: Bacteria and bacterial spores WIPES: Bacteria and bacterial spores
Field of use	BDC(bottle) and SPRAY: Household – Bathroom and hard surfaces other than kitchen
Application method(s)	**BDC (Bucket Dilutable Cleaner)**: Ready to use. Pour the neat product on sponge, spread on the surface to disinfect. Without pre-cleaning Rinsing required **SPRAY** - Ready to use Without pre-cleaning Rinsing required **WIPES** - Ready to use Without pre-cleaning Rinsing required

Application rate(s) and frequency	Application dose: **BDC (bottle):** 1/2 cap of product on a sponge corresponding to 18 g of product per m² ➢ for the product at 1.3% lactic acid leading to a dose of 0.23 g/m² of lactic acid. ➢ For the product at 2.6% lactic acid leading to a dose of 0.468 g/m² of lactic acid **SPRAY**: 5 pressures of spray product to cover 1m² and it corresponds to 5.5 g of product corresponding to: ➢ 0.13 g/m² of lactic acid (product a.s. concentration of 2.4%) and ➢ 0.18 g/m² of lactic acid. (product a.s. concentration of 3.2%) **WIPES**: wipes/m² 0.086-0.098 g of lactic acid/m² (1 wipe to be used to disinfect 1m²) Contact time: **BDC (bottle):** For formulations at 2.6% of Lactic Acid: 5 minutes For formulations at 1.3% of Lactic Acid: 15 minutes **SPRAY**: 5 minutes **WIPES:** 5 minutes Frequency: General public maximum frequency of use: Daily
Category(ies) of users	General public
Pack sizes and packaging material	**BDC (bottle)**: PET bottle 650, 750, 1000, 1250, 1300, 1500 and PE bottle 2000 mL **SPRAY**: PET or PE bottle 500, 600, 750 and 1000 mL **WIPES**: laminated PE/PET film with 25, 35, 40, 50, 60 wipes

Table 5. Use #2 - Disinfectant for domestic toilet bowl surfaces

Product Type	**PT2**
Where relevant, an exact description of the authorised use	**Hard surface disinfection – Disinfection for Toilets bowls surfaces**
Target organism (including development stage)	BDC (bottle) and SPRAY: Bacteria and bacterial spores WIPES: Bacteria and bacterial spores
Field of use	Household toilets

Application method(s)	**BDC (Bucket Dilutable Cleaner)**: Ready to use. Pour the neat product on sponge, spread on the surface to disinfect. Without pre-cleaning Rinsing required **SPRAY** - Ready to use Without pre-cleaning Rinsing required **WIPES** - Ready to use Without pre-cleaning Rinsing required
Application rate(s) and frequency	Application dose: **BDC (bottle):** 1/2 cap of product on a sponge corresponding to 18 g of product per m² ➢ for the product at 1.3% lactic acid leading to a dose of 0.23 g/m² of lactic acid. ➢ For the product at 2.6% lactic acid leading to a dose of 0.468 g/m² of lactic acid **SPRAY**: 5 pressures of spray product to cover 1m² and it corresponds to 5.5 g of product corresponding to: ➢ 0.13 g/m² of lactic acid (product a.s. concentration of 2.4%) and ➢ 0.18 g/m² of lactic acid. (product a.s. concentration of 3.2%) **WIPES**: wipes/m² 0.086-0.098 g of lactic acid/m² (1 wipe to be used to disinfect 1m²) Contact time: **BDC (bottle):** For formulations at 2.6% of Lactic Acid: 5 minutes For formulations at 1.3% of Lactic Acid: 15 minutes **SPRAY**: 5 minutes **WIPES:** 5 minutes Frequency: General public maximum frequency of use: Daily
Category(ies) of users	General public
Pack sizes and packaging material	**BDC (bottle)**: PET bottle 650, 750, 1000, 1250, 1300, 1500 and PE bottle 2000 mL **SPRAY**: PET or PE bottle 500, 600, 750 and 1000 mL **WIPES**: laminated PE/PET film with 25, 35, 40, 50, 60 wipes

2.2.2 Physical, chemical and technical properties

The tests have been performed in order to cover all the products of the family.

- Meta-SPC 1-2: the eight products of the meta SPC1-2 have a very similar pattern of composition. The representative product for this meta SPC is product BP3a; the product has a minimum content in active substance and this product has a more complex matrix with an UV absorber. This covers the 3 other products of the meta SPC with the same content of AS. The 4 products of the meta SPC with a higher content in active substance are covered by the test performed with the product BP7 of Meta SPC 3 (product having an active substance content close to the 4 remaining products of the meta SPC).
- Meta SPC3: the five products of this meta SPC have the same active substance content. The product BP7 differs for a more complex matrix with solvent. This product is the representative product for meta SPC3 and covers other products of the Meta SPC.
- Meta SPC4: BP5 is the single product of meta SPC4 and has been tested.
- Meta SPC5: among the 4 products, the product with the maximum active substance content over the meta SPC (BP11e) and over the BPF has been selected for testing. This covers other products of the meta SPC. Moreover the product BP11e is the product of the BPF with the maximum level of organic solvent, therefore it has been selected for the flash point test.

Properties for all Meta SPC have been listed in a single table.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
Physical state and colour and odourat 20 °C and 101.3 kPa	GIFAP monography N°17, 2nd Edition OPPTS 830.6304. Odour GIFAP	Meta SPC 1-2 Product BP3A - B02975830000 1.3% w/w lactic acid Batch: AF-00100-004	Transparent, light green liquid with a characteristic odour	Acceptable for product BP3A. This does not cover other products of the meta SPC as the meta SPC includes different fragrances or colorants.	[redacted] Certificate of analysis Solution of BP3A - B02975830000
		BP2b - B02943390008	Blue liquid	Appearance and colour of products provided in	Product MSDS
		BP3b - B02975830001	Green liquid		Product MSDS

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
		BP4b - B02975820001	Light blue liquid	MSDS have also been reported as additional information. Therefore, no more data are required for this property.	Product MSDS
		BP1b - B02913420012	Blue liquid		Product MSDS
		BP2a - B02943390004	Blue liquid		Product MSDS
		BP4a - B02975820000	Light blue liquid		Product MSDS
		BP1a - B02913420010	Blue liquid		Product MSDS
		Meta SPC3 Product BP7 – B02959350004 3.2% w/w lactic acid Batch: AF-00100-007	Homogeneous, transparent, colourless liquid with an odour similar to apple	Acceptable for product BP7. This does not cover other products of the meta SPC as the meta SPC includes different fragrances or colorants. Appearance and colour of products provided in MSDS have also been reported as additional information. Therefore, no more data are required for this property.	[redacted] Certificate of analysis Solution of BP7 – B02959350004
		BP6 - B029-5926-0004	Colourless liquid		Product MSDS
		BP8 - B029-7401-0001	Green liquid		Product MSDS
		BP9 - B029-7506-0000	Light yellow liquid		Product MSDS
		BP10 - B029-7503-0001	Light yellow liquid		Product MSDS
		Meta SPC4 Product BP5 – B02940950007 2.4% w/w lactic acid Batch : AF-00100-006	Homogeneous, transparent, blue liquid with an odour similar to aromatic citrus	Acceptable	[redacted] Certificate of analysis Solution of BP5 – B02940950007

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
		Meta SPC5 Product BP11E – B02318740005 4% w/w lactic acid BATCH: AF-00100-005	White wipes soaked with a transparent colourless homogenous liquid similar to floral violet	Acceptable for product BP11E. This does not cover other products of the meta SPC as the meta SPC includes different fragrances. However, no more data are required for this property.	[redacted] Certificate of analysis Solution of BP11E – B02318740005
Acidity / alkalinity	pH: CIPAC MT 75.3 Acidity: CIPAC MT 191 (as % w/w of H2SO4)				
Meta SPC1-2		BP3A - B02975830000 1.3% w/w lactic acid Batch: AF-00100-004	T_0 pH: 3.27 T_0 acidity: 0.67 % w/w	Acceptable for the 4 products of the meta SPC having an active substance content of 1.875%w/w, as the content of neutraliser (caustic soda) is identical within the meta SPC. The 4 remaining products could be covered with product BP7 of meta SPC 3 considering the active	[redacted]. Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP3A - B02975830000". Eurofins. Study N° 2019/6 AM
		BP2b - B02943390008	pH=3.1		Product MSDS
		BP3b - B02975830001	pH= 2.2-2.6		Product MSDS
		BP4b - B02975820001	pH= 2.2-2.6		Product MSDS

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
		BP1b - B02913420012	pH= 2.8-3.4	substance content. However, the content of neutraliser or pH adjuster is different. Therefore, pH values provided in MSDS products have also been reported as additional information.	Product MSDS
Meta SPC1-2 Meta SPC3		BP7 – B02959350004 3.2% w/w lactic acid Batch: AF-00100-007	T_0 pH: 2.60 T_0 acidity: 1.73 % w/w	Acceptable for all the products of the meta SPC as they have the same content of active substance and the same content of neutraliser and pH adjuster.	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP7 - B02959350004". . Eurofins Study N° 2019/8 AM
Meta SPC4		BP5 – B02940950007 2.4% w/w lactic acid Batch : AF-00100-006	T_0 pH: 2.46 T_0 acidity: 1.22 % w/w	Acceptable	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP5 - B02940950007". Eurofins

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
					Study N° 2019/7 AM
Meta SPC5		BP11E – B02318740005 4% w/w lactic acid BATCH: AF-00100-005	T_0 pH: 2.28 T_0 acidity: 2.16 % w/w	Acceptable for all products of the meta SPC as the tested product is the one with the maximum active substance content over the meta SPC. Moreover, all the products have the same content of neutraliser (caustic soda).	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP11E - B02318740005". Eurofins Study N° 2019/9 AM
Relative density / bulk density					
Meta SPC1-2	EC 440/2008 - A.3 Capillary stoppered pycnometer	"BP3A - B02975830000"	D^{20}_4 = 1.0078 at 20°C	Acceptable	[redacted] CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP3A - B02975830000"
Meta SPC1-2 Meta SPC3	EC 440/2008 - A.3 Capillary stoppered pycnometer	"BP7 – B02959350004"	D^{20}_4 = 1.0070 at 20°C	Acceptable	[redacted]. CHEMICAL/PHYSICAL ANALYSIS

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
					ON THE TEST ITEM "BP7 – B02959350004"
Meta SPC4	EC 440/2008 - A.3 Capillary stoppered pycnometer	"BP5 - B02940950007"	D^{20}_4 = 1.0036 at 20°C	Acceptable	[redacted] CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP5 - B02940950007"
Meta SPC5 (wipes impregnation liquid)	EC 440/2008 - A.3 Capillary stoppered pycnometer	"BP11E – SOLUTION OF B02318740005"	D^{20}_4 = 1.0047 at 20°C	Acceptable	[redacted] CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP11E – SOLUTION OF B02318740005"
Storage stability test – **accelerated storage**	CIPAC MT 46 Stability 40°C during 8 weeks	Some studies have been performed at 40°C due to the heat sensitivity of lactic acid (The applicant explained that they observed in the past inhibition of oligomers formation at higher temperatures which do not show the real situation of the product.)			
Meta SPC1-2	Appearance of the product: visual	BP3A - B02975830000 1.3% w/w lactic acid Batch: AF-00100-004	Appearance of the product: **T_0**: Transparent, light green, homogenous liquid **T_{8weeks}**:no variation from initial Appearance of packaging:	Acceptable for the 4 products of the meta SPC having an active substance content of 1.875%w/w.	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
	Appearance of the product: visual Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191		**T_0**: The packaging consist of a 1L transparent plastic (PET) bottle closed by a plastic screw cap. $T_{8\ weeks}$ = Weight loss: 0.66%, no variation in the appearance of the packaging <u>Active substance content</u>: T_0= 1.585 % w/w $T_{8\ weeks}$ = 1.575% w/w (99.4% of T0) <u>pH:</u> T_0=3.27 $T_{8\ weeks}$ =3.30 <u>Acidity:</u> T_0=0.67% w/w H_2SO_4 $T_{8\ weeks}$ =0.69% w/w H_2SO_4	The 4 remaining products are covered with stability data of product BP7 (meta SPC 3). The tested product is stable after 8 weeks at 40°C. Therefore, a shelf life of 2 years can be granted based on these results. The products of the meta SPC should not be stored above 40°C.	"BP3A - B02975830000". Eurofins Study N° 2019/6 AM
Meta SPC1-2 Meta SPC3 (spray)	Appearance of the product: visual Appearance of the product: visual Active substance analysis:	BP7 – B02959350004 3.2% w/w lactic acid Batch: AF-00100-007	<u>Appearance of the product</u>: **T_0**: Homogeneous, transparent, colourless liquid **T_{8weeks}**:no variation from initial <u>Appearance of packaging</u>: **T_0**: Transparent plastic (PET) 500ml bottle closed by plastic screw cap and a plastic trigger device apart from the sample main packaging.	The product is stable after 8 weeks at 40°C. However, the spray characteristics (spray pattern, discharge rate, clogging, particle size distribution) are missing and have been assessed in another study (storage at 54°C	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP7 - B02959350004". Eurofins Study N° 2019/8 AM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
	STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191		$T_{8\ weeks}$ = Weight loss: 0.99%, no variation in the appearance of the packaging <u>Active substance content</u>: T_0= 3.334 % w/w $T_{8\ weeks}$ = 3.221 % w/w (96.6% of T_0) <u>pH:</u> T_0=2.60 $T_{8\ weeks}$ =2.54 <u>Acidity:</u> T_0=1.73% w/w H_2SO_4 $T_{8\ weeks}$ =1.88% w/w H_2SO_4	for 2 weeks, see below).	
	54°C for 2 weeks Active substance analytical method: STULV19AA0142 -1- MdP_Rev.1	Spray BP8 B02974010001 3.2% w/w lactic acid Batch N° 15/04/22FR131J	<u>Appearance of the product</u>: **T_0**: Green transparent homogeneous liquid **$T2_{weeks}$**:no variation from initial <u>Appearance of packaging</u>: **T_0**: PET plastic bottle closed by a trigger dispenser $T_{2\ weeks}$: no variation from initial Weight loss: 0.51% <u>Active substance content</u>: T_0= 3.18 % w/w $T2_{\ weeks}$ = 3.19 % w/w (100.3% of T_0)	Acceptable The product is stable after 2 weeks at 54°C. Therefore, a shelf life of 2 years can be granted for products of meta SPC 3 based on these results.	[redacted] Control of critical parameters under stability conditions Eurofins Report STULV20AA4151 -1GLP Spray characteristics:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			pH: T_0=2.56 T2 $_{weeks}$ =2.56 Acidity: T_0=1.73% w/w H_2SO_4 T2 $_{weeks}$ =1.74% w/w H_2SO_4 Spray (Mesh Foam - Ref number 10180950): The percentage of particles < 50µm is T0: 0.83% with SD 0.81 T_{2weeks}: 2.1% with SD 0.65 The distribution median diameter (Dv50) is T0:241.2µm T_{2weeks}:229.4µm The mean diameter in volume is: T0: 311.3 µm T_{2weeks}: 292.7 µm T0: The spray pattern imprinted at 20cm distance described an elongated circle with a mean diameter of 11cm The average spray pattern angle is 31.9°		[redacted] LEREM Test report N° 9-525-3/20 [redacted]. LEREM Test report N° 9-525-2/20 included in EUROFINS Report N° 1170864A01 v2

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			T_{2weeks}: The spray pattern imprinted at 20cm distance described a flattened circle with a mean diameter of 10.7cm The average spray pattern angle is 30° Discharge rate: T0: 1.20 g/pump stroke T_{2weeks}:1.10 g/pump stroke T0 and T_{2weeks}: no clogging observed during the whole emptying of the samples		
Meta SPC4 (spray)	Appearance of the product: visual Appearance of the product: visual Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3	BP5 – B02940950007 2.4% w/w lactic acid Batch : AF-00100-006	<u>Appearance of the product</u>: **T_0**: Homogeneous, transparent, blue liquid **T_{8weeks}**:no variation from initial <u>Appearance of packaging</u>: **T_0**: Transparent plastic (PET) 500ml bottle closed by plastic screw cap and a plastic trigger device apart from the sample main packaging. $T_{8\ weeks}$ = Weight loss: 0.75%, no variation in the appearance of the packaging <u>Active substance content</u>: **T_0**= 2.489 % w/w	The product is stable after 8 weeks at 40°C. However, the spray characteristics (spray pattern, discharge rate, clogging, particle size distribution) are missing and have been assessed in another study (storage at 54°C for 2 weeks, see below).	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP5 - B02940950007". Eurofins Study N° 2019/7 AM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
	Acidity: CIPAC MT 191		**$T_{8\ weeks}$ =** 2.428 % w/w (97.6% of T_0) pH: T_0=2.46 $T_{8\ weeks}$ =2.41 Acidity: T_0=1.22% w/w H_2SO_4 $T_{8\ weeks}$ =1.31% w/w H_2SO_4		
	54°C for 2 weeks Active substance analytical method: STULV19AA0142-1-MdP_Rev.1	Spray BP5 – B02940950007 2.4% w/w lactic acid Batch: 0114GR10111-10:31	Appearance of the product: **T_0**: Light blue transparent homogeneous liquid **$T2_{weeks}$**: no variation from initial Appearance of packaging: **T_0**: PET plastic bottle closed by a trigger dispenser. $T2_{weeks}$: no variation of initial Weight loss: 0.66% Active substance content: **T_0**= 2.35 % w/w **$T_{2\ weeks}$ =** 2.37 % w/w (100.9% of T_0) pH: T_0=2.47 $T_{2\ weeks}$ =2.58 Acidity: T_0=1.29% w/w H_2SO_4	Acceptable The product is stable after 2 weeks at 54°C. Therefore, a shelf life of 2 years can be granted based on these results.	[redacted] Control of critical parameters under stability conditions Eurofins Report STULV20AA4152-1GLP Spray characteristics: [redacted]. LEREM Test report N° 9-525-3/20 [redacted]. LEREM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			$T_{2\ weeks}$ =1.28% w/w H_2SO_4 Spray (Standard Foam - Ref number 10187463): The percentage of particles < 50µm is T0: 0.97% with SD 0.79 T_{2weeks}: 0.97% with SD 0.53 The distribution median diameter (Dv50) is T0: 380.0 µm T_{2weeks}:403.0 µm The mean diameter in volume is: T0: 399.6 µm T_{2weeks}: 415.5 µm T0: The spray pattern imprinted at 20cm distance described an elongated circle with a mean diameter of 11cm The average spray pattern angle is 29.6° T_{2weeks}: The spray pattern imprinted at 20cm distance described an elongated circle with a mean diameter of 8.9cm The average spray pattern angle is 25.0° Discharge rate: T0: 1.11 g/pump stroke T_{2weeks}: 0.95 g/pump stroke		Test report N° 9-525-2/20 included in EUROFINS Report N° 1170864A01 v2

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			T0 and T_{2weeks}: no clogging observed during the whole emptying of the samples		
Meta SPC5 (wipes)	Appearance of the product: visual Appearance of the product: visual Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191	BP11E – B02318740005 4% w/w acid lactic BATCH: AF-00100-005	Appearance of the product: T_0: White wipes soaked with a transparent colourless homogenous liquid **T**$_{8weeks}$:no variation from initial Appearance of packaging: The packaging consist of a plastic (laminated PE/PET film) bag $T_{8\ weeks}$ = Weight loss: 10.31%, no variation in the appearance of the packaging Active substance content: T_0= 4.117 % w/w $T_{8\ weeks}$ = 5.311 % w/w (129% of T_0) pH: T_0=2.28 $T_{8\ weeks}$ =2.29 Acidity: T_0=2.16% w/w H_2SO_4 $T_{8\ weeks}$ =2.63% w/w H_2SO_4	Not acceptable An increase of the AS content is observed during the storage due to some evaporation of solvents resulting from a poor sealing of the packaging. It should be noted that for products of meta SPC5 the label indicates that "the products must not be stored at temperature above 30°C."	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP11E - B02318740005". Eurofins Study N° 2019/9 AM Technical Support: Wipes weight loss, increase in lactic acid, Mar, 2020

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			Explanation of the applicant on the increase of the active substance content: *Samples of wipes BP11E were manufactured in house to be sent to the stability on Eurofins lab, since there is no industrial equipment in the lab, the sealing has been done manually. Sealing of the laboratory samples might have affected the quantity of weight lost during the testing at external laboratory on 40°C condition and by consequence increase of Lactic Acid was higher than expected. Wipes products normally has certain weight loss, some solvents might have some migration or evaporation, lactic acid is not a volatile ingredient, therefore in less impregnation liquid more concentration of Active Ingredient would be found. Internal storage stabilities on wipes at 40°C during 13 weeks with a normal sealing from production has showed a loss weight of maximum 8% and an increase of lactic acid of maximum 5.71%.* Internal stability data of wipes with a normal sealing from production has been provided. A weight loss of maximum 6% is noted and an increase		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			of lactic acid is observed as well. These data are summarized after the table.		
	Appearance of the product: visual Appearance of the product: visual Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191	BP11D - AB WIPES PURE FRESHNESS 3,5% LACTIC ACID - B02318740004	<u>Storage for 8 weeks at 40°C:</u> <u>Appearance of the product</u>: T_0: White wipes soaked with a Clear whitish homogenous liquid **T**$_{8weeks}$:no variation from initial <u>Appearance of packaging</u>: The packaging consist of a plastic green bag with adhesive opening $T_{8\ weeks}$ = Weight loss: 10.3%, no variation from initial <u>Active substance content</u>: T_0= 3.604 % w/w $T_{8\ weeks}$ = 4.348% w/w (120.6% of T_0) <u>pH:</u> T_0=3.56 $T_{8\ weeks}$ =3.55 <u>Acidity:</u> T_0=1.18% w/w H_2SO_4 $T_{8\ weeks}$ =1.54% w/w H_2SO_4	Stability results of this product (BP11D) are similar to those of product BP11E. An increase of the AS content is observed after 8 weeks at 40°C. Therefore, the product could not be considered stable after 8 weeks at 40°C. Moreover, results on the product BP11D do not cover all the meta SPC range.	ACCELERATED STABILITY STUDY AT 40°C FOR 8 WEEKS ON THE TEST ITEM "BP11DAB WIPES PURE FRESHNESS3,5 % LACTIC ACID - B02318740004" Report: STULV20AA4430 -1 GLP (40°C)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
Storage stability test – **long term storage at ambient temperature**	Stability 20°C during 2 years				
Meta SPC1-2	Appearance of the product: visual Appearance of the product: visual Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191	BP3A - B02975830000 1.3% w/w lactic acid Batch: AF-00100-004	<u>Appearance of the product</u>: **T_0**: Transparent, light green, homogenous liquid T2 : no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial T24: no variation from initial <u>Appearance of packaging</u>: **T_0**: The packaging consists of a 1L transparent plastic (PET) bottle closed by a plastic screw cap. T2: no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial T24: no variation from initial Weight loss: T2 : 0.21% T6 : 0.48% T12 : 0.97% T18 : 1.43% T24 : 1.88%	Results show that the product is stable after 24 months at ambient temperature. A shelf life of 2 years is granted for this meta SPC based on these results.	[redacted]. Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP3A - B02975830000". Eurofins Study N° 2019/6 AM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			Active substance content : T_0= 1.585 % w/w T2 = 1.571 % w/w (99.1% of T0) T6 = 1.606 % w/w (101.3% of T0) T12 = 1.620 % w/w (102.2% of T0) T18 = 1.621% w/w (102.3% of T0) T24 = 1.614% w/w (101.8% of T0) pH T_0= 3.27 T2 = 3.24 T6 = 3.33 T12 = 3.34 T18 = 3.30 T24 = 3.31 Acidity (% w/w of H2SO4): T_0= 0.67 T2 = 0.61 T6 = 0.68 T12 = 0.69 T18 = 0.70 T24 = 0.70		
Meta SPC3 (spray)	Appearance of the product: visual Appearance of the product: visual	BP7 – B02959350004 3.2% w/w lactic acid Batch: AF-00100-007	Appearance of the product: **T_0**: Homogeneous, transparent, colourless liquid T2: no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial	Results show that the product is stable after 24 months at ambient temperature. A shelf life of 2 years is granted for this	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP7 -

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
	Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191 Spray rate: internal method Valve clogging: FAO Spray pattern: FEA 644		T24: no variation from initial <u>Appearance of packaging</u>: **T_0**: Transparent plastic (PET) 500ml bottle closed by plastic screw cap and a PP trigger device apart from the sample main packaging. T2: no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial T24: no variation from initial Weight loss: T2: 0.21% T6: 0.50% T12: 0.95% T18: 1.70% T24: 2.01% <u>Active substance content</u> : T_0= 3.334 % w/w T2: 3.221 % w/w (96.6% of T0) T6: 3.277 % w/w (98.3% of T0) T12: 3.217 % w/w (96.5% of T0) T18: 3.302 % w/w (99.1% of T0) T24: 3.260 % w/w (97.8% of T0) <u>pH</u> T_0= 2.60	meta SPC based these results.	B02959350004". Eurofins Study N° 2019/8 AM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			T2 = 2.48 T6 = 2.58 T12 = 2.66 T18 = 2.61 T24 = 2.52 <u>Acidity (% w/w of H2SO4):</u> T_0= 1.73 T2 = 1.82 T6 = 1.87 T12 = 1.88 T18 = 1.88 T24 = 1.89 Spray (Standard Foam - Ref number 10187463) <u>Spray rate:</u> **T_0**= 1.25 g T2 = 1.21g (RSD : 3.6%) T6 =1.26g (RSD 2.2%) T12 = 1.20g (RSD 3.6%) T18 = 1.24g (RSD 3.5%) T24 = 1.22g (RSD 2.9%) <u>Valve clogging</u> **T_0**= no clogging T2: no clogging T6: no clogging T12: no clogging T18: no clogging T24: no clogging		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			Spray pattern **T_0**= the shape of the spray was circular T24: the shape of the spray was an elongated circle		
Meta SPC4	Appearance of the product: visual Appearance of the product: visual Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191 Spray rate: internal method Valve clogging: FAO	BP5 – B02940950007 2.4% w/w lactic acid Batch : AF-00100-006	<u>Appearance of the product</u>: **T_0**: Homogeneous, transparent, blue liquid T2: no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial T24: no variation from initial <u>Appearance of packaging</u>: **T_0**: Transparent plastic (PET) 500ml bottle closed by plastic screw cap and a PP trigger device apart from the sample main packaging. T2: no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial T24: no variation from initial Weight loss: T2: 0.17% T6 : 0.49% T12 : 0.96% T18 : 1.53% T24 : 1.79%	Results show that the product is stable after 24 months at ambient temperature. A shelf life of 2 years is granted for this meta SPC based on these results.	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP5 - B02940950007". Eurofins Study N° 2019/7 AM For particle size distribution: Report n°1237843A01 v1, March 2021, [redacted] Report from LEREM N° 9-629-2/21, [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
	Spray pattern: FEA 644		Active substance content : **T_0**= 2.489 % w/w T2 = 2.427 % w/w (97.5% of T0) T6 = 2.424 % w/w (97.4% of T0) T12 = 2.445 % w/w (98.2% of T0) T18 = 2.585 % w/w (103.9% of T0) T24 = 2.375 % w/w (95.4% of T0) pH T_0= 2.46 T2 = 2.35 T6 = 2.36 T12 = 2.44 T18 = 2.48 T24 = 2.44 Acidity (% w/w of H2SO4) : T_0= 1.22 T2 = 1.27 T6 = 1.30 T12 = 1.31 T18 = 1.31 T24 = 1.32 Spray (Standard Foam - Ref number 10187463) Spray rate : **T_0**= 1.24 g (RSD = 3.0%) T2 = 1.13g (RSD = 3.5%) T6 =1.21 g (RSD = 2.2%)		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			T12 = 1.21 g (RSD = 2.7%) T18 = 1.23 g (RSD = 5%) T24 = 1.22 g (RSD = 1.4%) Valve clogging **T_0**= no clogging T2: no clogging T6: no clogging T12: no clogging T18: no clogging T24: no clogging Spray pattern **T_0**= the shape of the spray was circular **T**24= the shape of the spray was circular Particle size distribution by laser granulometry Before storage: The distribution median diameter Dv(50) is 380.0 µm. The mean diameter in volume is 399.6 µm (average of 3 measurements). The percentage of particles below 10µm is 0%. After storage: The distribution median diameter Dv(50) is 414.5 µm. The mean diameter in volume is 431.1 µm		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			(average of 3 measurements). The percentage of particles below 10µm is 0.17%.		
Meta SPC5	Appearance of the product: visual Appearance of the product: visual Active substance analysis: STULV19AA0142 - 1 GLP-MdP pH: CIPAC MT 75.3 Acidity: CIPAC MT 191	BP11E – B02318740005 4% w/w acid lactic BATCH: AF-00100-005	<u>Appearance of the product</u>: T0: White wipes soaked with a transparent colourless homogenous liquid T2: no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial T24: no variation from initial <u>Appearance of packaging</u>: The packaging consists of a plastic (laminated PE/PET film) bag T2: no variation from initial T6: no variation from initial T12: no variation from initial T18: no variation from initial T24: no variation from initial <u>Weight loss:</u> T2 = 1.32% T6 = 3.49% T12 = 6.71% T18 = 10.20% T24 = 15.06% <u>Active substance content</u> :	An increase of the AS content is observed during the storage due to some evaporation of solvents resulting from a poor sealing of the packaging. Therefore, a shelf life of 1 year is claimed by the applicant. This is considered acceptable. A shelf life of 12 months is granted for this meta SPC. It should be noted that for products of meta SPC5, the label indicates that "the products must not be stored at temperature above 30°C."	[redacted] Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP11E - B02318740005". Eurofins Study N° 2019/9 AM

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			T_0= 4.117 %w/w T2: 4.368 %w/w (106% of T_0) T6: 4.277 %w/w (103.9% of T_0) T12: 4.545 %w/w (110.4% of T_0) T18: 4.978% w/w (120.9% of T_0) T24: 5.340% w/w (129.7% of T_0) <u>pH</u> T_0= 2.28 T2 = 2.25 T6 = 2.29 T12 = 2.32 T18 = 2.31 T24 = 2.29 <u>Acidity (% w/w of H2SO4):</u> T_0= 2.16 T2 = 2.30 T6 = 2.26 T12 = 2.39 T18 = 2.51 T24 = 2.77		
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 Storage at 0°C for seven days				
Meta SPC1-2		BP3A - B02975830000 Batch: AF-00100-004	After 7 days at 0°C: green transparent homogeneous solution / no separated matter of any nature noticed	Acceptable	[redacted]. Low temperature

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			No variation from initial appearance	The product is stable after 7 days at 0°C.	stability on the test Item BP3A B02975830000. Final Report N°.: STULV19AA0129 -1 GLP
Meta SPC3		BP7 B02959350004. Batch: AF-00100-007	After 7 days at 0°C: colourless transparent homogeneous solution / no separated matter of any nature noticed No variation from initial appearance	Acceptable The product is stable after 7 days at 0°C.	[redacted]. Low temperature stability on the test Item BP7 B02959350004. Final Report N°.: STULV19AA0134 -1 GLP
Meta SPC4		BP5 B02940950007 Batch: AF-00100-006	After 7 days at 0°C: blue transparent homogeneous solution / no separated matter of any nature noticed No variation from initial appearance	Acceptable The product is stable after 7 days at 0°C.	[redacted]. Low temperature stability on the test Item BP5 B02940950007. Final Report N°.: STULV19AA0132 -1 GLP
Meta SPC5		BP11E - SOLUTION OF B02318740005 Batch: AF-00100-005	After 7 days at 0°C: colourless transparent homogeneous solution / no separated matter of any nature noticed No variation from initial appearance	Acceptable The product is stable after 7 days at 0°C.	[redacted] Low temperature stability on the test Item BP11E solution of B02318740005.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
					Final Report N°.: STULV19AA0137-1 GLP
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	The UV-spectrum of L(+) lactic acid shows that no absorbance in the wavelength range of 290-800 nm takes place. Therefore, L(+) lactic acid cannot undergo direct photolysis in sunlight. However, an UV absorber is present in the composition of products of meta SPC 1-2 and 4. Therefore, "store protected from light" should be added to the labels of products of both meta SPC.			Acceptable Products of meta SPC 1-2 and 4 should be protected from light.	RAC opinion on L-(+)-lactic acid adopted 9 March 2018. CLH-O-0000001412-86-191/F
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Temperature: data on temperature have been provided in the accelerated storage stability studies. The content of active substance in **Bottles** (meta SPC1-2) is stable after at 40°C for 8 weeks. The labels will indicate that "the products must not be stored at temperature above 40°C." The content of active substance in **SPRAY** products (meta SPC 3 and 4) is stable at 54°C for 2 weeks. No temperature limit will be mentioned on the labels. In **WIPES** the content of active substance is increasing of more than +10% after storage at 40°C for 8 weeks, therefore for products of meta SPC5 the label will indicate that "the products must not be stored at temperature above 30°C."	Acceptable	IUCLID

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			Humidity: product is water-based and packaging is closed. No effect of humidity is expected.		
Effects on content of the active substance and technical characteristics of the biocidal product – **reactivity towards container material**			No reactivity towards container material has been observed during storage stability studies	Acceptable	IUCLID
Wettability			Not relevant for an AL formulation	Not relevant	
Suspensibility, spontaneity and dispersion stability			Not relevant for an AL formulation	Not relevant	
Wet sieve analysis and dry sieve test			Not relevant for an AL formulation	Not relevant	
Emulsifiability, re-emulsifiability and emulsion stability			Not relevant for an AL formulation	Not relevant	
Disintegration time			Not relevant for an AL formulation	Not relevant	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
Particle size distribution, content of dust/fines, attrition, friability			Results have been reported in each accelerated storage stability test for Meta SPC 3 and 4.	Acceptable	[redacted] Particles size Distribution – Spray pattern – Discharge rate – Clogging. LEREM Test report N° 9-525/20 included in EUROFINS Report N° 1170864A01 Report from LEREM N° 9-629-2/21, Mathieu J.B and Flecheux F., 2021
Persistent foaming			Not relevant as the products are ready to use.	Acceptable	IUCLID
Flowability/Pourability/Dustability			Not relevant for an AL formulation	Not relevant	
Burning rate — smoke generators			Not relevant for an AL formulation	Not relevant	
Burning completeness —			Not relevant for an AL formulation	Not relevant	

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td>smoke generators</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Composition of smoke — smoke generators</td><td></td><td></td><td>Not relevant for an AL formulation</td><td>Not relevant</td><td></td></tr>
<tr><td rowspan="2">Spraying pattern – discharge rate-clogging</td><td></td><td></td><td>Spray pattern, discharge rate and clogging results have been reported in each accelerated storage stability test for Meta SPC 3 and 34. Particle size distribution is not required considered the type of the sprayers (foam).</td><td>Acceptable</td><td>[redacted] Particles size Distribution – Spray pattern – Discharge rate – Clogging. LEREM Test report N° 9-525-2/20 included in EUROFINS Report N° 1170864A01 v2</td></tr>
<tr><td></td><td>BP8 – Spray WC Power 750mL –Ajax with trigger mesh foam
Reference: 101895

Batch: 15/04/22FR131J</td><td>Spray pattern:
<table>
<tr><th>Samples</th><th>Filling level</th><th>Lenght (cm)</th><th>Height (cm)</th></tr>
<tr><td rowspan="3">1</td><td>Full</td><td>8</td><td>11</td></tr>
<tr><td>Half Full</td><td>11</td><td>13</td></tr>
<tr><td>Almost empty</td><td>12</td><td>14</td></tr>
<tr><td rowspan="3">2</td><td>Full</td><td>10</td><td>14</td></tr>
<tr><td>Half Full</td><td>9</td><td>10</td></tr>
<tr><td>Almost empty</td><td>10</td><td>13</td></tr>
<tr><td rowspan="3">3</td><td>Full</td><td>12</td><td>14</td></tr>
<tr><td>Half Full</td><td>10</td><td>12</td></tr>
<tr><td>Almost empty</td><td>11</td><td>12</td></tr>
</table></td><td>Acceptable</td><td>Report n°1237843A01 v1, [redacted]</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
The spray pattern describes an elongated circle, as the height is slightly superior to the length.

Discharge rate:
<table>
<tr><th>Samples</th><th>Filling level</th><th>Discharge rate (g/s)</th></tr>
<tr><td rowspan="4">1</td><td>Full</td><td>1,25</td></tr>
<tr><td>Half Full</td><td>1,16</td></tr>
<tr><td>Almost empty</td><td>1,21</td></tr>
<tr><td>Average</td><td>1,21</td></tr>
<tr><td rowspan="4">2</td><td>Full</td><td>1,18</td></tr>
<tr><td>Half Full</td><td>1,17</td></tr>
<tr><td>Almost empty</td><td>1,21</td></tr>
<tr><td>Average</td><td>1,19</td></tr>
<tr><td rowspan="4">3</td><td>Full</td><td>1,17</td></tr>
<tr><td>Half Full</td><td>1,18</td></tr>
<tr><td>Almost empty</td><td>1,24</td></tr>
<tr><td>Average</td><td>1,20</td></tr>
</table>
' : g/s = gram per stroke

Clogging:
The clogging was evaluated by emptying the 3 samples completely.
<table>
<tr><th>Sample</th><th>Pulverisation count until emptying</th><th>Total weight loss (g)</th></tr>
<tr><td>1</td><td>665</td><td>747,42</td></tr>
<tr><td>2</td><td>658</td><td>743,25</td></tr>
<tr><td>3</td><td>671</td><td>747,98</td></tr>
</table>
No clogging was observed on the 3 samples while emptying.

Laser diffraction – granulometry:
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>The distribution median diameter Dv(50) is 241.2 µm. The mean diameter in volume is 311.3 µm (average of 3 measurements). The percentage of particles below 10µm is 0.1%.</td><td></td><td></td></tr>
<tr><td></td><td></td><td>BP5 – Spray Antibacterial 500 mL – AJAX with trigger standard foam
Reference : 10187463

Batch: 0114GR10111</td><td>Spray pattern:
<table>
<tr><th>Samples</th><th>Filling level</th><th>Lenght (cm)</th><th>Height (cm)</th></tr>
<tr><td rowspan="3">1</td><td>Full</td><td>8</td><td>10</td></tr>
<tr><td>Half Full</td><td>10</td><td>11</td></tr>
<tr><td>Almost empty</td><td>9</td><td>11</td></tr>
<tr><td rowspan="3">2</td><td>Full</td><td>10</td><td>12</td></tr>
<tr><td>Half Full</td><td>10</td><td>12</td></tr>
<tr><td>Almost empty</td><td>10</td><td>12</td></tr>
<tr><td rowspan="3">3</td><td>Full</td><td>8</td><td>11</td></tr>
<tr><td>Half Full</td><td>11</td><td>13</td></tr>
<tr><td>Almost empty</td><td>10</td><td>12</td></tr>
</table>
The spray pattern describes an elongated circle, as the height is slightly superior to the length.

Discharge rate:</td><td>Acceptable</td><td>Report n°1237843A01 v1, [redacted]</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Samples</th><th>Filling level</th><th>Discharge rate (g/s)</th></tr>
<tr><td rowspan="4">1</td><td>Full</td><td>1,08</td></tr>
<tr><td>Half Full</td><td>1,20</td></tr>
<tr><td>Almost empty</td><td>1,21</td></tr>
<tr><td>Average</td><td>1,16</td></tr>
<tr><td rowspan="4">2</td><td>Full</td><td>1,03</td></tr>
<tr><td>Half Full</td><td>1,13</td></tr>
<tr><td>Almost empty</td><td>1,06</td></tr>
<tr><td>Average</td><td>1,07</td></tr>
<tr><td rowspan="4">3</td><td>Full</td><td>1,14</td></tr>
<tr><td>Half Full</td><td>1,06</td></tr>
<tr><td>Almost empty</td><td>1,10</td></tr>
<tr><td>Average</td><td>1,10</td></tr>
</table>
: g/s = gram per stroke

Clogging:
The clogging was evaluated by emptying the 3 samples completely.
<table>
<tr><th>Sample</th><th>Pulverisation count until emptying</th><th>Total weight loss (g)</th></tr>
<tr><td>1</td><td>480</td><td>502,23</td></tr>
<tr><td>2</td><td>488</td><td>512,82</td></tr>
<tr><td>3</td><td>483</td><td>508,56</td></tr>
</table>
No clogging was observed on the 3 samples while emptying.

Laser diffraction – granulometry:
The distribution median diameter Dv(50) is 380.0 µm. The mean diameter in volume is 399.6 µm (average of 3 measurements). The</td><td></td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			percentage of particles below 10µm is 0%.		
Physical compatibility			Not relevant as the products of the family are not intended for application with other products.	Acceptable	IUCLID
Chemical compatibility			Not relevant as the products of the family are not intended for application with other products.	Acceptable	IUCLID
Degree of dissolution and dilution stability			Not intended for dissolution or dilution	Not relevant	IUCLID
Surface tension	Method A.5 Digital tensiometer K11	BP11e-Solution of C02318740005 Meta SPC 5	Surface Tension at 20°C, Mean value: 28.0 mN/m Distilled water has a surface tension of 72.75 mN/m at 20°C; substances showing a surface tension lower than 60 mN/m under the conditions of this method should be regarded as being surface-active materials (see method A.5 Surface tension 2008). Therefore, the substance is considered as a surface-active.	Acceptable Only the product BP11e has been tested for surface tension and this product is considered as a surface-active. However, it should be noted that, based on composition data, this product is not representative of all products within the family.	INNOVHUB. 2019 Report N° RPT-SSC-180477
	-		Due to unacceptable risks for local effects, the uses proposed to be authorised for meta SPC 3 and 4 are not acceptable. The product tested above for surface tension is representative of the whole meta SPC 5 then we can consider the meta SPC 5 to be covered.		-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			For products of meta SPC 1-2, only one kind of wetting agent is added to the tested product. Considering its nature, the addition of this wetting agent is expected to decrease the surface tension of the products and they will still be surface active. That's what implied by expressing that tested product was worst case of the family.		
Viscosity					
Meta SPC1-2	OECD 114. Rheometer analysis performed applying a shear rate from 1500 [1/s] to 2500 [1/s]	"BP3A – B02975830000"	Viscosity (mPa·s) At 20°C= 1.7 At 40°C=1.2	Acceptable	[redacted] CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP3A – B02975830000"
Meta SPC1-2 Meta SPC3	OECD 114. Rheometer analysis performed applying a shear rate from 1500 [1/s] to 2500 [1/s]	"BP7 – B02959350004"	Viscosity (mPa·s) At 20°C= 1.5 At 40°C=1.1	Acceptable	[redacted] CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP7 – B02959350004"
Meta SPC4	OECD 114. Rheometer analysis performed applying a shear rate from 1500 [1/s] to 2500 [1/s]	"BP5 – B02940950007"	Viscosity (mPa·s) At 20°C= 1.6 At 40°C=1.3	Acceptable	[redacted] CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP5 – B02940950007"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
Meta SPC5	OECD 114. Rheometer analysis performed applying a shear rate from 1500 [1/s] to 2500 [1/s]	"BP11E – SOLUTION OF B02318740005"	Viscosity (mPa·s) At 20°C= 1.7 At 40°C=1.1	Acceptable	[redacted] CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP11E – SOLUTION OF B02318740005"

Internal stability data provided as technical support for the accelerated stability at 40°C for 8 weeks:

Table 1: Weight change of wipes from production

			40°C / 75%HR			
Study	Description	Initial weight	8wks weight	Weight Reduction %	13wks weight	Delta
20157344	EMO NLR Ajax Antibacterial / Fraicheur Pure Wipes	231.61	223.32	-3.58%	223.24	-3.61%
20157401	EMO NLR Ajax Antibacterial Coquelicots Wipes	228.88	222.16	-2.94%	221.73	-3.12%
20159885	Start Up NLR WIPE AB Fraîcheur Pure	222.58	NA	N/A	215.51	-3.18%
20159886	Start Up NLR WIPE AB Fraîcheur Intense	220.46	NA	N/A	212.15	-3.77%
20159887	Start Up NLR WIPE AB FDF Coquelicots	227	NA	N/A	219.22	-3.43%
20161065	Start Up NLR WIPE Ajax FDF Muguet	221.92	NA	N/A	213.01	-4.01%
20177897	SoP [CPG] WIPES La Croix 5 in 1	153.2	148.91	-2.80%	145.24	-5.20%
20177957	SoP [CPG] WIPES Ajax AB Bathroom Optimal 7	169.8	166.91	-1.70%	164.21	-3.29%
20177958	SoP [CPG] WIPES Ajax AB Kitchen Optimal 7	174.2	169.3	-2.81%	170.43	-2.16%
20188453	SOP Ajax Wipes Triple Action Vitres/Glas	NA	147.58	N/A	145.17	N/A
20193378	SOP Ajax Wipes Triple Action Vitres/Glas	148.06	143.33	-3.19%	142	-4.09%
	Weight average below 200	161.3150	155.2060	-2.63%	153.4100	-3.69%
	Weight average above 200	225.4083	222.7400	-3.26%	217.4767	-3.52%

Table 2: Internal data of lactic acid increase after 13 weeks aging

			40°C / 75%HR	
Study	Description	Initial LA Level	13 wks	% LA increase
20192709	Lab Ajax Antibacterial Fraicheur Pure	3.9	4.1	5.13%
20192739	Lab Ajax Antibacterial Fraicheur Pure	3.47	3.61	4.03%
20199331	Ajax biodegradable wipes/ WC Lactic acid 3.5%	3.5	3.7	5.71%

Conclusion on the physical, chemical and technical properties of the product

META SPC 1-2: Products are AL formulations. The tested product (BP3a) has a pH of 3.27, an acidity of 0.67%w/w, a density of 1.0078, with a dynamic viscosity of 1.7 mPa·s at 20°C. The test item was physically stable after 7 days at 0 °C and after 8 weeks at 40°C. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging. The products should be protected from light.

Shelf life: 2 years
The products should not be stored above 40°C.

META SPC 3: Products are AL formulations. The tested product (BP7) has a pH of 2.60, an acidity of 1.73%w/w, a density of 1.0070, with a dynamic viscosity of 1.5 mPa·s at 20°C. The test item was physically stable after 7 days at 0 °C and after 2 weeks at 54°C (BP8). The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging. The products should be protected from light.

Shelf life: 2 years

META SPC 4: Products are AL formulations. The tested product (BP5) has a pH of 2.46, an acidity of 1.22%w/w, a density of 1.0036, with a dynamic viscosity of 1.6 mPa·s at 20°C. The test item was physically stable after 7 days at 0 °C and after 2 weeks at 54°C. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging.

Shelf life: 2 years

META SPC 5: Products are AL formulations. The tested product (BP11e) has a pH of 2.28, an acidity of 2.16%w/w, a density of 1.0047, with a dynamic viscosity of 1.7 mPa·s at 20°C. The test item was physically stable after 7 days at 0 °C. The accelerated storage stability study shows a variation above 10% of the active substance after storage at 40°C for 8 weeks due to the poor sealing of the packaging. Therefore a mitigation measure should be added on the label "the products must not be stored at temperature above 30°C". The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in commercial packaging. Shelf life: 1 year The products should not be stored above 30°C.

2.2.3 Physical hazards and respective characteristics

For corrosive to metals properties, the tests have been performed in order to cover all the products of the family:

- Meta-SPC 1-2: The product BP3b having the maximum content of active substance (3.5% of lactic acid) has been tested. This covers the 7 other products of the Meta SPC.
- Meta SPC 3: The product BP7 having the maximum content of active substance (4% of lactic acid) has been tested. This covers the 4 other products of the Meta SPC.
- Meta SPC 4: BP5 is the single product of Meta SPC4 and has been tested.
- Meta SPC 5: Among the 4 products, the product with the maximum active substance content over the Meta SPC (BP11e) and with the maximum content of flammable solvents over the BPF has been tested. This covers the remaining products of the Meta SPC.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
Explosives	Structure analysis		Consideration of the structure indicates that L-(+)-lactic acid does not have explosive or oxidising properties. According to Regulation (EC) N°1272/2008 (CLP) criteria and screening procedure (as listed in appendix 6 to the UN Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria (6th revised edition, 2015) or in the ECHA endpoint specific guidance on information requirements. (R.7a, v6.0, July 2017, §R.7.1.11), No chemical group was identified in the list of constituents of the products and/or oxygen balance was above the limit. The products are water-based formulations. Therefore, explosive properties are not anticipated for the products. No further testing was considered.	Acceptable	RAC opinion on L-(+)-lactic acid adopted 9 March 2018. CLH-O-0000001412-86-191/F Appendix 6 to the UN Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria (6th revised edition, 2015)
Flammable gases			Not relevant as the product is a liquid	Not relevant	
Flammable aerosols			Not relevant as the product is a liquid	Not relevant	
Oxidising gases			Not relevant as the product is a liquid	Not relevant	
Gases under pressure			Not relevant as the product is a liquid	Not relevant	
Flammable liquids	A9 Flash point Rapid equilibrium	BP11e-Solution of B02318740005	Two test were performed and the same behaviour was observed in both determinations: the sample does not ignite and turns off the test flame at 86°C. No flash point observed until	Acceptable	[redacted] Determination of the Flash Point on the sample BP11e-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
	closed cup method	4% w/w lactic acid	86°C. The substance is not flammable according to CLP regulation. The product BP11e is the product of the BPF with the maximum level of organic solvent, therefore it has been selected for the flash point test.		Solution of B02318740005. INNOVHUB Report No 1900333.
Flammable solids			Not relevant as the product is a liquid	Not relevant	
Self-reactive substances and mixtures		According to the Guidance on the application of the CLP criteria, "substances and mixtures must be considered for classification in hazard class self-reactive property unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria". Based on the composition, the fragrance mixtures contain several substances that exhibit unsaturation in their molecular structure. Therefore, DSC tests of representative products of all Meta SPCs should be provided to confirm the non-classification in this hazard class. Moreover, if their heat of decomposition is higher than 300 J/g, the self-accelerating decomposition temperature (SADT) of the products should also be determined.		DSC tests of representative products of all Meta SPCs should be provided in post authorisation to confirm the non-classification in this hazard class.	-
Pyrophoric liquids			Experience in handling and use indicates that L-(+)-lactic acid is neither pyrophoric nor does it react with water to liberate flammable gases. Study for pyrophoric properties is deemed unnecessary based on the experience in handling, testing and use of the product and based on the chemical structure of the known constituents of the products that do not fall into critical categories described in ECHA guidance.	Acceptable	RAC opinion on L-(+)-lactic acid adopted 9 March 2018. CLH-O-0000001412-86-191/F

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
			The tests performed on the products and reported in this dossier showed that the products clearly does not react with air. Moreover, a review of the chemical structure of the known constituents suggests that there are no chemical groups present in these constituents that would imply pyrophoric properties. Therefore, the study was considered as unnecessary.		
Pyrophoric solids			Not relevant as the product is a liquid	Not relevant	
Self-heating substances and mixtures			According to Annex I 2.11.4.2 of the CLP Regulation, A self-heating substance or mixture is a liquid or solid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days). The test item is not in this case. In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating.	Acceptable	-
Substances and mixtures which in contact with water emit			Not relevant as the product is a liquid	Not relevant	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
flammable gases					
Oxidising liquids	Structure analysis		Consideration of the structure indicates that L-(+)-lactic acid does not have explosive or oxidising properties. Furthermore, the products are water-based formulations. No experimental study is available on the products. For all the ingredients (i.e. all CAS N° identified), regarding oxidising properties, no harmonised classification is listed in Annex VI to Regulation (EC) No.1272/2008 "CLP", and no self-classification is notified in the ECHA CLP inventory, nor proposed in the supplier's SDS. According to CLP criteria (Annex I §2.14.4), "For organic substances or mixtures, the classification procedure for this class shall not apply if: (a) the substance or mixture does not contain oxygen, fluorine or chlorine; or (b) the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen. For inorganic substances or mixtures, the classification procedure for these hazard classes	Acceptable	-

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>need not be applied if they do not contain oxygen or halogen."

Based on experience and use of these substances, and their limited content, it looks very unlikely that they exhibit oxidising properties.</td><td></td><td></td></tr>
<tr><td>Oxidising solids</td><td></td><td></td><td>Not relevant as the product is a liquid</td><td>Not relevant</td><td></td></tr>
<tr><td>Organic peroxides</td><td>Composition analysis</td><td></td><td>The product does not contain organic peroxides</td><td>Acceptable</td><td>-</td></tr>
<tr><td>Corrosive to metals</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Meta SPC 1-2 (BDC)</td><td>According to “UN-MTC, Section 37.4 –

7 days at 55°C</td><td>BP3b Ajax Healthy Home Sage and Apple 2.6% Lactic Acid-B02975830001”

Batch Adrian Lopez-0070-006</td><td>Two types of metal were tested: aluminium and steel. After 7 days at 55°C+1°C the “test evaluation at uniform corrosion” test proved to be negative since the weight loss showed to be less than 13.5%. The maximum weight loss measured was 3.5%.

<table><tr><th>Specimens position</th><th>Mass loss%</th></tr><tr><td colspan="2">Aluminium</td></tr><tr><td>Gas phase</td><td>-0.1470</td></tr><tr><td>Half way</td><td>0.6372</td></tr><tr><td>Dipped into the solution</td><td>0.7548</td></tr><tr><td colspan="2">Steel</td></tr></table></td><td>Acceptable
The products of meta SPC 1 are not classified as corrosive to metal H290 Met Corr. I.</td><td>[redacted]
Corrosion test on the test item “BP3B AJAX HEALTHY HOME SAGE AND APPLE 2.6% LACTIC ACID - B02975830001”
Report No STULV20AA2300-1
GLP</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Gas phase</td><td>0.5497</td></tr>
<tr><td>Half way</td><td>2.5703</td></tr>
<tr><td>Dipped into the solution</td><td>3.5015</td></tr>
</table>
However, variations in the appearance were observed for specimen in the gas phase and halfway for steel metal. For this metal and condition the “test evaluation at localized corrosion” was performed.

After 7 days at 55°C +1°C “test evaluation at localized corrosion” proved to be negative for both specimen since the deepest localized corrosion attack showed to be 34.4 µm (less than 120 µm).
<table>
<tr><th>Conditions</th><th>Depth of the strongest attack (µm)</th></tr>
<tr><td colspan="2">Steel</td></tr>
<tr><td>Dipped into the solution</td><td>Not performed</td></tr>
<tr><td>Gas phase</td><td>28.4</td></tr>
<tr><td>Half way</td><td>34.4</td></tr>
</table>
However, the specimen having the max mass loss% (steel dipped into the solution) has not been tested for localized corrosion.
</td><td></td><td></td></tr>
<tr><td>Meta SPC 3 (spray)</td><td>According to “UN-MTC,</td><td>BP7 AJAX ALL IN ONE – B0295935004</td><td>Two types of metal were tested: aluminium and steel. After 7 days at 55°C+1°C “test evaluation at uniform corrosion” proved to be negative since</td><td>Acceptable
The products of meta SPC 3 are</td><td>[redacted]
Corrosion test on the test item BP7 AJAX</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td>Section 37.4 –

7 days at 55°C</td><td>3.2% lactic acid

Batch: 0100FR13156</td><td>the weight loss showed to be less than 13.5%. The maximum weight loss measured was 9.9%. The same results were obtained with both types of metal.
<table>
<tr><th>Specimens position</th><th>Mass loss%</th></tr>
<tr><td colspan="2">Aluminium</td></tr>
<tr><td>Gas phase</td><td>0.0569</td></tr>
<tr><td>Half way</td><td>0.1157</td></tr>
<tr><td>Dipped into the solution</td><td>0.1695</td></tr>
<tr><td colspan="2">Steel</td></tr>
<tr><td>Gas phase</td><td>1.6521</td></tr>
<tr><td>Half way</td><td>4.6614</td></tr>
<tr><td>Dipped into the solution</td><td>9.9675</td></tr>
</table>
However, variations in the appearance were observed for steel specimen in the gas phase and half way and for aluminium specimen in the gas phase. For these metals and condition the “test evaluation at localized corrosion” was performed.
<table>
<tr><th>Conditions</th><th>Depth of the strongest attack (µm)</th></tr>
<tr><td colspan="2">Steel</td></tr>
<tr><td>Dipped into the solution</td><td>Not performed</td></tr>
</table></td><td>classified as corrosive to metal H290 Met Corr. I.</td><td>ALL IN ONE – B0295935004 Final report N° STULV204A2306-1 GLP</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Gas phase</td><td>133.3</td></tr>
<tr><td>Half way</td><td>87.3</td></tr>
<tr><td colspan="2">Aluminium</td></tr>
<tr><td>Dipped into the solution</td><td>Not performed</td></tr>
<tr><td>Gas phase</td><td>14.6</td></tr>
<tr><td>Half way</td><td>Not performed</td></tr>
</table>

After 7 days at 55°C +1°C "test evaluation at localized corrosion" proved to be negative for aluminium in gas phase and for steel halfway since the deepest localized corrosion attack showed to be less than 120 µm). For steel in the gas phase this test resulted positive since the deepest localized corrosion attack showed to be more than 120 µm (133.3µm).</td><td></td><td></td></tr>
<tr><td>Meta SPC 4 (spray)</td><td>According to "UN-MTC, Section 37.4 –

7 days at 55°C</td><td>BP5-Ajax Spray Antibac 2.4% LA – B0294095000 7"

Batch: 0114GR10111 1-10:31</td><td>Two types of metal were tested: aluminium and steel. After 7 days at 55°C+1°C "test evaluation at uniform corrosion" proved to be negative since the weight loss showed to be less than 13.5%. The maximum weight loss measured was 2.3%.
<table>
<tr><th>Specimens position</th><th>Mass loss%</th></tr>
<tr><td colspan="2">Aluminium</td></tr>
<tr><td>Gas phase</td><td>0.0469</td></tr>
<tr><td>Half way</td><td>0.4624</td></tr>
<tr><td>Dipped into the solution</td><td>0.8229</td></tr>
</table></td><td>Acceptable
The products of meta SPC 4 are not classified as corrosive to metal H290 Met Corr. I.</td><td>[redacted]
Corrosion test on the test item "BP5- AJAX SPRAY ANTIBAC 2.4% LA - B02940950007" Report No STULV20AA3176-1 GLP</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td colspan="2">Steel</td></tr>
<tr><td>Gas phase</td><td>-0.3744</td></tr>
<tr><td>Half way</td><td>1.5155</td></tr>
<tr><td>Dipped into the solution</td><td>2.3722</td></tr>
</table>

However, variations in the appearance were observed for steel specimen in the gas phase and half way and for aluminium specimen in halfway. For these metals and condition the "test evaluation at localized corrosion" was performed.
<table>
<tr><th>Conditions</th><th>Depth of the strongest attack (µm)</th></tr>
<tr><td colspan="2">Steel</td></tr>
<tr><td>Dipped into the solution</td><td>Not performed</td></tr>
<tr><td>Gas phase</td><td>107.8</td></tr>
<tr><td>Half way</td><td>22.0</td></tr>
<tr><td colspan="2">Aluminium</td></tr>
<tr><td>Dipped into the solution</td><td>Not performed</td></tr>
<tr><td>Gas phase</td><td>Not performed</td></tr>
<tr><td>Half way</td><td>16.8</td></tr>
</table>

After 7 days at 55°C +1°C "test evaluation at localized corrosion" proved to be negative for both metals and conditions since the deepest</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>localized corrosion attack showed to be 107.8 µm (less than 120 µm).</td><td></td><td></td></tr>
<tr><td>Meta SPC 5</td><td>According to "UN-MTC, Section 37.4 –

7 days at 55°C</td><td>BP11E — Solution of B0231874000 5 - Ajax Optimal 7 Wipes

Bathroom and Toilet at 4% of Lactic Acid

Batch Mariana Martinez Heredia-00038-001</td><td>Two types of metal were tested: aluminium and steel. After 7 days at 55°C+1°C "test evaluation at uniform corrosion" proved to be negative since the weight loss showed to be less than 13.5%. The maximum weight loss measured was 3.9%.
<table>
<tr><th>Specimens position</th><th>Mass loss%</th></tr>
<tr><td colspan="2">Aluminium</td></tr>
<tr><td>Gas phase</td><td>0.1031</td></tr>
<tr><td>Half way</td><td>0.7155</td></tr>
<tr><td>Dipped into the solution</td><td>0.9992</td></tr>
<tr><td colspan="2">Steel</td></tr>
<tr><td>Gas phase</td><td>0.0403</td></tr>
<tr><td>Half way</td><td>1.5786</td></tr>
<tr><td>Dipped into the solution</td><td>3.8963</td></tr>
</table>
However, variations in the appearance were observed for steel specimen in the gas phase and half way and for aluminium specimen in the gas phase. For these metals and conditions, the "test evaluation at localized corrosion" was performed.
<table>
<tr><th>Conditions</th><th>Depth of the strongest attack (µm)</th></tr>
<tr><td colspan="2">Steel</td></tr>
</table></td><td>Acceptable
The impregnation liquid of products is classified as corrosive to metal H290 Met Corr. I.

Therefore, products of meta SPC 5 are classified as corrosive to metal H290 Met Corr. I.</td><td>[redacted]
Corrosion test on the test item "BP11E-solution of B023178740005 – Ajax optimal 7 wipes bathroom and toilet at 4% of lactic acid. Final Report N° STULV20AA1707-1 GLP</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Dipped into the solution</td><td>Not performed</td></tr>
<tr><td>Gas phase</td><td>173.1</td></tr>
<tr><td>Half way</td><td>16.6</td></tr>
<tr><td colspan="2">Aluminium</td></tr>
<tr><td>Dipped into the solution</td><td>Not performed</td></tr>
<tr><td>Gas phase</td><td>13.1</td></tr>
<tr><td>Half way</td><td>Not performed</td></tr>
</table>

After 7 days at 55°C +1°C “test evaluation at localized corrosion” proved to be negative for aluminium in gas phase and for steel halfway since the deepest localized corrosion attack showed to be less than 120 µm. For steel in the gas phase this test resulted positive since the deepest localized corrosion attack showed to be 173.1 µm (more than 120 µm).
</td><td></td><td></td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td></td><td colspan="2">The test is not required for liquids not flammable in air.</td><td>Acceptable</td><td></td></tr>
<tr><td>Relative self-ignition temperature for solids</td><td></td><td></td><td>Not relevant as the product is a liquid</td><td>Not relevant</td><td></td></tr>
<tr><td>Dust explosion hazard</td><td></td><td></td><td>Not relevant as the product is a liquid</td><td>Not relevant</td><td></td></tr>
</table>

Conclusion on the physical hazards and respective characteristics of the product
The products within the biocidal product family are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties. The products of meta SPC 3 and 5 are classified as corrosive to metal H290 Met Corr. I. For self-reactive properties, DSC tests of representative products of all Meta SPCs should be provided in post authorisation to confirm the non-classification in this hazard class.

2.2.4 Methods for detection and identification

The product with the maximum active substance content over the meta-SPC and over the BPF has been tested (BP 11E). Analytical methods for other products can be read across from these data.

Information on the method used to extract the impregnated solution from the wipe:

As prescribed by SANCO 3030 reconstituted wetting solution were prepared at three concentration levels with a known amount of lactic acid using the certified raw material of lactic acid and a placebo. Dry wipes were soaked with reconstituted wetting solution (ratio: 2.4g of liquid for 1 g of solid) and then they were squeezed by a 20ml syringe.

The extracted liquids were analysed according the method of the report STULV19AA0142-1 GLP.

The quantity of lactic acid found in the extracted liquid corresponds to the quantity of the lactic acid used for the preparation of the wetting solution (average recovery 100.4%), so the extracted liquid has the same concentration of the reconstituted wetting solution.

A validation of the analytical method was performed. The method to be validated was the sponsor internal method "LAB 1110-11-Part C: Determination of Lactic acid Using Isocratic HILIC Methodology". The following parameters were verified during the study:

-Specificity

In order to demonstrate the specificity of the method, the following solutions were injected into the chromatographic system:

Blank (mobile phase), placebo solution, placebo extracted from wipes, standard solution, material solution and sample solution.

-Linearity

The linearity of the method was assessed at about 59%, 79% 100% 144% and 189% of the nominal ingredient concentration. The linearity does not cover products of Meta SPC 1-2 with a concentration of 1.875% of lactic acid (corresponding to 37.5% of the nominal ingredient concentration). However, considering the large range tested (59% - 189%), it is not expected to notice a difference at 37.5%. Moreover,

the possibility to double the amount of sample used for analysis for Meta-SPCs 1-2, leading to ~3.6 g of sample instead of ~1.8 g, would enable to be covered by the validation range.

-Precision

Precision is obtained performing the assay determination of the active substance in 6 samples and is expressed as RSD% of the tests results.

-Accuracy

Accuracy was performed on reconstituted samples at 59, 100 and 189% of the nominal ingredient concentration. The lowest level tested for accuracy does not cover products of Meta SPC 1-2 with a concentration of 1.875% of lactic acid (corresponding to 37.5% of the nominal ingredient concentration). However, considering the results at the 3 tested concentration levels, it is not expected to notice a variation of the recovery rate at 37.5%.

The placebo and raw material were provided by the sponsor to the external laboratory. Sodium Lactate reference standard was used to quantify lactic acid.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	HPLC-UV/ DAD	N=6 (2 preparations for each concentration level). Range= 2.4 to 7.6%w/w acid lactic or 0.43 to 1.36 mg/ml as acid lactic.	y= 84.918x-0.392 R=0.9998 N=5 levels used Range=2.4 to 7.6%w/w acid lactic or 0.43 to 1.36 mg/ml as acid lactic.	Blank and placebo do not interfere with the peak of active ingredient.	At 2.4%w/w: 100.0% At 4%w/w: 99.9% At 7.6%w/w: 101.2%	100.4 % recovery	2.08 RSD below RSD Horwitz (2.18%)		[redacted]. Analytical method validation for the quantification of lactic acid in the test Item BP11E solution of B02318740005.

									Final Report N°.: STULV19AA0142 -1 GLP

Conclusion on the methods for detection and identification of the product
An HPLC-UV method of analysis of active substance lactic acid in the test item BP11e developed and validated according to the SANCO/ 3030/99 rev.4 in the frame of this dossier. Regarding other methods of analysis, a letter of access to active substance data is submitted in IUCLID.

Analytical methods for SOCs have not been provided as these SOCs do not form during storage.

Relevant residues in food of plant and animal origin and in the environmental compartments arising from the application of L(+) lactic acid are not expected. Therefore, residue analytical methods for L(+) lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since L(+)lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

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

The products of COLGATE-PALMOLIVE LACTIC ACID PT2 family are ready-to-use products used for hard surfaces excluding kitchen and for domestic toilet bowl surface by non-professional users.
The products are intended:

- as domestic disinfectant on hard surfaces excluding kitchen (PT2) and
- as domestic disinfectant for domestic toilet bowl surface (PT2)

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

The products of COLGATE-PALMOLIVE LACTIC ACID PT2 family are intended to be used as bactericide on porous and non-porous hard surfaces.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products of COLGATE-PALMOLIVE LACTIC ACID PT2 family are able to produce a reduction in the number of viable bacterial cells (bactericidal activity) of relevant test organisms under defined conditions.

2.2.5.4 Mode of action, including time delay

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

2.2.5.5 Efficacy data

Efficacy of the COLGATE-PALMOLIVE LACTIC ACID PT2 product family

Laboratory studies were conducted with COLGATE-PALMOLIVE LACTIC ACID PT2 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 1-2:**

META-SPC1-2 contains ready to use products with lactic acid concentration ranging from 1.875% w/w to 3.5 % w/w as a Bucket Dilutable Cleaner, with range of variations for perfumes. Laboratory studies were conducted with representative products B029-1342-0012 (3.5 % L(+) lactic acid 80 %)) and B029-1342-0010 (1.875 % L(+) lactic acid 80 %):
Taking into account the variations of the co-formulants presented in the META-SPC1, it can be assumed that they have no significant impact on efficacy and the efficacy results of these representative products support the efficacy of the META-SPC1.

In PT2 area, no test standard is available to demonstrate the bacterial efficacy of products applied on porous hard surfaces. Nevertheless, the applicant proposed a test method based on an adaptation of EN13697, where a porous ceramic surface carrier (instead of a stainless-steel disk surface) was used.

- Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), with a product at 1.875% w/w lactic acid, 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 75 % v/v.
- Bactericidal activity is demonstrated in phase 2, step 2 test (EN 13697), with a product at 1.875 % w/w lactic acid, 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% v/v.
- Bactericidal activity is demonstrated in phase 2, step 2 test (adapted EN 13697), with a product at 1.875 % w/w lactic acid, at 20 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA), on porous ceramic surface. In these conditions, bactericidal activity is shown at the in-use concentration of 80% v/v.
- Bactericidal activity is demonstrated in phase 2, step 2 tests (EN 13697), with a product at 3.5 % w/w lactic acid, 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 80% v/v.

For the product at 3.5 % w/w lactic acid, only phase 2 step 2 test has been provided. The comparison between the formulation at 1.875% and 3.5 % w/w lactic acid differ mainly on the content of active substance. Read across is acceptable on the phase 2 step 1 tests..

Based on the efficacy data, it can be concluded that the bactericidal efficacy is demonstrated at the concentration of 1.875 % w/w lactic acid for a contact time of 15 minutes for porous and non-porous surfaces and at the concentration of 3.5 % w/w for a contact time of 5 minutes for non-porous surfaces, in dirty conditions at room temperature. Considering that all the products within a same Meta SPC cannot have

different contact time depending on the active substance content, the worst case contact time has be validated to 15 minutes for the whole META-SPC.

Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

Experimental data on the efficacy of the biocidal product against target organism(s)-META SPC 1-2								
	Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
1	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	BDC (Bucket Dilutable Cleaner) 1.5% L(+) lactic acid in product **BP1a** B029-1342-0010 *A statement is provided certifying that the product B029-1342-0006 is identical in terms of quantity and quality with the products B029-1342-0010*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	EN 1276:2009 Phase2, step1	Temperature: 20°C Contact time: 5 min Dirty conditions (3g/L bovine albumin) Concentrations tested: 80%-75% and 1%	Log reduction >5 The product is bactericidal at a concentration of 75% (v/v)	[redacted] *Test report S-2017-04065 PROVA* RI 1
2bis		PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	BDC (Bucket Dilutable Cleaner) 1.5% lactic acid in product **BP1a** B029-1342-0010 *A statement is provided certifying that the product B029-1342-0006 is identical in terms of*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	EN 13697:2015 Phase2, step2	Temperature: 20°C Contact time: 5 min Dirty conditions: (3g/L bovine albumin) Concentrations tested: 100%-75% and 1%	Not bactericidal activity against *Staphylococcus aureus* and *Enterococcus hirae.*	[redacted] *Test report S-2017-04066 PROVA* RI 3

			quantity and quality with the products B029-1342-0010					
2	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	BDC (Bucket Dilutable Cleaner) 1.5% L(+) lactic acid in product **BP1a** B029-1342-0010	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	EN 13697 Phase2, step2	Temperature: 20°C Contact time: 15 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 100%, 80% and 1%	Log reduction >4 The product is bactericidal at a concentration of 100% (v/v)	[redacted] *STUDY N° 934449A01* *Version n°1* RI 1
3	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	BDC (Bucket Dilutable Cleaner) 2.6% L(+) lactic acid in product **BP1b** B029-1342-0012 *A statement is provided certifying that the product "* *Ajax antibacterial all purpose cleaner liquid fresh"* *(663274) corresponds to formula B029-1342-0012*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	EN 13697 Phase2, step2	Temperature: 20°C Contact time: 5 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 100%, 80% and 1%	The product is bactericidal at a concentration of 80% (v/v)	[redacted] *STUDY N° 939039A02* *Version n°1* RI 1
4	Bactericidal disinfectant	PT2 Hard surface	BDC (Bucket Dilutable Cleaner)	*Pseudomonas aeruginosa*	EN 13697	Temperature: 20°C	Log reduction >4	[redacted]

		disinfection – Disinfection for Toilets bowls surfaces	1.5% L(+) lactic acid in product **BP1a** B029-1342-0010	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	Phase2, step2	Contact time: 15 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 100%, 80% and 1%	The product is bactericidal at a concentration of 100% (v/v)	*STUDY N° 3130.ATS.20.13697.1-V2* *Version n°1*

- **META SPC 3:**

META-SPC 3 contains ready to use products at 3.2% w/w Lactic acid as a Spray, with range of variations for perfumes. Laboratory studies were conducted with the representative products BP6 (B029-5926-0004, 3.2% w/w lactic acid) and the product BP8 (B029-7401-0001, 3.2% w/w lactic acid):
Taking into account the variations of the co-formulants presented in the META-SPC 3, it can be assumed that they have no impact on efficacy and the efficacy results of these representative products support the efficacy of the META-SPC 3.

In PT2 area, no test standard is available to demonstrate the bacterial efficacy of products applied on porous hard surfaces. Nevertheless, the applicant proposed a test method based on an adaptation of EN13697, where a porous ceramic surface carrier (instead of a stainless-steel disk surface) was used.

- Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276) at 20 °C, with a product at 3.2 %w/w lactic acid, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA) at the in-use concentration of 100 % v/v.

For non-porous surfaces:

- Bactericidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20 °C, with a product at 3.2 % w/w lactic acid, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA) at the in-use concentration of 100 % v/v.

For porous surfaces:

- Bactericidal activity is demonstrated in phase 2, step 2 test (adapted EN 13697) at 20 °C, with a product at 3.2 % w/w lactic acid, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA), on porous ceramic surface at the in-use concentration of 80 % v/v

Based on the efficacy data, it can be concluded that the bactericidal efficacy is demonstrated at the concentration of 3.2% w/w lactic acid, for a contact time of 5 minutes for porous and non-porous surfaces, in dirty condition, at room temperature.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

Experimental data on the efficacy of the biocidal product against target organism(s)-META SPC 3								
	Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**

6	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces SPRAY	SPRAY 3.2% L(+) lactic acid in product **BP6** B029-5926-0004 *Similar product B029-5926-0001* *tested see justification in table above and composition in annex 6*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	EN 1276:2010 Phase2, step1	Temperature: 20°C Contact time: 5 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 100%, 20% and 0.1%	Log reduction >5 The product is bactericidal at a concentration of 100% (v/v)	[redacted] *STUDY N° 847957A01* *Version n°1* RI 1
					EN 13697 Phase2, step2	Temperature: 20°C Contact time: 5 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 100%, 20% and 0.1%	Log reduction >4 The product is bactericidal at a concentration of 100% (v/v)	
7	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces SPRAY	SPRAY 3.2% L(+) lactic acid in product **BP8** B029-7401-0001 *Similar product B029-5926-0001* *tested see justification in table above and composition in annex 6*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	Adapted EN 13697 Phase2, step2 Ceramic porous surface	Temperature: 20°C Contact time: 5 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 1%, 80% and 97%	Log reduction >4 The product is bactericidal at a concentration of 80% (v/v)	[redacted] STUDY N°3130.ATS.20.13697.3 – V2 RI 2

- **META SPC 4:**

META-SPC 4 contains ready to use products at 2.4% w/w lactic acid as a spray, with range of variations for perfumes. Laboratory studies were conducted with the representative products B029-4095-0007 and "Ajax WC Power" (2.4 % L(+) lactic acid):
Taking into account the variations of the co-formulants presented in the META-SPC 4, it can be assumed that they have no impact on efficacy and the efficacy results of the representative products support the efficacy of the META-SPC 4.

In PT2 area, no test standard is available to demonstrate the bacterial efficacy of products applied on porous hard surfaces. Nevertheless, the applicant proposed a test method based on an adaptation of EN13697, where a porous ceramic surface carrier (instead of a stainless-steel disk surface) was used.

- Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276) with a product at 2.4% w/w lactic acid, at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA) at the in-use concentration of 40 % v/v.

For non-porous surfaces:

- Bactericidal activity is demonstrated in phase 2, step 2 test (EN 13697), with a product at 2.4% w/w lactic acid, at 20 °C, with contact times of 5 and 15 minutes, in dirty conditions (3.0 g/L BSA) at the in-use concentration of 40 % v/v.

For porous surfaces:

- Bactericidal activity is demonstrated in phase 2, step 2 test (adapted EN13697), with a product at 2.4% w/w lactic acid at 20 °C, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA), at the in-use concentration of 80 % v/v.

Based on the efficacy data, it can be concluded that the bacterial efficacy is demonstrated for products at 2,4% w/w lactic acid, for contact times of 5 and 15 minutes, in dirty conditions (3 g/L BSA), at room temperature on porous and non-porous surfaces.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

Experimental data on the efficacy of the biocidal product against target organism(s)-META SPC 4								
	Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
8	Bactericidal disinfectant	PT2 Hard surface	SPRAY	*Pseudomonas aeruginosa*	EN 1276:2010	Temperature: 20°C	Log reduction >5	[redacted]

		disinfection – Disinfection for Toilets bowls surfaces	2.4% L(+) lactic acid in product **BP5** B029-4095-0007 *Similar product B029-4095-0004 tested see justification in table above and composition in annex 6*	*Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	Phase2, step1	Contact time: 5 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 2%, 1% and 0.5% against *Pseudomonas aeruginosa* and *Escherichia coli*. 40%, 20% and 10 % against *Staphylococcus aureus* and *Enterococcus hirae*.	The product is bactericidal at a concentration of 40% (v/v).	*Rapport d'essai N°439/1110 -1* RI 1
9	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	SPRAY 2.4% L(+) lactic acid in product **BP5** B029-4095-0007 *the product antibacterien optimal 7 sans javel" (660013) is identical in terms of quantity and quality with the products B029-4095-0007*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	EN 13697 Phase2, step2	Temperature: 20°C Contact time: 5 min Dirty conditions (3g/L bovine albumin) Tested concentrations: 100%, 40% and 1%	Log reduction >4 The product is bactericidal at a concentration of 40% (v/v)	[redacted] *STUDY N° 934450A01 version n°2* RI 1
						Temperature: 20°C Contact time: 15 min Dirty conditions	Log reduction >4 The product is bactericidal at a	

						(3g/L bovine albumin) Tested concentrations: 100%, 40% and 1%	concentration of 40% (v/v)	
10	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	SPRAY 2.4% L(+) lactic acid 0051CP10111 "Ajax WC Power"	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*	EN 13697 Phase2, step2	Temperature: 20°C Contact time: 5 min Dirty conditions (3g/L bovine albumin) Hard porous surface tested (ceramic) Tested concentrations: 97%, 80% and 1%	Log reduction >4 The product is bactericidal at a concentration of 80% (v/v)	[redacted] *STUDY N° 3130.ATS.20.13697.3 version n°2* RI 2

- **META SPC 5:**

META-SPC 5 contains ready to use products with lactic acid concentration ranging from 3.5% to 4 % w/w as a wipe, with range of variations for perfumes. Laboratory studies were conducted with representative products B-023-1874-0004, Lingettes AJAX (3.5 % w/w lactic acid) and B-023-1874-0005 (4 % w/w lactic acid).
Taking into account the variations of the co-formulants presented in the META-SPC 5, it can be assumed that they have no impact on efficacy and the efficacy results of these representative products support the efficacy of the META-SPC 5.

In PT2 area, no test standard is available to demonstrate the bacterial efficacy of products applied on porous hard surfaces. Nevertheless, the applicant proposed a test method based on an adaptation of EN16115, where a porous surface carrier was used. The best porous surface candidate as carrier for testing was a porous ceramic.

For non-porous surfaces:

- Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276) at 20 °C, with a product at 3.5% w/w lactic acid, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA) at the in-use concentration of 75 % v/v.
- Bactericidal activity is demonstrated in phase 2, step 2 test (EN 16615), at 20 °C, with a product at 3.5% w/w lactic acid, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA+ 3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 20 % v/v.

- Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276) at 20 °C, with a product at 4% w/w lactic acid 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 75 % v/v.
- Bactericidal activity is demonstrated in phase 2, step 2 test (EN 16615), at 20 °C, with a product at 4% w/w lactic acid, with a contact time of 5 minutes, in dirty conditions (3.0 g/L BSA+ 3 mL/L sheep erythrocytes). In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.

Based on the efficacy data, it can be concluded that the bactericidal efficacy is demonstrated at the concentrations ranged from 3.5 to 4% w/w lactic acid, for a contact time of 5 minutes, in dirty conditions (3 g/L BSA+ 3 mL/L sheep erythrocytes), at room temperature on non-porous surfaces.
Regarding the claim for the use on porous surfaces, the efficacy data submitted did not support the demonstration of the efficacy. Indeed, according to the author of the efficacy trial, the bacterial inoculum is absorbed into the porous surface leading to a low recovery rate of the inoculum. The use on porous surfaces is not demonstrated.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

Experimental data on the efficacy of the biocidal product against target organism(s)-META SPC 5								
	Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
11	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	WIPES 3.5% L(+) lactic acid in product **BP11d** B-023-1874-0004 Test on impregnation liquid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	EN 1276:2009 Phase2, step1	Temperature: 20°C Contact time: 5 min Dirty conditions (3 g/L BSA) Concentrations tested: 1%, 75% and 80% v/v	Log reduction >5 The product is bactericidal at a concentration of 75 % (v/v)	[redacted]. *STUDY N° 980364A01* *Version n°1* RI 1
12	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	WIPES 4% L(+) lactic acid in product **BP11e** B-023-1874-0005 Test on impregnation liquid	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	EN 1276:2009 Phase2, step1	Temperature: 20°C Contact time: 5 min Dirty conditions (3 g/L BSA) Concentrations tested: 1%, 75% and 80% v/v	Log reduction >5 at a concentration of 75 % (v/v)	[redacted] *STUDY N° 980360A01* *Version n°1* RI 1
13	Bactericidal and yeasticidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	WIPES 3.5% L(+) lactic acid in product **BP11d** B-023-1874-0004 25 EUROWIPES - 3.5% LACTIC ACID IMPREGNATED WIPES (173.5g)	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans ATCC 10231,*	EN 16615:2015 Phase2, step2 Test with mechanical action	Temperature: 22°C±2.5°C Contact time: 5 min Dirty conditions: (3 g/l BSA + 3 mL/L sheep erythrocytes) (Note that the use of 3 g/l BSA + 3 mL / L sheep	Bacteria: Log reduction >5 at a concentration of 20% (v/v) Yeast: Log reduction >4 at a concentration of 10 %.	[redacted] *Final Report No :STULV19A A0228-1* *GLP* RI 1

						erythrocytes can be considered as worst case, because the use is not part of the medical area) Tested concentrations : 10, 20, 100% v/v		
14	Bactericidal and yeasticidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	WIPES 4% L(+) lactic acid in product **BP11e** B023-1874-0005 Wipes: 25 G&G 50 gms	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans ATCC 10231,*	EN 16615:2015 Phase2, step2 Test with mechanical action	Temperature: 22°C±2.5°C Contact time: 5 min Dirty conditions: (3 g/l BSA + 3 mL/L sheep erythrocytes) (Note that the use of 3 g/l BSA + 3 mL / L sheep erythrocytes can be considered as worst case, because the use is not part of the medical area) Tested concentrations : 10, 20, 100% v/v	Bacteria: Log reduction >5 at a concentration of 100 %(v/v) Yeasts: Log reduction > 4 at a concentration of 10 % v/v	[redacted] *Final Report No :STULV19A A0221-1* *GLP* RI 1

15	Bactericidal disinfectant	PT2 Hard surface disinfection – Disinfection for Toilets bowls surfaces	WIPES 3.5% L(+) lactic acid in product **BP11d** "Lingettes AJAX"	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	EN 16615 Phase2, step2	Temperature: 20°C Contact time: 5 min Dirty conditions (3 g/L BSA) Hard porous surface tested (ceramic) Tested concentrations : 10, 20, 100% v/v	The test item is considered as non-bactericidal on hard porous surfaces.	[redacted] *STUDY N° 3131.ATS.20.16615 version n°2* RI 3

Conclusion on the efficacy of the product

French competent authorities (FR CA) assessed that COLGATE-PALMOLIVE LACTIC ACID PT2 product family with four META SPC 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 1-2: Surface disinfection for PT2 uses by pouring on sponge and spreading on the hard porous and non-porous surface against bacteria, at room temperature, in dirty conditions, with a contact time of 15 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

META SPC 3: Surface disinfection for PT2 uses by spraying on hard porous and non-porous surfaces against bacteria, in dirty conditions, at room temperature, with a contact time of 5 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

META SPC 4: Surface disinfection for PT2 uses by spraying on hard porous and non-porous surfaces against bacteria in dirty conditions, at room temperature with a contact time of 5 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

META SPC 5: Surface disinfection for PT2 uses by ready to use wipes on hard non-porous surfaces against bacteria, in dirty conditions, at room temperature with a contact time of 5 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

2.2.5.6 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.

2.2.5.7 Known limitations

No undesirable or unintended side effects have been observed during the course of the studies with bottled (BDC) and Spray products.
For multipack wipes, close the package after opening.

2.2.5.8 Evaluation of the label claims

French competent authorities (FR CA) assessed that COLGATE-PALMOLIVE LACTIC ACID PT2 product family with four META SPC 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 1-2: Surface disinfection for PT2 uses by pouring on sponge and spreading on the hard porous and non-porous surfaces against bacteria, at room temperature, in dirty conditions, with a contact time of 15 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

META SPC 3: Surface disinfection for PT2 uses by spraying on hard porous and non-porous surfaces against bacteria, in dirty conditions, at room temperature, with a contact time of 5 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

META SPC 4: Surface disinfection for PT2 uses by spraying on hard porous and non-porous surfaces against bacteria in dirty conditions, at room temperature with a contact time of 5 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

META SPC 5: Surface disinfection for PT2 uses by ready to use impregnated wipes on hard non porous surfaces against bacteria, in dirty conditions, at room temperature with a contact time of 5 minutes.
Regarding the claim against bacterial spores, no efficacy data was presented. The efficacy against bacterial spore is not demonstrated.

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

The products of the COLGATE-PALMOLIVE LACTIC ACID PT2 family are ready to use products and are not intended for use with other biocidal product.

2.2.6 Risk assessment for human health

The COLGATE-PALMOLIVE_LACTIC ACID_PT2 biocidal products family (BPF) is composed of 4 meta SPC (meta SPC 1-2 (initially two meta SPCs merged into a single one), 3, 4 and 5) containing several products with a concentration of active substance L(+)-lactic acid ranging from 1.57% to 4.19% (technical concentration).
Products of the family are ready-to-use products supplied as BDC (Bucket Dilutable Cleaners) in bottle (meta SPC 1-2), as trigger sprays meta SPC 3 and 4) and as impregnated wipes (meta SPC 5), intended to be used by non-professional users for disinfection of toilets bowl and hard surfaces in PT2.
The pH of the products of the BPF is between 2.6 and 3.27.

2.2.6.1 Assessment of effects on Human Health

No acute oral and dermal toxicity study, nor skin and eye irritation studies neither skin sensitisation study have been performed on any product of the product family COLGATE-PALMOLIVE_LACTIC ACID_PT2.

Considering valid data available on each of the components in the mixture, classification of the products have been carried out according to the calculation rules laid down in the Regulation (EC) No 1272/2008 (CLP).
For the purpose of classification of the mixtures, the harmonised classification (when available) and classification proposed in the provided MSDS have been used for active substances and coformulants.

No human data is available.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Skin irritant
Justification for the value/conclusion	All the products of all the META SPC contain between 1.57% and 4.19% of active substance L(+)-lactic acid (technical) classified H314 (cat.1C) (ATP15). According to the classification rules laid down in the CLP regulation, a classification **Skin irrit. 2, H315: "Causes skin irritation" is required for the products of all meta SPCs of** COLGATE-PALMOLIVE_LACTIC ACID_PT2 family.
Classification of the product according to CLP	Skin Irrit. 2 – H315

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Serious eye damaging
Justification for the value/conclusion	Based on available data on the composition of the products, the sum of the relevant formulants classified H318 (Active substance and Decan-1-ol, ethoxylated (>2.5 moles EO) for Meta SPC 1-2 and 4) is equal or above the limit threshold of classification of 3% for all meta SPCs. According to the classification rules laid down in the CLP regulation, a classification **Eye Dam. 1, H318: "Causes serious eye damage" is required for the products of all meta SPCs of** COLGATE-PALMOLIVE_LACTIC ACID_PT2 family.
Classification of the product according to CLP	Eye Dam. 1 – H318

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The sum of the co-formulants classified for respiratory tract irritation (H335) is inferior to 0.1% for all meta SPCs. Therefore, no classification for respiratory tract irritation is required for the products of all meta SPCs of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family. Since the products of the family are neither classified for skin corrosion (only skin irritation) nor for acute toxicity by inhalation, the labelling EUH071 is not required even for the product for which an exposure to aerosols is expected.
Classification of the product according to CLP	Not irritant for respiratory tract.

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

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification for the skin sensitisation neither labelling EUH208 are required for any product of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family.
Classification of the product according to CLP	Not skin sensitizer.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizer for the respiratory tract
Justification for the value/conclusion	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification for the respiratory sensitisation is required for any product of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family.
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	-
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. The assessment is based on the available data on the composition of the products of the BPF and according to the classification rules laid down in the CLP Regulation.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic by oral route ATE_{mix} >2000 mg/kg for al META SPCs
Justification for the selected value	Based on available data on the composition of the products (see Confidential Annex) and according to the classification rules laid down in the CLP Regulation, no classification is required for the acute toxicity by oral route for any product of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family.
Classification of the product according to CLP	No classification

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not toxic by inhalation route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for the acute toxicity by inhalation for any product of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family.
Classification of the product according to CLP	No classification

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic by dermal route
Justification for the selected value	Based on available data on the composition of the products and according to the classification rules laid down in the CLP Regulation, no classification is required for the acute toxicity by dermal route for any product of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family.
Classification of the product according to CLP	No classification

Information on dermal absorption

No dermal absorption study has been submitted by the applicant. Therefore, according to the EFSA Guidance on dermal absorption (2017), the default dermal absorption value of 50% is chosen for the risk characterisation.

Values used in the Risk Assessment – Dermal absorption		
Substance	L(+)-lactic acid	Propan-2-ol (SOC for Meta SPC5)
Values	50% (if necessary)	50%
Justification for the selected values	According to EFSA Guidance 2017, a default value of 50% is chosen (water-based formulation, dilution)	According to EFSA Guidance 2017, a default value of 50% is chosen (water-based formulation, dilution)

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

As mentioned in the hazard assessment part (2.2.6.1), the following substance contributes to the classification:

- Decan-1-ol, ethoxylated (>2.5 moles EO) (Meta SPC 1-2 and 4)

According to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)" this classified ingredient that led to classification of products to the BPF should be considered as substance of concern (SoC). For this SoC, a banding evaluation is done according the scheme described in the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)", p356.

According to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)", an active substance (propan-2-ol) that acts as a co-formulant is present at a concentration of 0.1% (maximum) in the Meta SPC 5. As a Competent Authority Report (CAR) (with agreed reference values) is available for the Propan-2-ol, according to the Guidance on the BPR it should be identified as SoC.

Three substances have an European IOELV.

According to the "Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)" these substances should be identified as substance of concern (criterion number 5). However, following the e-consultation[3] of ES discussed and agreed in CG-45 (2021), IOELVs are not relevant for the general public.

Since the products of the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family are only intended to be used by non-professionals, these substances are only flagged and indicated as candidate to SoC by IOELV but not identified as SoC (please refer to Confidential Annex).

For additional information please refer to the confidential annex.

Available toxicological data relating to a mixture

None

Other

None

2.2.6.2 Exposure assessment and risk characterisation for human health

[3] Final Document "e-Consultation: Harmonized approach to consider a co-formulant as a substance of concern (SoC) based on its workplace exposure limits"- 29/01/2021.

Introductory remarks

The biocidal product family "COLGATE" is composed of 4 meta-SPC. The products are part of the Disinfectants, PT2: Disinfectants and algeacides not intended for direct application to humans or animals.

The products of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family are ready-to use products supplied in 3 types of packaging:

- Bottles for BDC (Bucket Dilutable Cleaner) (Meta SPC1-2)
- Trigger Spray (Meta SPC 3 and 4)
- Wipes (pre-impregnated) (Meta SPC 5)

They are intended to be used by non-professional users only for disinfection of domestic hard surfaces excluding kitchen surfaces (Use#1) and for disinfection of domestic toilet bowl surfaces (Use#2) as follows:

- BDC: 1/2 cap of product on a sponge corresponding to 18 g of product per m²
- Spray: 5 pressures of spray product to cover 1m² which corresponds to 5.5 g of product
- Wipes: 1 wipe to be used to disinfect 1m²

A rinsing is required after each product application.

Following the WG TOX I - 2021 that took place on March 2021 and in the frame of the discussion of the CAR of Lactic Acid TP6, it has been agreed not to perform the comparison of endogenous L-(+)-lactic acid with systemic exposure levels at product authorization. Consequently, any calculation regarding the estimation of level of exposure of lactic acid does not make sense anymore.

Therefore, since all the Meta SPCs of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family are classified Skin Irrit. 2 (H315) and Eye Dam. 1 (H318), only a qualitative local risk assessment has to be performed for the exposure to L-(+)-lactic.

In addition, a systemic risk assessment has been performed for the exposure to the propan-2-ol (SOC) for the products (impregnated wipes) of the Meta SPC 5.

Considerations on volatility of the propan-2-ol:

The relevance of the exposure and risk by inhalation to vapours of volatilised propan-2-ol can be screened with the HEEG 13 opinion (endorsed at TM IV 2011) on the assessment of inhalation exposure to volatilised biocides active substance.
If 0.328 * (mw * vp) ÷ AEL ≤ 1 (where mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa)), the risk from inhalation exposure is considered negligible.
The calculation is the following: 0.328*(60.09*5780) ÷ 10.7 = 10646.

This value being >1, the exposure to inhaled vapours of volatilised substance will be taken into account (if relevant for the exposure scenario).

Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the BPF

Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	na	No	na	Yes	na
Dermal	na	Yes	na	Yes	na
Inhalation	na	Yes	na	Yes	na

List of exposure scenarios

Summary table: exposure scenarios

The primary exposure of the Use#2 (disinfection of domestic toilet bowl surfaces) is considered to be covered by the primary exposure of the Use#1 (disinfection of domestic hard surfaces excluding kitchen surfaces).

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Use# 1: Hard surface disinfection		
Primary exposure		
Scenario [1]	**Application by mopping with a sponge (BDC: Bucket Dilutable Cleaner) (Meta SPC1-2)**	
Task [1.1]	**Application** *Pouring the biocidal product into the cap for dosing*	Non-professionals
Task [1.2]	**Application** *Pouring the content of the cap on a sponge*	Non-professionals
Task [1.3]	**Application** *Cleaning the surface with the product by wiping with the sponge*	Non-professionals
Task [1.4]	**Post application** *Cleaning of the sponge*	Non-professionals

Task [1.5]	**Post application** *Rinsing of the treated surfaces*	Non-professionals
Scenario [2]	**Application by spraying (Trigger spray) (Meta SPC 3&4)**	
Task [2.1]	**Application by spraying** *Spraying of the product on the surfaces using a trigger spray*	Non-professionals
Task [2.2]	**Post application** *Rinsing of the treated surfaces*	Non-professionals
Scenario [3]	**Application by wiping (RTU impregnated wipes)(Meta SPC 5)**	
Task [3.1]	**Application** *Wiping of the surface with the wipes impregnated with the product.*	Non-professionals
Task [3.2]	**Post application** *Rinsing of the treated surfaces*	Non-professionals
Secondary exposure		
Scenario [4]	**Secondary exposure to evaporation of substance from treated surfaces**	General public
Scenario [5]	**Secondary exposure – Dermal and oral exposure** Rubbing-off and hand-to-mouth exposure	General public
Use# 2: Toilet disinfection		
Primary exposure – Covered by the Primary exposure of the Use#1		
Scenario [6]	**Application by mopping with a sponge (BDC: Bucket Dilutable Cleaner) (Meta SPC1-2)**	
Task [6.1]	**Application** *Pouring the biocidal product into the cap for dosing*	Non-professionals
Task [6.2]	**Application** *Pouring the content of the cap on a sponge*	Non-professionals
Task [6.3]	**Application** *Cleaning the surface with the product by wiping with the sponge*	Non-professionals
Task [6.4]	**Post application** *Cleaning of the sponge*	Non-professionals
Task [6.5]	**Post application** *Rinsing of the treated surfaces*	Non-professionals
Scenario [7]	**Application by spraying (Trigger spray) (Meta SPC 3&4)**	
Task [7.1]	**Application by spraying** *Spraying of the product on the surfaces using a trigger spray*	Non-professionals
Task [7.2]	**Post application** *Rinsing of the treated surfaces*	Non-professionals
Scenario [8]	**Application by wiping (RTU impregnated wipes)(Meta SPC 5)**	
Task [8.1]	**Application** *Wiping of the surface with the wipes impregnated with the product.*	Non-professionals
Task [8.2]	**Post application** *Rinsing of the treated surfaces*	Non-professionals
Secondary exposure	**Not relevant**	

Secondary exposure to evaporation of lactic acid from treated surfaces is considered negligible.

Regarding the Use#2 (Toilet disinfection), the secondary exposure is considered negligible.

Reference values to be used in risk characterisation for Propan-2 ol (SoC – Meta SPC 5)

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort, medium and long-term (General population)	Inhalation, Human volonteer study	200 ppm or 68.2 mg/kg bw/d	6.4	100%	10.7 mg/kg bw/d

Professional users (including industrial users and trained professional users)

Not applicable. The product is intended to be used by non-professionals only.

Non-Professional users

Scenario [1] - Application by mopping with a sponge (BDC: Bucket Dilutable Cleaner) (Meta SPC1-2)

Local effects

- Qualitative risk assessment

The products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in bottles (BDC; Meta SPC 1-2) are intended to be used by non-professionals by applying the product on a sponge and cleaning of the hard surfaces by wiping with the sponge. The surfaces should be rinsed after cleaning.

The Meta SPC 1-2 is classified as follows:

- Skin Irrit. 2 (H315);
- Eye Dam. 1 (H318);

Therefore, according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C), a qualitative risk characterization for local effects is required when handling the product i.e. during the application and the post-application phases (Tasks [1.1], [1.2], [1.3], [1.4], [1.5]).

Table 1: **Local effects – Qualitative assessment during application by mopping with a sponge (BDC: Bucket Dilutable Cleaner) (Meta SPC1-2)**

Hazard		Exposure						Risk
Hazard category	**Effects in terms of C&L**	**Who is exposed**	**Tasks, uses, processes**	**Potential exposure routes**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM**	**Conclusion on risk** Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)
High	Eye Dam. 1 (H318)	Non-professional	Scenario [1] Tasks [1.1] [1.2] [1.3] [1.4] [1.5]	Ocular	Frequency: daily (applicant's data) Duration: equal to or less than few minutes per day	Practically no exposure since no splashes of the RTU product is expected.	No PPE, Labelling: • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use" (in order to eliminate the possible hand/eye contact) •"Avoid contact with eyes" •"Avoid splashes and spills during pouring" •The bottles sized above 1L and up to 2L must be adapted with a handle.	The risk is acceptable with the relevant RMMs. The uncertainties attached to conclusion are the following: (↓) Formulation: RTU product. No dilution to perform. No splashes generation to be expected. (↓) Mode of application: Product will be applied directly on the sponge. Contact between the opening of the bottles and the sponge is direct without space. No contact with eye expected. (↓)Labelling and RMMs to avoid contact of the product with eyes.

							Packaging: • Child-proof closure	(↓) No children and infant exposure assumed (↓) child-proof closure (↑) Exposure: a frequency of exposure equal to or less than once per week and equal to or less than few minutes per day cannot be ensured.
Low	Skin Irrit. (H315)	Non-professional	Scenario [1] Tasks [1.1] [1.2] [1.3] [1.4] [1.5]	Skin	Frequency: daily (applicant's data) Duration: equal to or less than few minutes per day	Skin exposure through potential liquid spills around the opening of the bottle and/or during application and rinsing of the product.	No PPE, Labelling: • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use" •"Avoid splashes and spills during pouring" •"Wash thoroughly the sponge with a great amount of water" •The bottles sized above 1L and up to 2L must be adapted with a handle.	The risk is acceptable with the relevant RMM. The uncertainties attached to conclusion are the following: (↓)Labelling and RMM "Wash hands after use" (↓) Exposure: a frequency of exposure equal to or less than one hour per day (↓) No children and infant exposure assumed (↓) child-proof closure (↑) Mode of application: Dermal contact with the product all long the application and post-application phases.

							Packaging: • Child-proof closure	

Conclusion - Scenario [1]

For products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in BDC (Meta SPC 1-2), **the risk during hard surface disinfection is acceptable** considering the qualitative risk assessment for local effects with the following risk mitigation measures (RMM):

- Wash hands after use
-
- Avoid contact with eyes
- Avoid splashes and spills during pouring.
- Wash thoroughly the sponge with a great amount of water.
- The bottles sized above 1L and up to 2L must be adapted with a handle.

and the packaging adapted with a child proof closure.

Scenario [2] - Application by spraying (Trigger spray) (Meta SPC 3&4)

Local effects

- Qualitative risk assessment

The products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged trigger spray (Meta SPC 3&4) are intended to be used by non-professionals by applying the product by spray on the hard surfaces. The surfaces should be rinsed after application.

The products are classified as follows:

- Skin Irrit. 2 (H315);
- Eye Dam. 1 (H318);

Therefore, according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C), a qualitative risk characterization for local effects is required when handling the product i.e. during the application and the post-application phases (Tasks [2.1] and [2.2]).

Table 2: **Local effects – Qualitative assessment during application by spraying (Trigger spray) (Meta SPC 3&4)**

Hazard		**Exposure**						**Risk**
Hazard category	**Effects in terms of C&L**	**Who is exposed**	**Tasks, uses, processes**	**Potential exposure routes**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM**	**Conclusion on risk** Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)
High	Eye Dam. 1 (H318)	Non-professional	Scenario [2] Tasks [2.1] & [2.2]	Eye	Frequency: daily (applicant's data) Duration: equal to or less than few minutes per day	Potential exposure to the droplets generated by the trigger spray during the application of the product.	None	The criteria needed to conclude for an acceptable risk **cannot be ensured.** The uncertainties attached to conclusion are the following: (↑) Packaging: Trigger spray. Generation of a cloud of droplets. (↑) Exposure: a frequency of exposure equal to or less than once per week and equal to or less than few minutes per day cannot be ensured.

								(↓) Packaging: product nozzle including distinct and easily determined open/closed positions which prevent accidental discharge of the spray (applicant's data) (↓) Modification of the formulation to avoid the generation of droplets.
Low	Skin Irrit. (H315)	Non-professional	Scenario [2] Tasks [2.1] & [2.2]	Skin	<u>Frequency:</u> daily (applicant's data) <u>Duration:</u> equal to or less than few minutes per day	Potential exposure to the droplets generated by the trigger spray during the application of the product and post-application.	No PPE, <u>Labelling:</u> • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use" <u>Packaging:</u> • Child-proof closure	The risk is acceptable with the relevant RMM. The uncertainties attached to conclusion are the following: (↓)Labelling and RMM "Wash hands after use" (↓) Exposure: a frequency of exposure equal to or less than one hour per day (↓) No children and infant exposure assumed (↓) child-proof closure (↑) Mode of application: Dermal contact with the product all long the application and post-application phases.

Conclusion - Scenario [2]

For products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in trigger spray (Meta SPC 3&4), **the risk during hard surface disinfection is not acceptable** considering the qualitative risk assessment for local effects.

Scenario [3] - Application by wiping (RTU impregnated wipes containing propane-2-ol)(Meta SPC 5)

Products of Meta SPC 5 are applied by wiping with ready-to-use impregnated wipes. Considering this mode of application, non-professionals are exposed to the product *via* dermal and inhalation routes simultaneously during application of the product. Since wet tissues are considered ready-to-use products, exposure from mixing and loading is not expected.

The exposure during the post-application task of rinsing the treated surfaces is considered to be covered by the exposure during the application by wiping.

Therefore, only one scenario of primary exposure is considered:

Description of Scenario [3.1]

Ready-to-use impregnated wipes are used to wipe bathroom and hard surfaces.

Inhalation exposure to aerosols generated during wiping is considered negligible.
However, inhalation exposure to vapors generated is expected.

To assess the exposure during this task, ConsExpo web and the Cleaning Fact Sheet have been used.
Dermal exposure has been also considered using the direct product contact – Instant application.

Vapor pressure of propan-2-ol is 5780 Pa at 25°C, which is higher than vapour pressure of water (3.2 kPa at 25°C).

The application rate claimed by the applicant for application by wiping is 1 wipe/m2
= 2.4449g product per wipe so 2.4449g product/m2
The expected total treated surface is 5 m^2 that can be wiped with impregnated wipes (CAR on propan-2-ol and UA discussions). Therefore, the amount of product deposited on the treated surface is 2.4449 g/m^2 x 5 m^2 = 12.2245 g.

Increasing release area mode has been considered because of treated surface area increases over time during wiping (ConsExpo Web Consumer Exposure models model documentation).

Molecular weight of Propan-2-ol (g/mol) 60.09

	Parameters	Value	Reference
Tier 1	Concentration of propan-2-ol	0.1%	
	Exposure duration (min)	240	ConsExpo default value

Description of Scenario [3.1]			
	Product amount for inhalation route (g)	12.2245 g	
	Room volume (m^3)	20	ConsExpo default value
	Ventilation rate (/h)	0.6	ConsExpo default value
	Application duration (min)	10	ConsExpo default value
	Release area (m^2)	5	Expert judgement
	Area of one hand – palm only	205 cm^2	Ad Hoc Recommendation 14 (2017)
	Product amount for dermal route (g)	0.25	ConsExpo default value
	Dermal absorption	50%	Dermal Absorption Default value – EFSA Guide 2017
	Body weight (kg)	60	Ad Hoc Recommendation 14 (2017)

Outcome of systemic exposure (propan-2-ol) and risk characterisation

Summary table: estimated systemic exposure and risk characterisation for non-professiona					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated tota uptake [mg/kg bw/day]**
Scenario [3] Primary Application Adult	1/no PPE	1.9×10^{-2}	2.1×10^{-3}	n.a	2.1×10^{-2}

The risk is considered acceptable for professional users during the application by wiping and the post-application task of rinsing the treated surfaces.

Local effects

- Qualitative risk assessment

The products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in RTU impregnated wipes (Meta SPC 5) are intended to be used by non-professionals by applying the product by wiping the hard surfaces with the impregnated wipes. The surfaces should be rinsed after cleaning.

The products are classified as follows:

- Skin Irrit. 2 (H315);
- Eye Dam. 1 (H318);

Therefore, according to the Guidance on the Biocidal Products Regulation - Volume III Human health - Assessment and Evaluation (Parts B + C), a qualitative risk characterization for local effects is required when handling the product i.e. during the application and the post-application phases (Tasks [3.1] and [3.2]).

Table 3: **Local effects – Qualitative assessment during application by wiping (RTU impregnated wipes)(Meta SPC 5)**

Hazard		Exposure						Risk
Hazard category	**Effects in terms of C&L**	**Who is exposed**	**Tasks, uses, processes**	**Potential exposure routes**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM**	**Conclusion on risk** Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)
High	Eye Dam. 1 (H318)	Non-professional	Scenario [3] Tasks [3.1]& [3.2]	Eye	<u>Frequency:</u> daily (applicant's data) <u>Duration:</u> equal to or less than few minutes per day	Practically no exposure expected.	No PPE, <u>Labelling:</u> • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use" (in order to eliminate the possible hand/eye contact) •"Avoid the contact with eyes"	The risk is acceptable with the relevant RMM. The uncertainties attached to conclusion are the following: (↓) Formulation: RTU product. No splashes generation expected. (↓)Labelling and RMM to avoid contact of the product with eyes. (↓) No children and infant exposure assumed (↓) child-proof closure (↑) presence of a plastic closure (↑) Exposure: a frequency of exposure equal to or less

								than once per week and equal to or less than few minutes per day cannot be ensured.
Low	Skin Irrit. (H315)	Non-professional	Scenario [3] Tasks [3.1]& [3.2]	Skin	<u>Frequency:</u> daily (applicant's data) <u>Duration:</u> equal to or less than few minutes per day	Potential exposure to the product during the application and post-application.	No PPE, <u>Labelling:</u> • According to CLP • Instructions for use and Storage • P sentence on the label • "Wash hands after use"	The risk is acceptable with the relevant RMM. The uncertainties attached to conclusion are the following: (↓)Labelling and RMM "Wash hands after use" (↓) Exposure: a frequency of exposure equal to or less than one hour per day (↓) No children and infant exposure assumed (↓) child-proof closure (↑) presence of a plastic closure (↑) Mode of application: Dermal contact with the product all long the application and post-application phases.

Conclusion - Scenario [3]

For products from the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged impregnated wipes (Meta SPC 5), **the risk during hard surface disinfection is acceptable** considering the systemic and local effects with the following risk mitigation measures (RMM):

- Wash hands after use
- Avoid the contact with eyes
- Keep out of reach of children and non-target animals/pets

General public

Secondary exposure to evaporation of propan-2-ol from treated surfaces (Scenari 4 and 5 – Meta SPC 5)

Considering the high volatility of the propan-2-ol which is present at a low content of 0.1%, its evaporation after application and rinsing is considered negligible.
Therefore the secondary exposure of the general public to the propan-2-ol is negligible.

Local effects (dermal and oral exposure)

All products of Meta-SPC 1-2, 3, 4 and 5 are classified Skin Irrit. 2 (H315) and Eye Dam. 1 (H318).

Therefore risk mitigation measures should be added in order to avoid direct contact with wet treated surfaces:

- Do not touch the surface until the surface is rinsed and dry
- Children should not be present during disinfection and until the surface is rinsed and dry

Monitoring data

None

Dietary exposure

By definition, PT02 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 COLGATE PALMOLIVE LACTIC ACID PT2 uses.

Residue definitions
Not relevant

List of scenarios
/

Information of non-biocidal use of the active substance

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.

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Not relevant

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Not relevant

Estimating transfer of biocidal active substances into foods as a result of non-professional use
Not relevant

Exposure associated with production, formulation and disposal of the biocidal product

Not relevant

Aggregated exposure

None

2.2.6.3 Risk characterisation for human health

[Please insert rows for additional reference values if necessary, e.g. for local effects.]

Maximum residue limits or equivalent
Not relevant

Risk for consumers via residues in food

By definition, PT02 biocidal product is not intended for direct application to humans or animals and is not used for direct contact with food or feeding stuffs. Thus no evaluation has been conducted with regard to risk for consumer under indirect exposure via food.

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

[Please, refer to Guidance for Human Health Risk Assessment, Volume III, Part B - to characterise the risk in case of exposure to several active substances or substances of concern within a product]

2.2.7 Risk assessment for animal health

The risk for animal health is considered covered by human health assessment.

2.2.8 Risk assessment for the environment

The biocidal product family (BPF) contain several biocidal products (BP) grouped into four sub-groups (meta-SPC). All BPs contain L(+) lactic acid. The data on active substance are provided by the assessment report of L(+) lactic acid for PT02, 03, 04[4]. The available ecotoxicological information are used for the environmental risk assessment.

One substance of concern has been identified, Propan-2-ol. However, since the Propan-2-ol has minor impact on the mixture toxicity no additional assessment is provided in the public PAR for this substance. Details about the classification or non-classification of co-formulants as substance of concern (SoC) can be found in the confidential PAR.

2.2.8.1 Effects assessment on the environment

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

No new ecotoxicological studies have been carried out with the biocidal product family. The active substance is either not classified as hazardous to the environment under Reg. (EC) 1272/2008, and the co-formulants classified as hazardous to the environment are not present at sufficient concentrations to trigger hazard classification. The products are thus not classified for the environment.

Refer to confidential PAR for further explanations.

Further Ecotoxicological studies

No new data is available.

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

Data waiving	
Information requirement	No new data is available.
Justification	The biocidal product family is not anticipated to have any effect on non-target organisms (flora and fauna), as the application is indoors only.

[4] Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Assessment Report L(+) lactic acid Product-type 02, 03 and 04, June 2017

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

Data waiving	
Information requirement	Not relevant.
Justification	The product is not to be used outdoors and therefore this endpoint does not apply.

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

Data waiving	
Information requirement	Not relevant.
Justification	The product is not accessible to non-target organisms. It is therefore not edible.

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

No new data is available.

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

Refer to the exposure assessment below.

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

At WGII2020, it was stated that Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) Lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not be taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (Tier 1). Modelling of groundwater exposure in case of Lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater, without need for further calculations.

For soil concentration calculations, a DT50 of 30 days was stated without the need of further studies.

Leaching behaviour (ADS)

No new data is available.

Testing for distribution and dissipation in soil (ADS)

No new data is available.

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

No new data is available.

Testing for distribution and dissipation in air (ADS)

No new data is available.

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

No new data is available.

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

No new data is available.

PNEC values summary table

The effect assessment of the BPs on the environment is concluded from ecotoxicity and e-fate data from the active substance assessment report.
Based on the L(+) lactic acid assessment report, the relevant PNECs for the environmental risk characterisation are reported below.

PNEC		Justification
$PNEC_{STP}$	10 mg/L	An NOEC of 100 mg/L from an activated sludge respiration test no inhibitory effect is reported in the AR (2017). An assessment factor (AF) of 10 was applied to the NOEC to derive the PNEC.
$PNEC_{water}$	3.9 mg/L	The $PNEC_{water}$ presented in the AR (2017) was derived from the EC_{50} of 3900 mg/L for fish and an AF of 1000.
$PNEC_{sediment,EPM}$	4.8 mg/kg ww	Equilibrium partitioning method
$PNEC_{soil,EPM}$	1.9 mg/kg ww	Equilibrium partitioning method

2.2.8.2 Exposure assessment

All BPs are intended to be used for the disinfection of household hard surfaces (PT02), i.e. bathroom and hard surfaces other than kitchen, as well as toil bowl surfaces.

Product types and maximum concentrations of active substance in BPs of Meta-SPC are presented in the table below:

Meta-SPC	Product type	Product description	Mode of application	Maximum concentration L(+) lactic acid
Meta-SPC 1-2	PT2	Bucket Dilutable Cleaners	Mopping, scrubbing	2.93%
Meta-SPC 3	PT2	Sprays	Spraying	3.35%
Meta-SPC 4	PT2	Sprays	Spraying	2.51%
Meta-SPC 5	PT2	Wipes	Wiping with ready to use impregnated wet wipes	4.19%

In the Emission Scenario Document for Product Type 2[5], two emission scenarios for disinfectants used in the sanitary sector are presented:
(1) based on tonnage and
(2) based on consumption.

The tonnage approach presented in the confidential PAR indicates that the consumption approach is the worst case one.

According to the Report on the Workshop for PT 1-6 [6] both approaches shall be presented.

General information

Assessed PT	PT 2
Assessed scenarios	**Scenario 1 :** Disinfectants used for sanitary purposes based on an average consumption (ESD RIVM 2001, Table 2.2, p.10)

[5] RIVM Report 601450008 Supplement to the methodology for risk evaluation of biocides, Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), RIVM, March 2001

[6] WORKSHOP on environmental risk assessment for Product Types 1 to 6, European Commission, 2008

ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001
Approach	**Scenario 1:** Average consumption
Distribution in the environment	Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	**Scenario 1:** Production: No Formulation No Use: Yes Service life: No
Remarks	-

Emission estimation

Scenario 1 – Disinfectants used for sanitary purposes - Average consumption approach

Input parameters for calculating the local emission				
Input	**Value**		**Unit**	**Remarks**
Scenario: Disinfectants used for sanitary purposes based on an average consumption				
Number of inhabitants feeding one STP*(N_{local})*	10 000		[-]	Default
Fraction of substance disintegrated during or after application (before release to the sewage system) (F_{disint})	0		[-]	Default
Penetration factor of disinfectant *(F_{penetr})*	0.5		[-]	Default
Active substance in product ($C_{product}$)	Meta SPC1-2	2.93E-02	kg.l^{-1}	Maximum value considering product densities close to 1.
	Meta SPC3	3.35E-02		
	Meta SPC4	2.51E-02		
	Meta SPC5	4.19E-02		
Consumption per capita *($Q_{product}$)*	0.007 (General purpose and lavoratory)		l.cap^{-1}.d^{-1}	Default
Fraction released to wastewater *(F_{water})*	1		[-]	Default

Calculations for Scenario [1]

$$Elocal_{water} = N_{local} \times Q_{product} \times C_{product} \times F_{penetr} \times (1 - F_{disint}) \times F_{water}$$

Resulting local emission to relevant environmental compartments					
Compartment	**Local emission (Elocal) [kg/d]**				**Remarks**
Wastewater	Meta SPC1-2	Meta SPC3	Meta SPC4	Meta SPC5	-
	1.03E+00	1.17E+00	8.79E-01	1.47E+00	

The highest estimated local emission value of L(+) lactic acid to wastewater results from uses of BPs of Meta-SPC5. The following exposure calculations were performed considering highest emission values to environment obtained for BPs of Meta-SPC5 as it covers emissions following uses of BPs of all Meta-SPCs.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	Yes	Yes	No	No	Yes	No	Yes	Yes	Not relevant

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	90.08	g/mol	AR 2017
Vapour pressure (at 20°C)	0.4	Pa	AR 2017
Water solubility (at 25°C)	1 000 000	mg/l	AR 2017
Log Octanol/water partition coefficient	-0.74	Log 10	AR 2017
Organic carbon/water partition coefficient (Koc)	20	l/kg	AR 2017
Henry's Law Constant (at 20°C)	3.60E-05	Pa/m3/mol	AR 2017
Biodegradability	Ready biodegradable, not failing 10-days window criterion		AR 2017
DT_{50} for degradation in soil	30	d (at 12ºC)	30d as refinement for 90d value in AR (WGII2020)
ktotal (0.2 m relevant for STP)	2.61E-02	d-1	Calculated

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	All Scenarios	
Air	2.50E-05	-
Water	22.5	-
Sludge	0.20	-
Degraded in STP	7.73E+01	-

Calculated PEC values

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}** (EPM covered by water)	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/m^3]	[µg/l]
Scenario 1 (Meta SPC5)	1.65E-01	1.65E-02	n.r.	3.75E-03	2.42E+00

n.r.: Not relevant

The concentration of the active substance L(+) Lactic acid in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 µg/L). A qualitative argumentation for non performing Focus Pearl refinement is developed in the following section "Risk characterization".

Primary and secondary poisoning

Primary poisoning

As the proposed uses of BPs will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

The secondary poisoning assessment is not relevant for the active substance L(+) Lactic acid. This substance is unlikely to bioaccumulate in aquatic or terrestrial environment according to the ECHA Guidance Vol IV Part B+C. It has a low Log Kow (-0.74 < 3) and a BCF < 100 L/kg (BCF_{fish} = 4.80E-02 L/kg and $BCF_{earthworm}$ = 6.78 L/kg). These values indicate a negligible potential for bioconcentration in biota and no accumulation of this substance in the food chain is expected.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: As stated in the L(+) lactic acid assessment report, L(+) lactic acid is not considered to be used as fumigant. The vapour pressure of L(+) lactic acid is 0.4 Pa at 20°C and the Henry constant is 3.6 x 10^{-5} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+) lactic acid to

the atmosphere are unlikely to occur. Due to an estimated half-life in the atmosphere of 2.71 d corresponding to 3.91 d for the chemical lifetime the potential for long-range transport of L(+) lactic acid in air is indicated (ref. to Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004): " ... a chemical that migrates significantly through the air, its half-life in air should be greater than two days ... "). However, according to the Vol IV Part B+C (2017) effects on stratospheric ozone and acidification are not expected because L(+) lactic acid does not contain halogens, nitrogen or sulphur substituents. L(+) lactic acid shows no absorption bands in the so-called atmospheric window (range from 800 to 1200 nm). Therefore, L(+) lactic acid has no global-warming potential.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values		
	Meta-SPC	**PEC/PNEC$_{STP}$**
Scenario 1	Meta-SPC5	1.65E-02

Conclusion: The calculated PEC/PNEC value for the sewage treatment plant (STP) is significantly < 1. Therefore, the proposed use of all BPs does not pose a risk to microorganisms in the STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values			
	Meta-SPC	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$ PNEC EPM: covered by surface water**
Scenario 1	(Meta SPC5)	4.23E-03	n.r.

Conclusion: The calculated PEC/PNEC value for surface water (covering sediment) is significantly < 1. Therefore, the proposed use of all BPs does not pose a risk to aquatic compartment.

Terrestrial compartment

Calculated PEC/PNEC values		
	Meta-SPC	**PEC/PNEC$_{soil}$**
Scenario 1	(Meta SPC5)	1.97E-03

Conclusion: The calculated PEC/PNEC value for soil is significantly < 1. Therefore, the proposed use of all BPs does not pose a risk to terrestrial compartment.

Groundwater

	Meta-SPC	**PEClocal$_{groundwater}$ (µg/l)**
Scenario 1	(Meta SPC5)	2.42E+00

The calculated value for PEClocalgroundwater exceeds the limit value in groundwater of 0.1 µg.L^{-1} for biocides (Directives 2006/118/EC and 98/83/EC).

Nevertheless, for L(+) Lactic acid, it was decided during the WG-II-2020 that only arguments to support a qualitative assessment without further calculations should be provided. The harmonized justification is presented below:

"Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic.

For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed."

Primary and secondary poisoning

Primary poisoning

As the proposed uses of BPs will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

As detailed in the exposure assessment section above, active substance L(+) Lactic Acid has a log Kow <3 and BCF < 100. Thus, these values indicate a negligible potential for bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for this substance.

In conclusion, for this biocidal product family, risks are acceptable for all compartments under all the scenarios.

Mixture toxicity

All BPs contain only one active substance. There are no substances of concern with regard to the environment. An assessment of the mixture toxicity is therefore not necessary.

Aggregated exposure (combined for relevant emission sources)

As stated in the L(+) lactic acid assessment report, According to the " Decision tree on the need for estimation of aggregated exposure" (BIP6 . 7 Decision Tree Agg Expo) the requirement for aggregated exposure estimations was checked for L(+) lactic acid. L(+) lactic acid is also regulated in other regulatory areas (e.g. cosmetics regulation, food legislation). The amount of L(+) lactic acid that is used annually for biocidal purposes amounts to 5% of the total production and import volume of L(+) lactic acid in the EU in 2012. Thus, the biocidal use of L(+) lactic acid accounts for less than 10% of the total production and import volume in the EU."
The intended uses of the BPF products are widely dispersive and do not represent a specific emission pattern. Consequently, it has been concluded that no aggregated exposure assessment for a.s. L(+) lactic acid has to be performed.

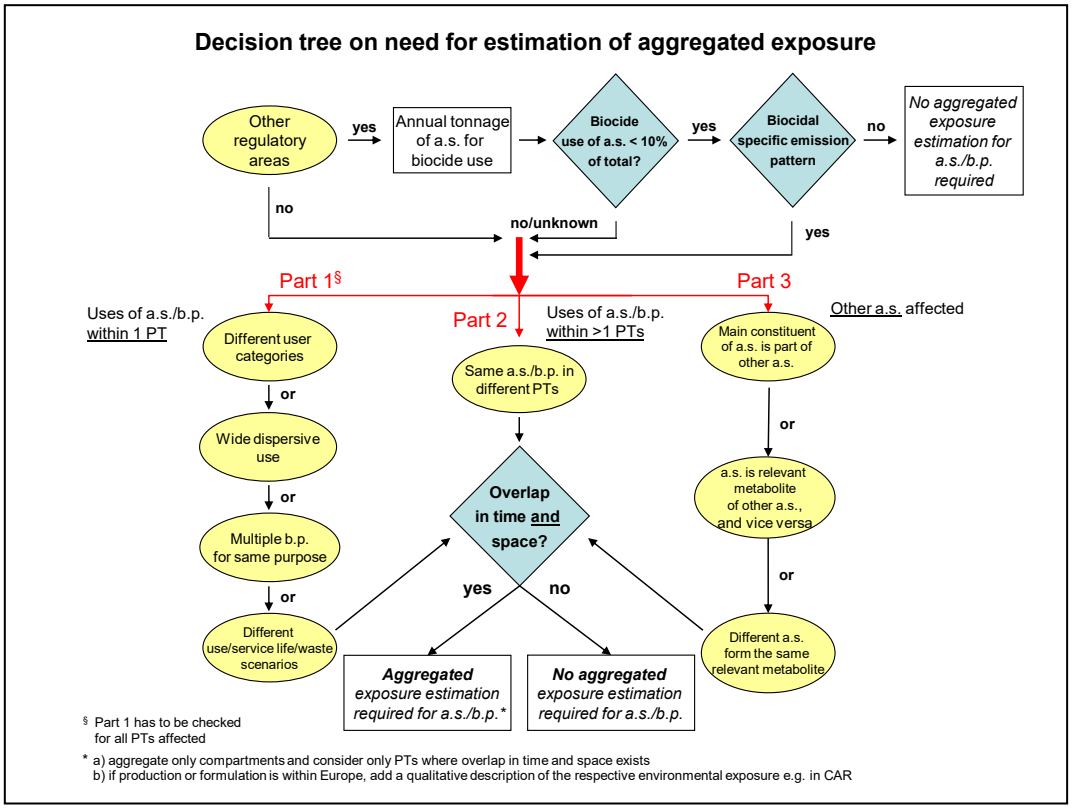

Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
The biocidal product family (BPF) contains several biocidal products (BP) grouped into four sub-groups (meta-SPC). All BPs are intended to be used for disinfection of household hard surfaces, i.e. on bathroom surfaces and toilets bowls surfaces. One substances of concern has been identified for the environment, Propan-2-ol, but since the SoC has minor impact on the mixture toxicity no additional assessment is provided in the public PAR for this substance. It has been demonstrated that uses of the BPF does not pose a risk to environmental compartments.

2.2.9 Measures to protect man, animals and the environment

[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.
[Please, refer to Guidance for Human Health Risk Assessment, Volume III, Part B - to characterise the risk in case of exposure to several products]

2.2.11 Comparative assessment

[Please, delete if not relevant]

[Please include a reference to the comparative assessment report to be forwarded to ECHA, the other MSs and to the Commission, in accordance with Art. 23(2) of the BPR].

2.2.11.1 Screening phase

- Description of the assessment of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance.
- Consideration on whether the active substance(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but that benefit from derogation in accordance with Article 5(2) of the BPR.
- Conclusion of the screening phase: Stop comparative assessment / Tier IA / Tier IB / Tier II

2.2.11.2 Tier IA

- Description of biocidal products included in the comparison
- Main outcome of the comparison for:
    - risk for human health, animal health and the environment
    - significant economic or practical disadvantages
- Conclusion of Tier IA: Tier IB / Tier II

2.2.11.3 Tier IB

- Main outcome of the comparison for:
    - risk for human health, animal health and the environment
    - significant economic or practical disadvantages
- Conclusion of Tier IB: End of comparative assessment / Tier II

2.2.11.4 Tier II

- Description of non-chemical alternatives included in the comparison
- Main outcome of the comparison for:
    - risk for human health, animal health and the environment
    - efficacy
    - significant economic or practical disadvantages
- Conclusion of Tier II: stop comparative assessment/ End of comparative assessment

2.2.11.5 Overall conclusion

- Final recommendation in terms of restriction(s) or prohibition of the biocidal product subject to comparative assessment.

[Please see the latest version of the SPC in the relevant Member State to see all the authorised uses and RMMs authorised for the product].

3 Annexes[7]

3.1 List of studies for the biocidal product (family)

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]		QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF BECTERIVIDAN ACTIVITY OF CHEMICAL DISINFECTANTS AND ANTISPETICS USED IN FOOD, INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS (S-2017-04065 PROVA)	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		EVALUATION OF THE BACTERICIDAL ACTIVITY OF THE PRODUCT "CLEAN FRESH" (660014) ACCORDING TO NF EN 13697(1)	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF BECTERIVIDAN ACTIVITY OF CHEMICAL DISINFECTANTS AND ANTISPETICS USED IN FOOD, INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS (S-2017-04066 PROVA)	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		RAPPORT D'ESSAI N°439/1110-1	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		EVALUATION OF THE BACTERICIDAL ACTIVITY OF THE PRODUCT "AJAX ANTIBACTERIAL ALL PURPOSE CLEANER LIQUID FRESH" (663274) ACCORDING TO NF EN 13697(1)	Yes	COLGATE-PALMOLIVE R&D
[redacted]		EVALUATION OF THE BACTERICIDAL ACTIVITY OF THE PRODUCT "ANTIBACTERIEN OPTIMAL 7 SANS JAVEL" (660013) ACCORDING TO NF EN 13697(1)	Yes	COLGATE-PALMOLIVE SERVICES SA

[7] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

[redacted]		BACTERICIDAL EFFECTIVENESS-ACTIVITE BACTERICIDE SELON EN 1276 ET EN 13697-RAPPORT N°847957A01	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		SUSPENSION BACTERICIDAL EFFECTIVENESS IN DIRTY CONDITIONS ON IMPREGNATION LIQUID AB WIPES 3.5%	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		SUSPENSION BACTERICIDAL EFFECTIVENESS IN DIRTY CONDITIONS ON IMPREGNATION LIQUID AB WIPES 4% LACTIC ACID	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		BACTERICIDAL AND YEASTICIDAL ACTIVITY ON NON-POROUS SURFACE WITH MECHANICAL ACTION EMPLOYING WIPES IN MEDICAL AREA IN DIRTY CONDITIONS ON 25 WIPES OF 50 GSM, JACOB HOLM INDUSTRIES-3.5% LACTIC ACID IMPREGNATED WIPES	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		BACTERICIDAL AND YEASTICIDAL ACTIVITY ON NON-POROUS SURFACE WITH MECHANICAL ACTION EMPLOYING WIPES IN MEDICAL AREA IN DIRTY CONDITIONS ON 25 WIPES OF 50 GSM, NBOND NONWOVENS-4% LACTIC ACID IMPREGNATED WIPES	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		EVALUATION OF THE BACTERICIDAL ACTIVITY OF THE PRODUCT "AJAX WC POWER" (780069) ON THE BASIS OF NF 13697	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]		EVALUATION OF THE BACTERICIDAL ACTIVITY OF THE AJAX WIPES (3.5% LACTIC ACID BP11D) ACCORDING TO A METHOD BASED ON NF EN 16615	Yes	COLGATE-PALMOLIVE SERVICES SA
[redacted]	2019	Certificate of analysis Solution of BP3A - B02975830000	No	Colgate Palmolive Services SA
[redacted]	2019	Certificate of analysis Solution of BP7 – B02959350004	No	Colgate Palmolive Services SA
[redacted]	2019	Certificate of analysis Solution of BP5 – B02940950007	No	Colgate Palmolive Services SA

[redacted]	2019	Certificate of analysis Solution of BP11E – B02318740005	No	Colgate Palmolive Services SA
[redacted]	2019	Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP3A - B02975830000" Report no. 2019/6 AM	No	Colgate Palmolive
[redacted]	2019	Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP7 - B02959350004" Report no. 2019/8 AM	No	Colgate Palmolive
[redacted]	2019	Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP5 - B02940950007" Report no. 2019/7 AM	No	Colgate Palmolive
[redacted]	2019	Stability study 8 weeks at 40°C and 24 months at 20°C on the test item "BP11E - B02318740005" Report no. 2019/9 AM	No	Colgate Palmolive
[redacted]	2019	CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP3A - B02975830000" Report no. AAC41560,	No	Colgate Palmolive Services SA
[redacted]	2019	CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM BP7 - B02959350004 Report no. AAC41555	No	Colgate Palmolive Services SA
[redacted]	2019	CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP5 - B02940950007" Report no. AAC41557	No	Colgate Palmolive Services SA
[redacted]	2019	CHEMICAL/PHYSICAL ANALYSIS ON THE TEST ITEM "BP11E - SOLUTION OF B02318740005"	No	Colgate Palmolive Services SA
[redacted]	2020	Particle size distribution - Spray Pattern -Discharge rate - Clogging Report no. N° 9-525-2/20 embeded in Eurofins Report N° 1170864A01 v3	No	Colgate Palmolive Services SA
[redacted]	2020	Particle Size distribution - Spray pattern - Discharge rate - Clogging Report no. N°9-525-3/20	No	Colgate Palmolive Services SA

[redacted]	2021	Granulometric particle size analysis on one type of pump sprays. Report from LEREM N° 9-629-2/21	No	Colgate Palmolive Services SA
[redacted]	2020	STABILITY STUDY AT 40°C FOR 8 WEEKS ON THE TEST ITEM "BP11D - AB WIPES PURE FRESHNESS 3,5% LACTIC ACID - B02318740004"	No	Colgate Palmolive Services SA
[redacted]	2019	LOW TEMPERATURE STABILITY ON THE TEST ITEM "BP3A - B02975830000" Report no. STULV19AA0137-1 GLP	No	Colgate Palmolive Services SA
[redacted]	2019	LOW TEMPERATURE STABILITY ON THE TEST ITEM "BP7 - B02959350004" Report no. STULV19AA0134-1 GLP	No	Colgate Palmolive Services SA
[redacted]	2019	LOW TEMPERATURE STABILITY ON THE TEST ITEM "BP5 - B02940950007" Report no. STULV19AA0132-1 GLP	No	Colgate Palmolive Services SA
[redacted]	2019	LOW TEMPERATURE STABILITY ON THE TEST ITEM "BP11E - SOLUTION OF B02318740005" Report no. STULV19AA0137-1 GLP	No	Colgate Palmolive Services SA
[redacted]	2019	Determination of the Flash Point on the sample BP11e-Solution of B02318740005	No	Colgate Palmolive Services SA
[redacted]	2020	CORROSION TEST ON THE TEST ITEM "BP7 AJAX ALL IN ONE-B02959350004" Report no. STULV20AA2306-1	No	Colgate Palmolive Services SA
[redacted]	2020	CORROSION TEST ON THE TEST ITEM "BP11E - SOLUTION OF B02318740005 - AJAX OPTIMAL 7 WIPES BATHROOM AND TOILET AT 4% OF LACTIC ACID" Report no. STULV20AA1707-1	No	Colgate Palmolive Services SA
[redacted]	2020	CORROSION TEST ON THE TEST ITEM "BP3B AJAX HEALTHY HOME SAGE AND APPLE 2.6% LACTIC ACID - B02975830001" Report no. STULV20AA2300-1	No	Colgate Palmolive Services SA
[redacted]	2020	CORROSION TEST ON THE TEST ITEM "BP5- AJAX SPRAY ANTIBAC 2.4% LA - B02940950007" Report no. STULV20AA3176-1	No	Colgate Palmolive Services SA

[redacted]	2019	ANALYTICAL METHOD VALIDATION FOR THE QUANTIFICATION OF LACTIC ACID IN THE TEST ITEM "BP11E – B02318740005" Report no. STULV19AA0142-1 GLP	No	Colgate Palmolive Services SA

3.2 Output tables from exposure assessment tools

Human risk assessment: Scenario [3.1] Application by wiping with impregnated wiped (SoC Propan-2-ol – Meta SPC 5).

Scenario Primary WIPES.xlsx

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[8]

3.6 Confidential annex

3.7 Other

8 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.