

Official Journal of the European Union

L 297



English edition

Legislation

Volume 65

17 November 2022

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2022/2252 of 11 November 2022 granting a Union authorisation for the biocidal product family ‘Brenntag GmbH Propan-2-ol Product Family’ ⁽¹⁾** 1
- ★ **Commission Implementing Regulation (EU) 2022/2253 of 14 November 2022 granting a Union authorisation for the biocidal product family ‘Colgate-Palmolive Lactic acid PT 2’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ⁽¹⁾** 33

DECISIONS

- ★ **Council Implementing Decision (EU) 2022/2254 of 14 November 2022 authorising Bulgaria to introduce a special measure derogating from Article 287 of Directive 2006/112/EC on the common system of value added tax** 69
- ★ **Commission Decision (EU) 2022/2255 of 24 October 2022 on the initiation of the detailed examination of certain performance targets contained in the revised draft performance plan for the third reference period submitted at functional airspace block level by Belgium, Germany, France, Luxembourg, and the Netherlands pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council (notified under document C(2022) 7438) ⁽¹⁾** 71
- ★ **Commission Decision (EU) 2022/2256 of 15 November 2022 on the initiation of the detailed examination of certain performance targets contained in the revised draft performance plan for the third reference period submitted at functional airspace block level by Switzerland pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council (notified under document C(2022) 8076) ⁽¹⁾** 80

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

Corrigenda

- ★ **Corrigendum to Commission Implementing Regulation (EU) 2019/1383 of 8 July 2019 amending and correcting Regulation (EU) No 1321/2014 as regards safety management systems in continuing airworthiness management organisations and alleviations for general aviation aircraft concerning maintenance and continuing airworthiness management (OJ L 228, 4.9.2019) 83**

- ★ **Corrigendum to Council Decision (EU) 2022/1975 of 13 October 2022 on the position to be taken on behalf of the European Union within the Trade Committee established by the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part as regards the amendment of Annexes 10-A and 10-B to the Agreement (OJ L 271, 19.10.2022) 84**

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2252

of 11 November 2022

granting a Union authorisation for the biocidal product family ‘Brenntag GmbH Propan-2-ol Product Family’*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 30 June 2016, Brenntag GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘Brenntag GmbH Propan-2-ol Product Family’ of product-types 1, 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-BL025673-43 in the Register for Biocidal Products.
- (2) ‘Brenntag GmbH Propan-2-ol Product Family’ contains propan-2-ol as the active substance, which is included in the Union list of approved active substance referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 1, 2 and 4.
- (3) On 15 March 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 4 November 2021, the Agency submitted to the Commission an opinion ⁽²⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘Brenntag GmbH Propan-2-ol Product Family’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Brenntag GmbH Propan-2-ol Product Family’ is a ‘biocidal product family’ within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 22 November 2021, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 7 October 2021 on the Union authorisation of ‘Brenntag GmbH Propan-2-ol Product Family’ (ECHA/BPC/290/2021), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Brenntag GmbH Propan-2-ol Product Family'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on biocidal products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027707-0000 is granted to Brenntag GmbH for the making available on the market and use of the biocidal product family 'Brenntag GmbH Propan-2-ol Product Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union Authorisation is valid from 7 December 2022 to 30 November 2032.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Brenntag GmbH Propan-2-ol Product Family

Product type 1 – Human hygiene (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: EU-0027707-0000

R4BP asset number: EU-0027707-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Brenntag GmbH Propan-2-ol Product Family
------	--

1.2. **Product type(s)**

Product type(s)	PT01 – Human hygiene (Disinfectants) PT04 – Food and feed area (Disinfectants) PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
-----------------	---

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Brenntag GmbH
	Address	Messeallee 11, 45131 Essen Germany
Authorisation number	EU-0027707-0000	
R4BP asset number	EU-0027707-0000	
Date of the authorisation	7 December 2022	
Expiry date of the authorisation	30 November 2032	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Kesla Pharma Wolfen GmbH
Address of manufacturer	Kesla-Str. 1, 06803 Bitterfeld Germany
Location of manufacturing sites	Kesla-Str. 1, 06803 Bitterfeld Germany

Name of manufacturer	Dreve GmbH
Address of manufacturer	Max-Planck-Str. 31, 59423 Unna Germany
Location of manufacturing sites	Kesla Pharma Wolfen GmbH, Kesla-Str. 1, 06803 Bitterfeld Germany
Name of manufacturer	Buzil-Werk Wagner GmbH & Co. KG
Address of manufacturer	Fraunhoferstr. 17, 87700 Memmingen Germany
Location of manufacturing sites	Fraunhoferstr. 17, 87700 Memmingen Germany
Name of manufacturer	Wigol W. Stache GmbH
Address of manufacturer	Textorstr. 2, 67547 Worms Germany
Location of manufacturing sites	Textorstr. 2, 67547 Worms Germany
Name of manufacturer	KiiltoClean Oy
Address of manufacturer	Tengströminkatu 6, FI-20630 Turku Finland
Location of manufacturing sites	PL 157, FI-20101 Turku Finland
Name of manufacturer	Witty GmbH und Co. KG
Address of manufacturer	Herrenrothstr. 12, 86424 Dinkelscherben Germany
Location of manufacturing sites	Herrenrothstr. 12, 86424 Dinkelscherben Germany
Name of manufacturer	Carl Roth GmbH und Co. KG
Address of manufacturer	An der Mole 5, 76189 Karlsruhe Germany
Location of manufacturing sites	An der Mole 5, 76189 Karlsruhe Germany
Name of manufacturer	Pro-cura Hy-med GmbH
Address of manufacturer	Stresemannstrasse 364, 22761 Hamburg Germany
Location of manufacturing sites	A.F.P., Otto-Brenner-Str. 16, 21337 Lüneburg Germany
Name of manufacturer	Pico-medical GmbH
Address of manufacturer	Fangdieckstr. 24, 22547 Hamburg Germany
Location of manufacturing sites	A.F.P., Otto-Brenner-Str. 16, 21337 Lüneburg Germany
Name of manufacturer	Anti-Germ International GmbH
Address of manufacturer	Oberbrühlstr. 16, 87700 Memmingen Germany
Location of manufacturing sites	Oberbrühlstr. 16, 87700 Memmingen Germany
Name of manufacturer	LCI FLOWEY
Address of manufacturer	2 ZAC Klengbusbiert, 7795 Bissen Luxembourg
Location of manufacturing sites	2 ZAC Klengbusbiert, 7795 Bissen Luxembourg

Name of manufacturer	Hofmann & Sommer GmbH und Co. KG
Address of manufacturer	Lindenstr.11, 07426 Königsee-Rottenbach Germany
Location of manufacturing sites	Lindenstr.11, 07426 Königsee-Rottenbach Germany
Name of manufacturer	Girelli Alcool srl
Address of manufacturer	Via Thomas Edison 5, 20080 Zibido San Giacomo (MI) Italy
Location of manufacturing sites	Via Thomas Edison 5, 20080 Zibido San Giacomo (MI) Italy
Name of manufacturer	Brenntag S.p.A.
Address of manufacturer	Via Cusago 150/4, 20158 Milano (MI) Italy
Location of manufacturing sites	Via Cusago 150/4, 20158 Milano (MI) Italy
Name of manufacturer	I.C.F. Srl
Address of manufacturer	Via G.B. Benzoni 50, 26020 Palazzo Pignano (CR) Italy
Location of manufacturing sites	Via G.B. Benzoni 50, 26020 Palazzo Pignano (CR) Italy
Name of manufacturer	Brenntag SA
Address of manufacturer	90 Avenue du Progrès, 69 680 Chassieu France
Location of manufacturing sites	90 Avenue du Progrès, 69 680 Chassieu France
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes-Platz 1, 45472 Muelheim a.d. Ruhr Germany
Location of manufacturing sites	Stinnes-Platz 1, 45472 Muelheim a.d. Ruhr Germany
Name of manufacturer	BCD Chemie GmbH
Address of manufacturer	Schellerdamm 16, 21079 Hamburg Germany
Location of manufacturing sites	Schellerdamm 16, 21079 Hamburg Germany
Name of manufacturer	HYDRACHIM
Address of manufacturer	Z.A. ROUTE DE ST POIX, 35370 LE PERTRE France
Location of manufacturing sites	Z.A. du piquet, 35370 Etreilles France
Name of manufacturer	Langguth Chemie GmbH
Address of manufacturer	Wandalenstrasse 6, 86343 Königsbrunn Germany
Location of manufacturing sites	Wandalenstrasse 6, 86343 Königsbrunn Germany

Name of manufacturer	Burgess Galvin & Co
Address of manufacturer	Jamestown Road, 11 Finglas, Dublin Ireland
Location of manufacturing sites	Jamestown Road, 11 Finglas, Dublin Ireland
Name of manufacturer	Tristel
Address of manufacturer	Lynx Business Park, Fordham Road, CB8 7NY Snailwell, Cambridge United Kingdom
Location of manufacturing sites	Lynx Business Park, Fordham Road, CB8 7NY Snailwell, Cambridge United Kingdom
Name of manufacturer	Brenntag Schweizerhall
Address of manufacturer	Elsässerstrasse 231, 4056 Basel Switzerland
Location of manufacturing sites	Elsässerstrasse 231, 4056 Basel Switzerland
Name of manufacturer	ORAPI
Address of manufacturer	5 Allee des Cerdes, Pi de la Plaine de L'ain, 01150 Saint Vulbas France
Location of manufacturing sites	5 Allee des Cerdes, Pi de la Plaine de L'ain, 01150 Saint Vulbas France
Name of manufacturer	Copak S.A.
Address of manufacturer	Z.I. du Madrillet, rue de la Chênaie, 76800 Saint-Etienne-du-Rouvray France
Location of manufacturing sites	Z.I. du Madrillet, rue de la Chênaie, 76800 Saint-Etienne-du-Rouvray France
Name of manufacturer	Water Technology Limited
Address of manufacturer	TOGHER INDUSTRIAL EST, T12KPF2 CORK, DUBLIN Ireland
Location of manufacturing sites	TOGHER INDUSTRIAL EST, T12KPF2 CORK, DUBLIN Ireland
Name of manufacturer	AF International, Electrolube: Divisions of H K Wentworth Ltd
Address of manufacturer	AASHBY PARK, COALFIELD WAY, ASHBY DE LA ZOUCH, LE65 1JF LEICESTERSHIRE United Kingdom
Location of manufacturing sites	AASHBY PARK, COALFIELD WAY, ASHBY DE LA ZOUCH, LE65 1JF LEICESTERSHIRE United Kingdom
Name of manufacturer	Bello Mondo bvba
Address of manufacturer	Helststraat 150-159, 2630 Aartselaar Belgium
Location of manufacturing sites	Laboratoria Smeets N.V., Fotografielaan 42, B-2610 Antwerpen-Wilrijk Belgium

Name of manufacturer	CERICHEM BIOPHARM SRL
Address of manufacturer	Viale Einaudi snc (z.i.), 71042 Cerignola (FG) Italy
Location of manufacturing sites	Viale Einaudi snc (z.i.), 71042 Cerignola (FG) Italy
Name of manufacturer	Otto Fischar GmbH & Co. KG
Address of manufacturer	Kaiserstr. 221, 66133 Saarbruecken Germany
Location of manufacturing sites	Kaiserstr. 221, 66133 Saarbruecken Germany
Name of manufacturer	Caesar & Loretz GmbH
Address of manufacturer	Herderstr. 31, 40721 Hilden Germany
Location of manufacturing sites	Herderstr. 31, 40721 Hilden Germany
Name of manufacturer	Karl-Josef Kost Alkohole & Produkte aus Alkohol KG
Address of manufacturer	Rauentalshöhe 4, 56073 Koblenz Germany
Location of manufacturing sites	Rauentalshöhe 4, 56073 Koblenz Germany

1.5. Manufacturer(s) of the active substance(s)

Active substance	Propan-2-ol
Name of manufacturer	ExxonMobil
Address of manufacturer	4999 Scenic Highway, LA 70897 Baton Rouge, Louisiana United States
Location of manufacturing sites	4999 Scenic Highway, LA 70897 Baton Rouge, Louisiana United States
Active substance	Propan-2-ol
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601, Vodelingenenplaat, 3196 KK Rotterdam Netherlands
Location of manufacturing sites	Vondelingenweg 601, Vodelingenenplaat, 3196 KK Rotterdam Netherlands
Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany
Location of manufacturing sites	Römerstrasse 733, 47443 Moers Germany Shamrockstraße 88, 44623 Herne Germany

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,7	70,0

2.2. Type(s) of formulation

Formulation(s)	Meta SPC 1: CL – Contact gel or Liquid Meta SPC 3: CL – Contact gel or Liquid Meta SPC 2: XX – Others: Ready-to-Use trigger spray
----------------	---

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC 1
------------	------------

1.2. Suffix to the authorisation number

Number	1-1
--------	-----

1.3. Product type(s)

Product type(s)	PT01 – Human hygiene (Disinfectants)
-----------------	--------------------------------------

2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,7	70,0

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	Meta SPC 1: CL – Contact gel or Liquid
----------------	--

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Keep container tightly closed. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER/doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents to in accordance with local regulations. Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1

Use # 1 – Use 1 – Contact Gel or Liquid – Hygienic handrub – Professional user

Product type	PT01 – Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Bacteria (incl. Mycobacteria), Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Enveloped viruses Common name: - Development stage: -

Field(s) of use	Indoor For professional use only. For use in private, public, healthcare and industrial areas and in areas for professional activities.
Application method(s)	Method: Direct application to both hands, rubbing Detailed description: -
Application rate(s) and frequency	Application Rate: 3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 60 seconds per application. Dilution (%): - Number and timing of application: Up to 25 disinfections per day, 5 day(s) per week
Category(ies) of users	Professional
Pack sizes and packaging material	— Bottle HD-PE: 0,1L – 2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) — Can HD-PE: 5L – 60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE)) — Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) — IBC container HD-PE: 1000L; (Screw caps (HD-PE))

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

1) For professional use only.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

- 2) Products must be shaken before use.
- 3) Only apply on dry and visibly clean hands.
- 4) For hand disinfection a ready-to-use gel or liquid (3 ml) is poured into the palms of one hand and the complete surface of both hands are moistened and rubbed for 60 seconds per application.

5.2. Risk mitigation measures

- 1) Avoid contact with eyes.
- 2) Keep out of reach of children and pets.
- 3) Use only in well-ventilated areas.
- 4) For refilling a funnel must be applied.
- 5) The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and/or organisational measures:

The use of eye protection during refilling of the product is recommended.

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

- 1) IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
- 2) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

- 1) Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
- 2) Do not let product enter drains.
- 3) Contact waste disposal services.
- 4) Contaminated packaging: Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging that cannot be cleaned are to be disposed of in the same manner as the product.
- 5) Do not burn, or use a cutting torch on, the empty drum. Risk of explosion.

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

- 1) Store in a well-ventilated place.
- 2) Keep cool.
- 3) Keep container tightly closed.
- 4) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- 5) Shelf-life: 24 months

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	Wofasept AHA	Market area: EU			
	Otovita® Professional Handgel	Market area: EU			
Authorisation number	EU-0027707-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,7

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

Trade name(s)	Budenat® Protect Hand D807	Market area: EU			
Authorisation number	EU-0027707-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Handsteril OG	Market area: EU			
	Disinfection for Hands OG	Market area: EU			
	2-Propanol 70 %	Market area: EU			
	Isopropylalkohol Königseer Biozid	Market area: EU			
	Isogel Königseer Biozid Plus	Market area: EU			
	Isogel Königseer Biozid	Market area: EU			
	ISO 70	Market area: EU			
	Brensolv K68	Market area: EU			
	Isopropanol 70 Biocide	Market area: EU			

	Isopropanol 70	Market area: EU			
	Hand- und Oberflächendesinfektion	Market area: EU			
Authorisation number	EU-0027707-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	Handsteril OG blau	Market area: EU			
Authorisation number	EU-0027707-0004 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,0

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

Trade name(s)	Easysept	Market area: EU			
Authorisation number	EU-0027707-0005 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Witty-Lavalin D	Market area: EU			
	proCura Spray PUR	Market area: EU			
	Orlin Suprades HD	Market area: EU			
	Esept	Market area: EU			
	Bio Tec Des HD	Market area: EU			

Authorisation number	EU-0027707-0006 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

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

Trade name(s)	Curacid HD-sept	Market area: EU			
Authorisation number	EU-0027707-0007 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,8

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

Trade name(s)	Esept Gel	Market area: EU			
Authorisation number	EU-0027707-0008 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,4

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

Trade name(s)	Mano Germs	Market area: EU			
Authorisation number	EU-0027707-0009 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Deogel Mani	Market area: EU			
	Deovet	Market area: EU			
	Deogel Hands	Market area: EU			
	Deomed	Market area: EU			
	Dermigel profumato	Market area: EU			
Authorisation number	EU-0027707-0010 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	Isogel	Market area: EU			
	Vetgel	Market area: EU			
	Icfigel	Market area: EU			
	Skingel	Market area: EU			
	Sanigel	Market area: EU			
	Dermigel	Market area: EU			
	Gel mimani	Market area: EU			
Authorisation number	EU-0027707-0011 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	Alcodet profumato		Market area: EU		
Authorisation number	EU-0027707-0012 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	Handsan	Market area: EU			
	Manisan	Market area: EU			
	Sanimed	Market area: EU			
Authorisation number	EU-0027707-0013 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	ELIGEL	Market area: EU			
Authorisation number	EU-0027707-0014 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	ELIGEL Perfum	Market area: EU			
Authorisation number	EU-0027707-0015 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	Desmila VSI	Market area: EU			
	mobilomed Skinsoft Expert	Market area: EU			
	SiMa CleanTecMano	Market area: EU			
	Funny Hygienikum	Market area: EU			

Authorisation number	EU-0027707-0016 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,8

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

Trade name(s)	Desmila VSI C	Market area: EU			
Authorisation number	EU-0027707-0017 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Desmila LSI	Market area: EU			
	mobilomed Skinsoft Professional	Market area: EU			
Authorisation number	EU-0027707-0018 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64,7

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

Trade name(s)	Desmila LSI C	Market area: EU			
Authorisation number	EU-0027707-0019 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64,7

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

Trade name(s)	Desmila LSI pure	Market area: EU			
Authorisation number	EU-0027707-0020 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64,7

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC 2
------------	------------

1.2. Suffix to the authorisation number

Number	1-2
--------	-----

1.3. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants) PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
-----------------	--

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,8	70,0

2.2. Type(s) of formulation of the meta SPC 2

Formulation(s)	Meta SPC 2: XX – Others: Ready-to-Use trigger spray
----------------	---

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Keep container tightly closed. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER/doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents to in accordance with local regulations. Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 2

Use # 1 – Use 1 – Liquid Spray – Small surface disinfection – Professional user

Product type	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria (incl. Mycobacteria), Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of small non-porous surfaces, materials, equipment and furniture in private, public, healthcare, industrial areas and in areas for professional activities.
Application method(s)	Method: Spraying Detailed description: -

Application rate(s) and frequency	Application Rate: For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces at room temperature. Dilution (%): - Number and timing of application: Application according to requirements, one application per use, 4 times per day. Small surface disinfection(other than healthcare): Bactericidal and yeasticidal: contact time at least 1 min In healthcare area: Bactericidal and yeasticidal: contact time at least 5 min
Category(ies) of users	Professional
Pack sizes and packaging material	— Bottle HD-PE: 0,1L – 2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) — Can HD-PE: 5L – 60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE)) — Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) — IBC container HD-PE: 1000L; (Screw caps (HD-PE))

4.1.1. Use-specific instructions for use

- 1) Apply the ready-to-use product to the surface by spraying. Make sure to wet surfaces completely and wait for 1 minute (general surface disinfection) or 5 minutes (surfaces in healthcare area)
- 2) For use at room temperature.
- 3) Application according to requirements, one application per use, 4 times per day.

4.1.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and/or organisational measures:

The use of eye protection during refilling of the product is recommended.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. Use description

Table 3

Use # 2 – Use 2 – Liquid Spray – Disinfection for small food contact surfaces – Professional user

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of small non-porous surfaces in food sector or food processing industries (including breweries, dairy industry and meat industry).
Application method(s)	Method: Spraying Detailed description: -
Application rate(s) and frequency	Application Rate: For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces at room temperature. Dilution (%): - Number and timing of application: Application according to requirements, one application per use, 4 times per day. Small surface disinfection: Bactericidal and yeasticidal: contact time at least 1 min In Breweries/meat industry: Bactericidal and yeasticidal: contact time at least 5 min In dairy industry: Bactericidal and yeasticidal: contact time at least 15 min

Category(ies) of users	Professional
Pack sizes and packaging material	— Bottle HD-PE: 0,1L – 2,5L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP)) — Can HD-PE: 5L – 60L; (Screw caps (PE/LDPE/HD-PE) or safety caps (HD-PE)) — Drum HD-PE: 200L; (Plastic plug with venting system (HD-PE) or Plastic plug for tap (HD-PE) or plastic tap (HD-PE) or seal caps (HD-PE)) — IBC container HD-PE: 1000L; (Screw caps (HD-PE))

4.2.1. *Use-specific instructions for use*

- 1) Apply the ready-to-use product to the surface by spraying. Make sure to wet surfaces completely and wait for at least 1 min (general surface disinfection), 5 min (surface disinfection in breweries or meat industry) or at least 15 min (surface disinfection in dairy industry).
- 2) For use at room temperature.
- 3) Application according to requirements, one application per use, 4 times per day.

4.2.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and/or organisational measures: The use of eye protection during handling of the product is recommended.

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

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 2

5.1. **Instructions for use**

- 1) Products must be shaken before use.
- 2) Do not apply more than 20 mL/m².
- 3) Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

- 1) Avoid contact with eyes.
- 2) For refilling a funnel must be applied.
- 3) The product must only be applied for disinfection of small surfaces.
- 4) Keep out of reach of children and pets.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

- 5) Use only in well-ventilated areas.
- 6) Keep children and pets away from rooms where disinfection is taking place.
- 7) Provide adequate ventilation before children and pets enter treated rooms.

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

- 1) IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
- 2) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

- 1) Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
- 2) Do not let product enter drains.
- 3) Contact waste disposal services.
- 4) Contaminated packaging: Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging that cannot be cleaned are to be disposed of in the same manner as the product.
- 5) Do not burn, or use a cutting torch on, the empty drum. Risk of explosion.

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

- 1) Store in a well-ventilated place.
- 2) Keep cool.
- 3) Keep container tightly closed.
- 4) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- 5) Shelf-life: 24 months

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	proCura Spray PUR	Market area: EU
	Witty-Express Ultra	Market area: EU
	Witty-AQUA MEGA	Market area: EU
	Anti-Germ DES ALC-IP	Market area: EU
	BTS 6000	Market area: EU
	Bio Tec Des AX	Market area: EU

Authorisation number	EU-0027707-0021 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

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

Trade name(s)	Isopropanol 70 Biocide	Market area: EU
	Isopropanol 70	Market area: EU
	Isopropylalkohol Königseer Biozid	Market area: EU
	Isogel Königseer Biozid Plus	Market area: EU
	Gold	Market area: EU
	Füllersteril PPP	Market area: EU
	Isopropylalkohol 70 % Gew.	Market area: EU
	Fast Germs	Market area: EU
	BACTINYL IPA 70 %	Market area: EU
	SAFE CLEANER SR	Market area: EU
	Isopropylalkohol Königseer Flächen Biozid	Market area: EU
	Isonet	Market area: EU
	Isonet AL	Market area: EU
	Sanificante Alcolico	Market area: EU
	Isogerm	Market area: EU
	Isogerm AL	Market area: EU
	Isonet PU	Market area: EU
	Alidet	Market area: EU
	Sanocasa	Market area: EU
	Frigosano	Market area: EU
	Hygien Food	Market area: EU
	Medicalsan	Market area: EU
	Alcohol Sanitized	Market area: EU
	Alkosan	Market area: EU
	Biofarm	Market area: EU

	Allkill	Market area: EU			
	DETERQUAT PRO SR	Market area: EU			
	Galtec Isoprop Bactericide	Market area: EU			
	Amphisol 70	Market area: EU			
	AISW 100	Market area: EU			
	Steril Spray PPP	Market area: EU			
	Hand- und Oberflächendesinfektion	Market area: EU			
Authorisation number	EU-0027707-0022 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	Budenat® Rapid Effect D 446	Market area: EU
	IPA 300	Market area: EU
	Easydes IPA	Market area: EU
	Sonet	Market area: EU
	Sonet Forte	Market area: EU
	Isosan Forte	Market area: EU
	Germisan	Market area: EU
	Sanivet	Market area: EU
	Alidet Forte	Market area: EU
	Germidet	Market area: EU
	Isoclean	Market area: EU
	Alcohol Sanitized Strong	Market area: EU
	Alkosan Strong	Market area: EU
	Isonet Strong	Market area: EU
	Desmila HSI	Market area: EU
	Vetasept pur	Market area: EU
Authorisation number	EU-0027707-0023 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Isopropanol/Wasser 65/35 %	Market area: EU			
Authorisation number	EU-0027707-0024 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,0

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

Trade name(s)	Curacid Food Rapid	Market area: EU			
	Dr Desi Küchendesinfektion	Market area: EU			
Authorisation number	EU-0027707-0025 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,8

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

Trade name(s)	Deogerm	Market area: EU
	Deosan	Market area: EU
	Medicaldeo	Market area: EU
	Deonet	Market area: EU
	Deofloor	Market area: EU
	Sanocasa Profumato	Market area: EU
Authorisation number	EU-0027707-0026 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Desmila HSI C	Market area: EU			
	Vetasept Lemon	Market area: EU			
Authorisation number	EU-0027707-0027 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Desmila HSI D	Market area: EU			
	Vetasept Fresh	Market area: EU			
Authorisation number	EU-0027707-0028 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Desmila HSI P	Market area: EU			
	Vetasept Pfirsich	Market area: EU			
Authorisation number	EU-0027707-0029 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

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

Trade name(s)	Desmila AFI	Market area: EU			
	Hygienic I	Market area: EU			
Authorisation number	EU-0027707-0030 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64,7

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC 3
------------	------------

1.2. Suffix to the authorisation number

Number	1-3
--------	-----

1.3. Product type(s)

Product type(s)	PT01 – Human hygiene (Disinfectants)
-----------------	--------------------------------------

2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,7	70,0

2.2. Type(s) of formulation of the meta SPC 3

Formulation(s)	Meta SPC 3: CL – Contact gel or Liquid
----------------	--

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Keep container tightly closed. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER/doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents to in accordance with local regulations. Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 4

Use # 1 – Use 1 – Contact Gel or Liquid – Hygienic handrub – Non-professional user

Product type	PT01 – Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Bacteria (incl. Mycobacteria), Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Enveloped viruses Common name: - Development stage: -
Field(s) of use	Indoor For use in private and public areas.

Application method(s)	Method: Direct application to both hands, rubbing Detailed description: -
Application rate(s) and frequency	Application Rate: 3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 60 seconds per application. Dilution (%): - Number and timing of application: Up to 5 disinfections per day, 5 day(s) per week
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Bottle HD-PE: 0,1L – 1,0L; (Screw caps (HD-PE) or caps (PP) or pump caps (PP) or trigger spray caps (PP) or safety caps (PP))

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 3

5.1. **Instructions for use**

- 1) Comply with the instructions for use.
- 2) Products must be shaken before use.
- 3) Only apply on dry and visibly clean hands.
- 4) For hand disinfection a ready-to-use gel or liquid (3 ml) is poured into the palms of one hand and the complete surface of both hands are moistened and rubbed for 60 seconds per application.
- 5) The authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label:
 - Trigger spray: Apply 3 or 4 spray strokes (depending on the trigger spray cap)

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

- Pump spray: Apply 3 pump strokes
- Bottle: Visual observation

5.2. Risk mitigation measures

- 1) Avoid contact with eyes.
- 2) Use by children only under supervision of an adult.
- 3) Use only in well-ventilated areas.

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

- 1) If medical advice is needed, have product container or label at hand.
- 2) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing for five minutes.
- 3) Call a POISON CENTER or doctor if you feel unwell.
- 4) If eye irritation persists: Get medical advice/attention.
- 5) IF INHALED OR SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

5.4. Instructions for safe disposal of the product and its packaging

- 1) Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
- 2) Do not let product enter drains.
- 3) Contact waste disposal services.
- 4) Contaminated packaging: Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging that cannot be cleaned are to be disposed of in the same manner as the product.
- 5) Do not burn, or use a cutting torch on, the empty drum. Risk of explosion.

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

- 1) Store in a well-ventilated place.
- 2) Keep cool.
- 3) Keep container tightly closed.
- 4) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- 5) Keep out of reach of children and pets.
- 6) Shelf-life: 24 months

6. OTHER INFORMATION

-

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	Frend Hand Sanitiser Gel	Market area: EU
Authorisation number	EU-0027707-0031 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	65,3

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

Trade name(s)	Biogat H-Des	Market area: EU			
Authorisation number	EU-0027707-0032 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70,0

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

Trade name(s)	Neo-Amisept	Market area: EU			
Authorisation number	EU-0027707-0033 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,0

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2253**of 14 November 2022****granting a Union authorisation for the biocidal product family ‘Colgate-Palmolive Lactic acid PT 2’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 29 January 2019, Colgate Palmolive Sp. Z.o.o submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named ‘Colgate-Palmolive_Lactic acid_PT 2’ of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of France had agreed to evaluate the application. The application was recorded under case number BC-HK051319-37 in the Register for Biocidal Products.
- (2) ‘Colgate-Palmolive Lactic acid PT 2’ contains L-(+)-lactic acid as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 2.
- (3) On 25 August 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 23 March 2022, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘Colgate-Palmolive Lactic acid PT 2’ and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Colgate Palmolive Lactic acid PT 2’ is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 12 April 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘Colgate-Palmolive Lactic acid PT 2’.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 2 March 2022 on the Union authorisation of ‘Colgate-Palmolive Lactic acid PT2’ (ECHA/BPC/317/2022), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

- (8) In its opinion, the Agency recommends that the authorisation holder conducts a differential scanning calorimetry test for representative products of all meta-SPCs of 'Colgate-Palmolive Lactic acid PT 2' as a condition in the authorisation. That test should confirm that representative products of those meta-SPCs are not to be classified as self-reactive mixture. The Commission agrees with that recommendation and considers that the submission of the results of that test should be a condition relating to the making available on the market and use of the biocidal product family 'Colgate Palmolive Lactic acid PT 2' in all meta SPCs pursuant to Article 22(1) of Regulation (EU) No 528/2012. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1), point (d), of that Regulation based on existing data.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0028421-0000 is hereby granted to Colgate Palmolive Sp. Z.o.o for the making available on the market and use of the biocidal product family 'Colgate-Palmolive Lactic acid PT 2' subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 5 December 2022 to 30 November 2032.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

TERMS AND CONDITIONS (EU-0028421-0000)

The authorisation holder shall conduct a differential scanning calorimetry test for representative products of all meta-SPCs of 'Colgate-Palmolive_Lactic acid_PT 2'. The test shall be conducted in accordance with section 1.6.2 of the Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment (ECHA, March 2022) ⁽¹⁾ in order to confirm that the representative products of those meta-SPCs are not to be classified as self-reactive mixture.

By 5 June 2023 the authorisation holder shall submit the results of the test to the Agency.

⁽¹⁾ https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_i_parts_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b

ANNEX II

Summary of product characteristics for a biocidal product family

COLGATE-PALMOLIVE_LACTIC ACID_PT2

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals
(Disinfectants)

Authorisation number: EU-0028421-0000

R4BP asset number: EU-0028421-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	COLGATE-PALMOLIVE_LACTIC ACID_PT2
------	-----------------------------------

1.2. Product type(s)

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

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Colgate-Palmolive (Poland) Sp. Z.o.o
	Address	Wybrzeże Gdynskie 6D, 01-531 Warszawa Poland
Authorisation number	EU-0028421-0000	
R4BP asset number	EU-0028421-0000	
Date of the authorisation	5 December 2022	
Expiry date of the authorisation	30 November 2032	

1.4. Manufacturer(s) of the biocidal products

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

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

1.5. Manufacturer(s) of the active substance(s)

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkelsedijk 46, NL-4200 AA Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46, NL-4200 AA Gorinchem Netherlands

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Bioquímica SA
Address of manufacturer	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.
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

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,57	4,19
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	0,0	3,0
Propan-2-ol		Non-active substance	67-63-0	200-661-7	0,0	0,1

2.2. Type(s) of formulation

Formulation(s)	AL – Any other liquid
----------------	-----------------------

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	META SPC 1-2 PT2 BDC
------------	----------------------

1.2. Suffix to the authorisation number

Number	1-1
--------	-----

1.3. **Product type(s)**

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

2. META SPC 1 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,57	2,93
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0	3,0

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation(s)	AL – Any other liquid
----------------	-----------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read carefully and follow all instructions. Wash thoroughly after handling. IF ON SKIN:Wash with plenty of water. 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/.... Specific treatment (see on this label). If skin irritation occurs:Get medical advice. Take off contaminated clothing.And wash it before reuse.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. 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(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage:
Field(s) of use	Indoor Household – Bathroom porous and non-porous hard surfaces other than kitchen.
Application method(s)	Method: Manual application Detailed description: Pour the neat product on sponge, spread on the surface to disinfect (without pre-cleaning). Rinsing is required.
Application rate(s) and frequency	Application Rate: 18 g of product per m ² on a sponge. Dilution (%): - Number and timing of application: Ready to use. Contact time: 15 minutes Room temperature Frequency: Daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	PET bottle 650, 750, 1000, 1250, 1300, 1500 and PE bottle 2000 ml

4.1.1. Use-specific instructions for use

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

4.1.2. Use-specific risk mitigation measures

-

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

-

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

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

-

4.2. 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(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage:
Field(s) of use	Indoor Household toilets – Disinfection for Toilets bowls surfaces – Porous and non-porous hard surface disinfection
Application method(s)	Method: Manual application Detailed description: Pour the neat product on sponge, spread on the surface to disinfect (without pre-cleaning). Rinsing is required.
Application rate(s) and frequency	Application Rate: 18 g of product per m ² on a sponge Dilution (%): - Number and timing of application: Ready to use. Contact time: 15 minutes Room temperature Frequency: daily
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	PET bottle 650, 750, 1000, 1250, 1300, 1500 and PE bottle 2000 mL

4.2.1. *Use-specific instructions for use*

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

4.2.2. *Use-specific risk mitigation measures*

-

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

-

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

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

-

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

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

5.2. **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.

5.3. **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

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

- 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.
- IF INHALED: 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

5.4. 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

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

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

6. OTHER INFORMATION

-

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	B029-1342-0015	Market area: EU
	Ajax APC Antibacterial Blue @ 1,3 % LA (ref B029-1342-0015)	Market area: EU
	Ajax Antibakteriell	Market area: EU
	Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh; Ajax Απολυμαντικό Clean Fresh	Market area: EU
	Ajax Optimal 7 Antibactérien Fraîcheur Océan; Ajax Multi-surfaces Antibactérien Fraîcheur Océan; Ajax Antibacterial Ocean Fresh	Market area: EU
	Ajax Antibakteriell	Market area: EU
	Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh; Ajax Απολυμαντικό Clean Fresh	Market area: EU
	Ajax Disinfettante Clean Fresh	Market area: EU
	Ajax Antibacteriano Ultra Frescura	Market area: EU

	Ajax Antibacteriano		Market area: EU		
	Ajax Antibacterial Blue		Market area: EU		
	Ajax Désinfectant/Ajax Desinfecterend; Ajax Désinfectant Clean Fresh/Ajax Desinfecterend Clean Fresh; Ajax Désinfectant Fraîcheur Océan/Ajax Desinfecterend Oceaan Frisheid; Ajax Antibactérien/Ajax Antibacterieel		Market area: EU		
	Ajax Desinfectant; Ajax Desinfectant Clean Fresh; Ajax Desinfectant Oceaan Frisheid; Ajax Antibacterieel		Market area: EU		
Authorisation number	EU-0028421-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,57
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0

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

Trade name(s)	B029-1342-0014	Market area: EU
	Ajax APC Antibacterial Blue @ 2,6 % LA (B029-1342-0014)	Market area: EU
	Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh + (Plus)	Market area: EU
	Ajax Απολυμαντικό Clean Fresh + (Plus)	Market area: EU
	Ajax Απολυμαντικό Χωρίς Χλώριο Clean Fresh + (Plus)	Market area: EU
	Ajax Απολυμαντικό Clean Fresh + (Plus)	Market area: EU
	Ajax Disinfettante Clean Fresh + (Plus)	Market area: EU
	Ajax Antibacteriano Ultra Frescura + (Plus)	Market area: EU
	Ajax Antibacteriano + (Plus)	Market area: EU

	Ajax Antibacteriano Ultra Frescura	Market area: EU			
	Ajax Antibacterial Blue Plus	Market area: EU			
Authorisation number	EU-0028421-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	2,93
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0

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

Trade name(s)	B029-4339-0011		Market area: EU		
	Ajax APC Liquid Blue@ 1,3 % LA (ref B029-4339-0011)		Market area: EU		
	Ajax Απολυμαντικό Χωρίς Χλώριο Ocean Fresh		Market area: EU		
	Ajax Απολυμαντικό Ocean Fresh		Market area: EU		
	Ajax Maison Pure		Market area: EU		
	Ajax Απολυμαντικό Ocean Fresh		Market area: EU		
	Ajax Disinfettante Ocean Fresh		Market area: EU		
	Ajax Antibacteriano Frescura do Oceano		Market area: EU		
	Ajax Antibacteriano Frescura del Océano		Market area: EU		
	Ajax Antibacterial Pure Home		Market area: EU		
	Ajax Απολυμαντικό Χωρίς Χλώριο Ocean Fresh		Market area: EU		
Authorisation number	EU-0028421-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,57

Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0
--	--	-------------------------	------------	-----------	-----

7.4. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	B029-4339-0010		Market area: EU		
	Ajax APC Liquid Blue @ 2,6 % LA (B029-4339-0010)		Market area: EU		
	Ajax Απολυμαντικό Χωρίς Χλώριο Ocean Fresh + (Plus); Ajax Απολυμαντικό Ocean Fresh + (Plus)		Market area: EU		
	Ajax Απολυμαντικό Χωρίς Χλώριο Ocean Fresh + (Plus); Ajax Απολυμαντικό Ocean Fresh + (Plus)		Market area: EU		
	Ajax Blu		Market area: EU		
	Ajax Disinfettante Ocean Fresh + (Plus)		Market area: EU		
	Ajax Pure Home		Market area: EU		
	Ajax Antibacteriano		Market area: EU		
	Ajax Antibacteriano Frescura do Oceano + (Plus)		Market area: EU		
	Ajax Antibacteriano Frescura del Océano + (Plus)		Market area: EU		
	Ajax Antibacterial Pure Home Plus		Market area: EU		
Authorisation number	EU-0028421-0004 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	2,93
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0

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

Trade name(s)	B029-7583-0003	Market area: EU
	Ajax Healthy Home & Happy Blossom @ 1,3 % LA (B029-7583-0003)	Market area: EU
	Ajax Reines Zuhause Salbei & Apfelblüten and Ajax Maison Pure Salbei & Apfelblüten and Ajax Pure Home Salbei & Apfelblüten and Ajax Essential Purity Salbei & Apfelblüten and Ajax Pureté Essentielle Salbei & Apfelblüten	Market area: EU
	Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Pureté Essentielle Sage & Apple Blossom	Market area: EU
	Ajax Pure Home 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	Market area: EU
	Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Pureté Essentielle Sage & Apple Blossom	Market area: EU
	Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Pureté Essentielle Sage & Apple Blossom	Market area: EU
	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	Market area: EU

Ajax Reines Zuhause Salbei & Apfelblüten; Ajax Maison Pure Salbei & Apfelblüten; Ajax Pure Home Salbei & Apfelblüten; Ajax Essential Purity Salbei & Apfelblüten; Ajax Puredé Essentielle Salbei & Apfelblüten	Market area: EU
Ajax Pure Home 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;	Market area: EU
Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Puredé Essentielle Sage & Apple Blossom	Market area: EU
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	Market area: EU
Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Puredé Essentielle Sage & Apple Blossom	Market area: EU
Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Puredé Essentielle Sage & Apple Blossom	Market area: EU
Ajax Maison Pure Sauge & notes de Fleur de Pommier; Ajax Pure Home Sauge & notes de Fleur de Pommier; Ajax Essential Purity Sauge & notes de Fleur de Pommier; Ajax Puredé Essentielle Sauge & notes de Fleur de Pommier	Market area: EU

Ajax Pure Home Szalwia i Kwiat Jabłoni; Ajax Maison Pure Szalwia i Kwiat Jabłoni; Ajax Essential Purity Szalwia i Kwiat Jabłoni; Ajax Pureté Essentielle Szalwia i Kwiat Jabłoni; Ajax Pure Home Sage & Apple Blossom	Market area: EU
Ajax Pure Home Salva & Flor de Macieira	Market area: EU
Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Pureté Essentielle Sage & Apple Blossom	Market area: EU
Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Pureté Essentielle Sage & Apple Blossom	Market area: EU
Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Pureté Essentielle Sage & Apple Blossom	Market area: EU
Ajax Hogar Limpio y Saludable con Flor de Manzana	Market area: EU
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	Market area: EU
Ajax Pure Home Sage & Apple Blossom	Market area: EU

	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					Market area: EU
	Ajax Pure Home Sage & Apple Blossom; Ajax Maison Pure Sage & Apple Blossom; Ajax Essential Purity Sage & Apple Blossom; Ajax Pureté Essentielle Sage & Apple Blossom					Market area: EU
	Ajax Pure Home Salie & Appelbloesem; Ajax Pure Home Appelbloesem; Ajax Pure Home Appelbloesem Frisheid; Ajax Pure Home Appelbloesem Frisheid Antibacterieel					Market area: EU
Authorisation number	EU-0028421-0005 1-1					
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,57	
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0	

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

Trade name(s)	B029-7583-0002		Market area: EU		
	Ajax Healthy Home & Happy Blossom @ 2,6 % LA (B029-7583-0002)		Market area: EU		
	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)		Market area: EU		
	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)		Market area: EU		
	Ajax Healthy Home Allegría Floreale; Ajax Healthy Home Fioritura Allegra; Ajax Casa Sana Fioritura Allegra; Ajax Casa Sana Fiore Allegro; Ajax Casa Sana Allegría Floreale; Ajax Healthy Home Fiore Allegro.		Market area: EU		
	Ajax Pure Home Salva & Flor de Macieira + (Plus)		Market area: EU		
	Ajax Hogar Limpio y Saludable con Flor de Manzana + (Plus)		Market area: EU		
	Ajax Pure Home Sage & Apple Blossom Plus		Market area: EU		
Authorisation number	EU-0028421-0006 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	2,93
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0

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

Trade name(s)	B029-7582-0000	Market area: EU
	Ajax Healthy Home Sage & Elder Flower @ 1,3 % LA (B029-7583-0000)	Market area: EU
	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	Market area: EU
	Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
	Ajax Pure Home Sage & Elderflower; Ajax Healthy Home Sage & Elderflower; Ajax Απολυμαντικό Pure Home Sage & Elderflower; Ajax Pure Home Φασκόμηλο & Κουφοξυλιά; Ajax Pure Home Κουφοξυλιά & Φασκόμηλο;	Market area: EU
	Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
	Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
	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	Market area: EU

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	Market area: EU
Ajax Pure Home Sage & Elderflower; Ajax Healthy HomeSage & Elderflower; Ajax Απολυμαντικό Pure Home Sage & Elderflower; Ajax Pure Home Κουφοξυλιά & Φασκόμηλο; Ajax Pure Home Φασκόμηλο & Κουφοξυλιά; Ajax Pure Home Άνθη Ακτίας & Φασκόμηλο	Market area: EU
Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
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;	Market area: EU
Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
Ajax Maison Pure Sauge & Fleur de Sureau; Ajax Pure Home Sauge & Fleur de Sureau; Ajax Essential Purity Sauge & Fleur de Sureau; Ajax Pureté Essentielle Sauge & Fleur de Sureau	Market area: EU

	Ajax Pure Home Szalwia i Kwiat Czarnego Bzu; Ajax Maison Pure Szalwia i Kwiat Czarnego Bzu; Ajax Essential Purity Szalwia i Kwiat Czarnego Bzu; Ajax Pureté Essentielle Szalwia i Kwiat Czarnego Bzu; Ajax Pure Home Sage & Elderflower; Ajax Pure Home Sage & Elderflower	Market area: EU
	Ajax Pure Home Salva & Flor de Sabugueiro	Market area: EU
	Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
	Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
	Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower	Market area: EU
	Ajax Hogar Limpio y Saludable con Flor de Saúco	Market area: EU
	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	Market area: EU
	Ajax Pure Home Sage & Elder Flower	Market area: EU

	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		Market area: EU		
	Ajax Pure Home Sage & Elderflower; Ajax Maison Pure Sage & Elderflower; Ajax Essential Purity Sage & Elderflower; Ajax Pureté Essentielle Sage & Elderflower		Market area: EU		
	Ajax Pure Home Salie & Vlierbloesem; Ajax Pure Home Vlierbloesem; Ajax Pure Home Vlierbloesem Frisheid; Ajax Pure Home Vlierbloesem Frisheid Antibacterieel		Market area: EU		
Authorisation number	EU-0028421-0007 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,57
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0

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

Trade name(s)	B029-7582-0001		Market area: EU		
	Ajax Healthy Home Sage & Elder Flower @ 2,6 % LA (B029-7582-0001)		Market area: EU		
	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)		Market area: EU		
	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)		Market area: EU		
	Ajax Healthy Home Salvia e Fiore di Sambuco + (Plus); Ajax Casa Sana Salvia e fiore di Sambuco + (Plus)		Market area: EU		
	Ajax Pure Home Salva & Flor de Sabugueiro + (Plus)		Market area: EU		
	Ajax Hogar Limpio y Saludable con Flor de Saúco + (Plus)		Market area: EU		
	Ajax Pure Home Sage & Elder Flower Plus		Market area: EU		
	Authorisation number	EU-0028421-0008 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	2,93
Decan-1-ol, ethoxylated (> 2.5 moles EO)		Non-active substance	26183-52-8	500-046-6	3,0

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	META SPC5 PT2 WIPES
------------	---------------------

1.2. **Suffix to the authorisation number**

Number	1-2
--------	-----

1.3. **Product type(s)**

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

2. META SPC 2 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	3,67	4,19
Propan-2-ol		Non-active substance	67-63-0	200-661-7	0,1	0,1

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation(s)	AL – Any other liquid
----------------	-----------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Causes skin irritation. Causes serious eye damage. May be corrosive to metals.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read carefully and follow all instructions. Wash thoroughly after handling.

	IF ON SKIN:Wash with plenty of water. 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/.... Specific treatment (see on this label). If skin irritation occurs:Get medical advice. Take off contaminated clothing.And wash it before reuse. Keep only in original packaging. Absorb spillage to prevent material damage. Store in a corrosive resistant/... container with a resistant inner liner.
--	--

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. 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(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage:
Field(s) of use	Indoor Household – Bathroom and non-porous hard surfaces other than kitchen.
Application method(s)	Method: Wiping Detailed description: Without pre-cleaning Rinsing required
Application rate(s) and frequency	Application Rate: - Dilution (%): - Number and timing of application: Ready to use Contact time: 5 minutes Room temperature Frequency: daily
Category(ies) of users	General public (non-professional)
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

4.1.1. Use-specific instructions for use

— For multipack wipes, close the package after opening

4.1.2. Use-specific risk mitigation measures

-

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

-

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

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

-

4.2. Use description

Table 4

Use # 2 – Toilet bowl surfaces disinfection

Product type	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage:
Field(s) of use	Indoor Household toilets – Disinfection for Toilets bowls surfaces – Non-porous hard surface disinfection
Application method(s)	Method: Wiping Detailed description: Without pre-cleaning Rinsing required
Application rate(s) and frequency	Application Rate: - Dilution (%): - Number and timing of application: Ready to use Contact time: 5 minutes Frequency: daily
Category(ies) of users	General public (non-professional)
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

4.2.1. *Use-specific instructions for use*

4.2.2. *Use-specific risk mitigation measures*

-

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

-

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

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

-

5. GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 2

5.1. **Instructions for use**

- Comply with the instruction of 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

5.2. **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.

5.3. **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.
- IF INHALED: 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

5.4. **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

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

5.5. **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

6. OTHER INFORMATION

-

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	B023-1874-0010	Market area: EU
	Ajax Optimal 7 Wipes Bathroom and Toilet @ 3,5 % (ref B023-1874-0010)	Market area: EU
	Ajax Antibakterielle Reinigungstücher Bad & WC; Ajax Power Antibakterielle Reinigungstücher Bad & WC	Market area: EU
	Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
	Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
	Ajax Expert Μπάνιο & Λεκάνη; Ajax Μπάνιο & Λεκάνη; Πανάκια Ajax Μπάνιο & Λεκάνη; Ajax Πανάκια Μπάνιο & Λεκάνη; Ajax Plant Based Μπάνιο & WC Απολυμαντικό	Market area: EU
	Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
	Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
	Ajax Optimal 7 Salle de bain & WC Antibactérien; Ajax Salle de bain & WC Antibactérien; Ajax Power Anticalcaire; Ajax Lingettes Antibactériennes Salle de Bain & WC; Ajax Lingettes Désinfectantes Salle de Bain & WC	Market area: EU

Ajax Ultra 7 Antibakterielle Reinigungstücher Bad & WC; Ajax Antibakterielle Reinigungstücher Bad & WC; Ajax Power Antibakterielle Reinigungstücher Bad & WC	Market area: EU
Ajax Μπάνιο & Λεκάνη; Ajax Expert Μπάνιο & Λεκάνη; Ajax Μπάνιο & Λεκάνη; Πανάκια Ajax Μπάνιο & Λεκάνη; Ajax Πανάκια Μπάνιο & Λεκάνη; Ajax Plant Based Μπάνιο & WC Απολυμαντικό	Market area: EU
Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
Ajax Salviettine Bagno e WC; Salviette Ajax Plant Based Bagno	Market area: EU
Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC, Ajax Łazienka i WC	Market area: EU
Toalhitas Ajax Casa de Banho Frescura Pura; Ajax Plant Based Casa de Banho & Ação Antibacteriana	Market area: EU
Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
Ajax Power Bathroom; Ajax Power Antilimescale; Ajax Bathroom & WC	Market area: EU
Ajax Baños	Market area: EU

	Ajax antibakterielle Reinigungstücher Bad & WC/Ajax lingettes nettoyantes antibactériennes Bain & WC		Market area: EU		
	Ajax Antibacterial Wipes Pure Freshness		Market area: EU		
	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		Market area: EU		
	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		Market area: EU		
Authorisation number	EU-0028421-0009 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	3,67
Propan-2-ol		Non-active substance	67-63-0	200-661-7	0,1

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

Trade name(s)	B023-1874-0011		Market area: EU		
	Ajax Optimal 7 Wipes Bathroom and Toilet @ 4 % (ref B023-1874-0011)		Market area: EU		
	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		Market area: EU		
	Ajax Μπάνιο & Λεκάνη + (Plus); 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		Market area: EU		
	Ajax Salviettine Bagno e WC + (Plus); Salviette Ajax Plant Base Bagno		Market area: EU		
	Toalhitas Ajax Casa de Banho Frescura Pura + (Plus); Ajax Plant Based Casa de Banho & Ação Antibacteriana		Market area: EU		
	Ajax Baños + (Plus)		Market area: EU		
	Ajax antibakterielle Reinigungstücher Bad & WC/Ajax lingettes nettoyantes antibactériennes Bain & WC		Market area: EU		
	Ajax Antibacterial Wipes Pure Freshness Plus		Market area: EU		
	Authorisation number	EU-0028421-0010 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	4,19
Propan-2-ol		Non-active substance	67-63-0	200-661-7	0,1

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

Trade name(s)	B023-1873-0006	Market area: EU
	Ajax Optimal 7 Wipes Multisurfaces @ 3,5 % (ref B023-1873-0006)	Market area: EU
	Ajax Ultra 7 Antibakterielle Reinigungstücher; Ajax Antibakterielle Reinigungstücher; Ajax Power Antibakterielle Reinigungstücher	Market area: EU
	Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
	Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
	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	Market area: EU
	Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
	Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
	Ajax Optimal 7 Surfaces Grasses Antibactérien; Ajax Surfaces Grasses; Ajax Power; Ajax Multisurfaces, Ajax Lingettes Antibactériennes Multi-Surfaces; Ajax Lingettes Désinfectantes Multi-Surfaces	Market area: EU
	Ajax Ultra 7 Antibakterielle Reinigungstücher; Ajax Antibakterielle Reinigungstücher; Ajax Power Antibakterielle Reinigungstücher	Market area: EU
	Ajax Για Όλες τις Επιφάνειες; 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	Market area: EU

Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
Ajax Salviettine Multiuso; Salviette Ajax Plant Based Multiuso	Market area: EU
Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
Toalhitas Ajax Multiusos Frescura Intensa; Ajax Plant Based Multiusos & Ação Antibacteriana	Market area: EU
Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
Ajax Power Multipurpose; Ajax Multipurpose; Ajax Multisurface	Market area: EU
Ajax Toallitas Multiusos	Market area: EU
Ajax antibakterielle Allzweck-Tücher/Ajax lingettes nettoyantes antibactériennes Multi-Usages	Market area: EU
Ajax Antibacterial Wipes Intense Freshness	Market area: EU
Ajax Antibacterial Wipes Multisurface; Ajax Lingettes Antibactériennes Multi-Surfaces/ Ajax Antibacteriële Doekjes Multi-Oppervlakken; Ajax Lingettes Désinfectantes Multi-Surfaces/Ajax Desinfecterende Doekjes Multi-Oppervlakken	Market area: EU
Ajax Antibacterial Wipes Multisurface; Ajax Antibacteriële Doekjes Multi-Oppervlakken; Ajax Desinfecterende Doekjes Multi-Oppervlakken	Market area: EU

Authorisation number	EU-0028421-0011 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	3,67
Propan-2-ol		Non-active substance	67-63-0	200-661-7	0,1

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

Trade name(s)	B023-1873-0005	Market area: EU
	Ajax Optimal 7 Wipes Multisurfaces @ 4 % (ref B023-1873-0005)	Market area: EU
	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	Market area: EU
	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	Market area: EU
	Ajax Salviettine Multiuso; Ajax Optimal 7 Salviettine Multiuso+; Ajax Salviettine Multiuso+; Salviette Ajax Plant Base Multisup	Market area: EU
	Toalhitas Ajax Multiusos Frescura Intensa + (Plus); Ajax Plant Based Multiusos & Ação Antibacteriana	Market area: EU
	Ajax Toallitas Multiusos + (Plus)	Market area: EU
	Ajax antibakterielle Allzweck-Tücher/Ajax lingettes nettoyantes antibactériennes Multi-Usages	Market area: EU

	Ajax Antibacterial Wipes Intense Freshness Plus		Market area: EU		
Authorisation number	EU-0028421-0012 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	4,19
Propan-2-ol		Non-active substance	67-63-0	200-661-7	0,1

DECISIONS

COUNCIL IMPLEMENTING DECISION (EU) 2022/2254

of 14 November 2022

authorising Bulgaria to introduce a special measure derogating from Article 287 of Directive 2006/112/EC on the common system of value added tax

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax ⁽¹⁾, and in particular Article 395(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Article 287, point (17), of Directive 2006/112/EC allows Bulgaria to exempt from value added tax (VAT) taxable persons whose annual turnover is no higher than the equivalent in national currency of EUR 25 600 at the conversion rate on the day of its accession.
- (2) By letter registered with the Commission on 17 May 2022, Bulgaria requested an authorisation to introduce a special measure derogating from Article 287, point (17), of Directive 2006/112/EC and thus to exempt from VAT taxable persons whose annual turnover is no higher than the equivalent in national currency of EUR 51 130 at the conversion rate on the day of its accession ('the special measure'). The special measure would be applicable until 31 December 2024, the date by which Member States are to transpose Council Directive (EU) 2020/285 ⁽²⁾. It follows from that Directive that, from 1 January 2025, Member States will be allowed to exempt from VAT the supply of goods and services made by taxable persons whose annual turnover in a given Member State does not exceed a threshold of EUR 85 000 or the equivalent in national currency.
- (3) Pursuant to Article 395(2), second subparagraph, of Directive 2006/112/EC, the Commission transmitted the request made by Bulgaria to the other Member States, by letter of 26 July 2022. By letter of 27 July 2022, the Commission notified Bulgaria that it had all the information necessary for the appraisal of the request.
- (4) The special measure is in line with Directive (EU) 2020/285, which seeks to reduce the compliance burden of small enterprises and avoid distortions of competition in the internal market.
- (5) The special measure will remain optional for taxable persons as they may still opt for the normal VAT arrangements pursuant to Article 290 of Directive 2006/112/EC.
- (6) According to the information provided by Bulgaria, the special measure will only have a negligible effect on the overall amount of tax revenue Bulgaria collects at the stage of final consumption.

⁽¹⁾ OJ L 347, 11.12.2006, p. 1.

⁽²⁾ Council Directive (EU) 2020/285 of 18 February 2020 amending Directive 2006/112/EC on the common system of value added tax as regards the special scheme for small enterprises and Regulation (EU) No 904/2010 as regards the administrative cooperation and exchange of information for the purpose of monitoring the correct application of the special scheme for small enterprises (OJ L 62, 2.3.2020, p. 13).

- (7) Following the entry into force of Council Regulation (EU, Euratom) 2021/769 ⁽³⁾, there is to be no compensation calculation carried out by Bulgaria with regard to the VAT-based own resource statement for the financial year 2022 onwards.
- (8) Given that Bulgaria expects that the special measure will result in reduced VAT obligations and thus a reduction in the administrative burden and compliance costs for both small enterprises and the tax authorities, and given the lack of any major impact on the total VAT revenue generated, Bulgaria should be authorised to introduce the special measure.
- (9) The application of the special measure should be limited in time. The time limit should be sufficient to allow the Commission to evaluate the effectiveness and appropriateness of the threshold. Moreover, pursuant to Article 3(1) of Directive (EU) 2020/285, Member States are to adopt and publish, by 31 December 2024, the laws, regulations and administrative provisions necessary to comply with Article 1 of that Directive, which amends Directive 2006/112/EC and lays down simpler VAT rules for small enterprises, and apply those provisions from 1 January 2025. It is therefore appropriate to authorise Bulgaria to apply the special measure until 31 December 2024,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from Article 287, point (17), of Directive 2006/112/EC, Bulgaria is authorised to exempt from VAT taxable persons whose annual turnover is no higher than the equivalent in national currency of EUR 51 130 at the conversion rate on the day of its accession.

Article 2

This Decision shall take effect on the date of its notification.

It shall apply until 31 December 2024.

Article 3

This Decision is addressed to Bulgaria.

Done at Brussels, 14 November 2022.

For the Council
The President
J. BORRELL FONTELLES

⁽³⁾ Council Regulation (EU, Euratom) 2021/769 of 30 April 2021 amending Regulation (EEC, Euratom) No 1553/89 on the definitive uniform arrangements for the collection of own resources accruing from value added tax (OJ L 165, 11.5.2021, p. 9).

COMMISSION DECISION (EU) 2022/2255**of 24 October 2022****on the initiation of the detailed examination of certain performance targets contained in the revised draft performance plan for the third reference period submitted at functional airspace block level by Belgium, Germany, France, Luxembourg, and the Netherlands pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council***(notified under document C(2022) 7438)***(Only the Dutch, French and German texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky ⁽¹⁾ (the framework Regulation), and in particular Article 11(3) point (c), second paragraphs, thereof,

Having regard to Commission Implementing Regulation (EU) 2019/317 of 11 February 2019 laying down a performance and charging scheme in the single European sky and repealing Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 ⁽²⁾, and in particular Article 15(1) and (3) thereof,

Whereas:

GENERAL CONSIDERATIONS

- (1) Pursuant to Article 10 of Implementing Regulation (EU) 2019/317, Member States are to draw up, either at national level or at the level of functional airspace blocks ('FABs'), binding performance targets for each reference period of the performance scheme for air navigation services and network functions. Those performance targets have to be consistent with the Union-wide targets adopted by the Commission for the reference period concerned.
- (2) Union-wide performance targets for the third reference period ('RP3') were originally set out in Commission Implementing Decision (EU) 2019/903 ⁽³⁾. As those Union-wide performance targets and the draft RP3 performance plans subsequently submitted in October 2019 by Member States were drawn up before the outbreak of the COVID-19 pandemic in March 2020, they did not take account of the considerable reduction in air traffic due to the measures taken by the Member States and third countries to contain the pandemic.

⁽¹⁾ OJ L 96, 31.3.2004, p. 1.

⁽²⁾ OJ L 56, 25.2.2019, p. 1.

⁽³⁾ Commission Implementing Decision (EU) 2019/903 of 29 May 2019 setting the Union-wide performance targets for the air traffic management network for the third reference period starting on 1 January 2020 and ending on 31 December 2024 (OJ L 144, 3.6.2019, p. 49).

- (3) In response to the impact of the COVID-19 pandemic on the provision of air navigation services, exceptional measures for RP3, which derogate from the provisions of Implementing Regulation (EU) 2019/317, were set out in Commission Implementing Regulation (EU) 2020/1627 ⁽⁴⁾. The Commission adopted, on 2 June 2021, Implementing Decision (EU) 2021/891 ⁽⁵⁾ setting revised Union-wide performance targets for RP3. On this basis, Member States submitted to the Commission, in October 2021, draft performance plans containing revised local performance targets for RP3.
- (4) Commission Implementing Decision (EU) 2022/728 ⁽⁶⁾ on the inconsistency of certain performance targets contained in the draft national and functional airspace block performance plans was addressed to Belgium, Germany, Greece, France, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Romania, and Sweden.
- (5) In respect of the draft performance plan for RP3 established at functional airspace block level by Belgium, Germany, France, Luxembourg, and the Netherlands ('draft FABEC performance plan'), the Commission found that the cost-efficiency performance targets for the Belgium-Luxembourg *en route* charging zone are not consistent with the Union-wide performance targets and issued recommendations for the revision of those targets.
- (6) In response to Russia's war of aggression against Ukraine, which started on 24 February 2022, the Union has imposed restrictive measures which prohibit Russian air carriers, any Russian-registered aircraft and any non-Russian-registered aircraft which is owned or chartered, or otherwise controlled by any Russian natural or legal person, entity or body, from landing in and taking off from, or overflying the territory of the Union. Those restrictive measures and the counter-measures adopted by Russia have led to changes in air traffic in European airspace. Certain Member States have been severely affected by a significant reduction in the number of overflights in the airspace under their responsibility. However, at Union-wide level, the observed impact of those measures on the number of flights has been limited, which is in contrast with the sharp reduction of air traffic across Europe that resulted from the outbreak of the COVID-19 pandemic.
- (7) Belgium, Germany, France, Luxembourg, and the Netherlands submitted, on 13 July 2022, a revised draft FABEC performance plan for RP3 for assessment by the Commission.
- (8) The performance review body, assisting the Commission in the implementation of the performance scheme pursuant to Article 11(2) of Regulation (EC) No 549/2004, has submitted to the Commission a report containing its advice on the assessment of the revised draft FABEC performance plan.
- (9) In accordance with Article 15(1) of Implementing Regulation (EU) 2019/317, the Commission has assessed the consistency of the local performance targets contained in the revised draft FABEC performance plan on the basis of the assessment criteria laid down in point 1 of Annex IV to that Implementing Regulation, and taking account of local circumstances. In respect of each key performance area and the related performance targets, the Commission has complemented its assessment by reviewing the elements set out in point 2 of Annex IV to that Implementing Regulation.

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/1627 of 3 November 2020 on exceptional measures for the third reference period (2020-2024) of the single European sky performance and charging scheme due to COVID-19 pandemic (OJ L 366, 4.11.2020, p. 7).

⁽⁵⁾ Commission Implementing Decision (EU) 2021/891 of 2 June 2021 setting revised Union-wide performance targets for the air traffic management network for the third reference period (2020-2024) and repealing Implementing Decision (EU) 2019/903 (OJ L 195, 3.6.2021, p. 3).

⁽⁶⁾ Commission Implementing Decision (EU) 2022/728 of 13 April 2022 on the inconsistency of certain performance targets contained in the draft national and functional airspace block performance plans submitted by Belgium, Germany, Greece, France, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Romania, and Sweden pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period and setting out recommendations for the revision of those targets (OJ L 135, 12.5.2022, p. 4).

- (10) The Eurocontrol STATFOR base traffic forecast published in June 2022 takes account of the changed circumstances referred to in recital (6). Based on that forecast, the Commission notes that Belgium, Germany, France, Luxembourg, and the Netherlands are not foreseen to experience major changes in air traffic flows over RP3 as a result of Russia's war in Ukraine. Therefore, those changed circumstances do not directly impact the performance targets contained in the revised draft FABEC performance plan or the assessment of those targets in respect of their consistency with the Union-wide performance targets.

REASONS FOR INITIATING A DETAILED EXAMINATION

Performance targets giving rise to doubts

- (11) The table below shows the initial RP3 *en route* cost-efficiency performance targets for the Belgium-Luxembourg charging zone, as contained in the draft FABEC performance plan submitted in 2021, and the corresponding revised performance targets contained in the revised draft FABEC performance plan submitted in July 2022.

En route charging zone of Belgium-Luxembourg	2014 baseline value	2019 baseline value	2020-2021	2022	2023	2024
<i>Initial en route cost-efficiency targets (contained in the draft FABEC performance plan submitted in 2021), expressed as determined en route unit cost (in real terms in 2017 prices)</i>	73,13 EUR	83,28 EUR	189,52 EUR	113,26 EUR	108,51 EUR	103,82 EUR
Revised en route cost-efficiency targets (contained in the revised draft FABEC performance plan), expressed as determined en route unit cost (in real terms in 2017 prices)	81,78 EUR	83,26 EUR	189,52 EUR	104,47 EUR	94,18 EUR	89,87 EUR

- (12) The Commission notes that the performance targets for calendar years 2022, 2023 and 2024 have been revised downwards, whilst the baseline value for 2014 has been revised upwards. Furthermore, a minor technical adjustment, which is not of significance for the assessment of the performance targets, has been applied with regard to the baseline value for 2019.
- (13) Belgium and Luxembourg have justified the proposed adjustment of the baseline value for 2014 mainly by the changes in the cost allocation methodology between *en route* and terminal services, which were introduced in RP3. A similar adjustment has been applied for the 2019 baseline value and was already included in the draft FABEC performance plan submitted in 2021.
- (14) The Commission observes that the revision of cost-efficiency targets for the time period from 2022 to 2024 leads to an overall determined unit cost ("DUC") reduction of -11,6 % over those three calendar years and of -8,2 % over RP3 as a whole. Those DUC reductions result both from the updated traffic assumptions used in the revised draft performance plan and from the downward revision of the determined costs expressed in real terms in 2017 prices.
- (15) The changes to the traffic forecast for calendar years 2022 to 2024 are presented in the table below. The Commission notes that the traffic forecast used in the revised draft performance plan is based on the Eurocontrol STATFOR June 2022 base traffic forecast.

En route charging zone of Belgium-Luxembourg	2022	2023	2024
<i>Initial traffic forecast (contained in the draft performance plan submitted in 2021), expressed in thousands of en route service units</i>	2 066	2 226	2 387
Updated traffic forecast (contained in the revised draft performance plan), expressed in thousands of en route service units	2 108	2 445	2 542
Difference	+ 2,0 %	+ 9,8 %	+ 6,5 %

- (16) The revised determined costs for calendar years 2022 to 2024, expressed in real terms in 2017 prices, are shown in the table below.

En route charging zone of Belgium-Luxembourg	2022	2023	2024
<i>Initial determined costs in real terms in 2017 prices (contained in the draft performance plan submitted in 2021)</i>	234 M EUR	242 M EUR	248 M EUR
Revised determined costs in real terms in 2017 prices (contained in the revised draft performance plan)	220 M EUR	230 M EUR	228 M EUR
Difference	- 5,9 %	- 4,7 %	- 7,8 %

- (17) The Commission notes that inflation assumptions underlying the setting of determined costs have been revised significantly upwards, as outlined in the table below.

En route charging zone of Belgium-Luxembourg	2022	2023	2024
<i>Initial inflation index, with forecasted year-on-year change in inflation in parenthesis (data contained in the draft performance plan submitted in 2021)</i>	107,7 (1,9 %)	109,7 (1,8 %)	111,6 (1,8 %)
Revised inflation index, with year-on-year change in inflation in parenthesis (data contained in the revised draft performance plan)	115,6 (7,8 %)	119,6 (3,4 %)	121,8 (1,9 %)

- (18) Due to the update of the inflation forecast, the revised determined costs in nominal terms for calendar years 2022 to 2024, which are displayed below, remain largely unchanged and are even increased by +2,9 % for calendar year 2023, despite being lower in real terms as presented in recital (16).

En route charging zone of Belgium-Luxembourg	2022	2023	2024
<i>Initial determined costs in nominal terms (contained in the draft performance plan submitted in 2021)</i>	250 M EUR	262 M EUR	273 M EUR
Revised determined costs in nominal terms (contained in the revised draft performance plan)	250 M EUR	269 M EUR	272 M EUR
Difference	+ 0,1 %	+ 2,9 %	- 0,3 %

- (19) The Commission further observes that the determined costs for 2024 include a one-off reduction amounting to approximately EUR 8,3M in nominal terms.

- (20) The Commission notes that three air navigation service providers, namely skeyes, MUAC and ANA Luxembourg, are included in the scope of the Belgium-Luxembourg *en route* charging zone. With regard to the costs of service provision in the charging zone, 62 % of the determined costs of 2024 are incurred by skeyes, whilst MUAC represents 35 % of the cost base for that same year. Only 3 % of the total costs of service provision in the charging zone are allocated to ANA Luxembourg, and those costs are exclusively incurred for the provision of approach services in the airspace around Luxembourg airport.

Findings

- (21) The Commission has assessed the consistency of the revised cost-efficiency targets proposed for the Belgium-Luxembourg *en route* charging zone based on the criteria laid down in points 1.4(a), (b) and (c) of Annex IV to Implementing Regulation (EU) 2019/317.
- (22) Concerning the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the *en route* DUC trend at charging zone level of +1,9 % over RP3 underperforms the Union-wide trend of +1,0 % over the same period. The Commission notes that this constitutes an improvement from the DUC trend of +5,7 % calculated on the basis of the draft FABEC performance plan submitted in 2021.
- (23) Concerning the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the long-term *en route* DUC trend at charging zone level over the second reference period ('RP2') and RP3 of +1,1 % underperforms the long-term Union-wide trend of -1,3 % over the same period. The Commission notes that this constitutes an improvement from the long-term DUC trend of +4,0 % calculated on the basis of the draft FABEC performance plan submitted in 2021. With reference to recital (13), this improvement is partially due to the adjustment of the baseline value for 2014 for the charging zone.
- (24) Concerning the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the baseline value for the DUC of EUR 83,26 of Belgium and Luxembourg in EUR2017 is 13,2 % higher than the average baseline value of 73,53 EUR2017 of the relevant comparator group. The Commission notes that the difference becomes even larger during RP3, as the *en route* DUC of Belgium and Luxembourg for 2024 is higher by 29,8 % than the average of the comparator group.
- (25) Furthermore, it is necessary to examine whether the deviations observed in recitals (22) to (24) above from the criteria set out in points 1.4(a), 1.4(b) and 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex, provided that the observed deviations from the Union-wide DUC trend and from the long-term Union-wide DUC trend are exclusively due to additional determined costs related to measures necessary to achieve the performance targets in the key performance area of capacity or to restructuring measures within the meaning of Article 2(18) of Implementing Regulation (EU) 2019/317.
- (26) The Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported by Belgium and Luxembourg in the revised draft FABEC performance plan and the determined costs that would be required to meet the RP3 Union-wide DUC trend is approximately EUR 8,2 M in EUR2017, whilst a corresponding estimated deviation from the long-term Union-wide trend amounts to approximately EUR 43,7 M in EUR2017.
- (27) Similarly as in the draft FABEC performance plan submitted in 2021, Belgium and Luxembourg continue to contend that airspace complexity is one of the key drivers behind the deviation of the revised draft performance plan from the Union-wide DUC trends. The revised draft FABEC performance plan continues to highlight that the complexity of the Belgium-Luxembourg airspace constitutes a factor increasing the relative workload of air traffic controllers and thus weighting negatively on air traffic controller productivity and on the *en route* cost base.

- (28) However, the Commission notes that Belgium and Luxembourg have not demonstrated, in the revised draft FABEC performance plan, that the complexity of the provision of air navigation services in the charging zone would have increased compared to RP2 or that additional costs would be incurred in RP3 because of a change in the complexity of operations.
- (29) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission notes that Belgium and Luxembourg refer in the revised draft FABEC performance plan to additional determined costs incurred over RP3 by the *en route* air navigation service providers skeyes and MUAC in relation to measures to increase capacity.
- (30) The Commission observes that seven capacity-related measures for skeyes and MUAC are substantiated in the revised draft FABEC performance plan as a justification for the observed deviation from the Union-wide cost-efficiency trends. Four of those measures were already detailed in the draft FABEC performance plan submitted in 2021, whilst three additional measures specific to MUAC have been included.
- (31) Regarding skeyes, the revised draft FABEC performance plan outlines measures aimed at maintaining appropriate levels of air traffic controller (ATCO) capacity in order to address the ageing of the air traffic controller workforce and the consequent high number of retirements expected during RP3 and the fourth reference period ('RP4').
- (32) Such measures include in particular the recruitment and training of new air traffic controllers in order to replace the planned retirements and deliver the capacity required by the forecasted traffic. Furthermore, skeyes is reported to incur significant costs in relation to the 'DISPO-scheme' which, in accordance with Belgian law ⁽⁷⁾, requires air traffic controllers to be withdrawn from duty five years before their retirement date. During those five years, they are eligible for pre-retirement and receive an allowance equaling between 75 % and 85 % of their last salary. According to the information provided in the draft performance plan, air traffic controllers are currently placed in DISPO at the age of 56 and this age limit is due to be raised to 57 from 2025 onwards. The Commission notes that no mitigation measures have been presented by Belgium in order to limit the considerable and growing financial impact of the DISPO scheme on the RP3 cost base.
- (33) The Commission further observes that the total costs presented in the revised draft performance plan in respect of the measures outlined in recitals (31) and (32) have been re-evaluated for calendar years 2022 to 2024, leading to an increase of 22,4 % in 2022, of 49,0 % in 2023 and of 36,8 % in 2024.
- (34) Furthermore, the revised draft FABEC performance plan refers to additional costs that skeyes will incur in respect of the replacement of its air traffic management ('ATM') system with a single, integrated and harmonized airspace management system with MUAC and the Belgian Defense, which aims to support the integration of civil and military ATM services and to enhance capacity and operational efficiencies. The Commission observes that the costs associated with that measure are estimated to be lower than indicated in the draft FABEC performance plan submitted in 2021, by -9,5 % in 2023 and by -11,9 % in 2024.
- (35) In respect of MUAC, Belgium and Luxembourg report, similarly as in the draft FABEC performance submitted in 2021, that the collective agreement concluded in 2019 constitutes a measure for the achievement of capacity targets because it aims, in essence, to increase the availability of ATCOs in order to meet traffic demand. The flexibility provisions introduced into the agreement are accompanied by an increase of salary scales by nearly 11 %, which impacts the cost base over the whole reference period. The Commission observes that the costs presented in the revised draft FABEC performance plan in respect of this measure have been revised for calendar years 2022-2024, leading to an increase of 7,4 % in 2022, of 9,0 % in 2023 and of 9,2 % in 2024.
- (36) Due to the magnitude of the changes in the costs referred to in recitals (33), (34) and (35), the Commission considers that Belgium and Luxembourg should further explain and detail the assumptions underlying the calculation of those costs.

⁽⁷⁾ Royal Decree of 23 April 2017.

- (37) The revised draft FABEC performance plan reiterates that the achievement of capacity targets by MUAC requires an enhanced post-operations analysis process, related tools and 'business intelligence facilities' enabling the further optimization of the planning of daily operations. Belgium and Luxembourg indicate that this set of measures, named the 'PABI' project, is foreseen to provide a 'slight amount of additional capacity' and to result in some ATFM delay reductions by avoiding unnecessary operational restrictions for airspace users (referred to as 'over-regulation'). The estimated costs of this project remain unchanged from the draft FABEC performance plan submitted in 2021. The Commission considers that the contribution of the PABI initiative to the achievement of local capacity targets should be further substantiated in order to evaluate whether the related additional costs can be determined as necessary and proportionate for deviating from Union-wide cost-efficiency trends.
- (38) Furthermore, the revised draft performance plan includes three additional measures by MUAC which are regarded by Belgium and Luxembourg to generate additional costs necessary for the achievement of capacity targets. Those measures comprise the ab-initio training of air traffic controllers, the employment of additional air traffic controllers for the Brussels sector of MUAC and a new manpower planning system.
- (39) Having regard to the evaluation made by the performance review body, the additional total costs reported by Belgium and Luxembourg in respect of the capacity-enhancement measures referred to in recitals (30) to (38) are significantly lower than the deviation from the long-term Union-wide DUC trend observed in recitals (23) and (26). Therefore, even if one were to accept that all of those measures are necessary and proportionate in view of achieving the local capacity targets, it is clear that the deviation from the long-term DUC trend exceeds in monetary terms the additional costs associated with those measures. That deviation is hence not exclusively due to additional determined costs related to measures necessary to achieve the performance targets in the key performance area of capacity.
- (40) Therefore, the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Belgium and Luxembourg.
- (41) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it suffices to mention that Belgium and Luxembourg have not presented in the revised draft performance plan any restructuring measures which would justify a deviation from the Union-wide DUC trend or from the Union-wide long-term DUC trend. Therefore, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Belgium and Luxembourg.

CONCLUSIONS

- (42) On the grounds of the findings set out in recitals (11) to (41), the Commission considers, at this stage of the assessment of the revised draft FABEC performance plan, that doubts remain as to the consistency of the cost-efficiency performance targets proposed for the Belgium-Luxembourg *en route* charging zone.
- (43) Accordingly, the Commission notes that the recommendations set out in Article 3 of Implementing Decision (EU) 2022/728 with regard to those performance targets have not been adequately addressed in the revised draft FABEC performance plan.
- (44) In particular, the Commission observes that the revised cost-efficiency performance targets proposed for the Belgium-Luxembourg charging zone are consistent neither with the RP3 Union-wide DUC trend, nor with the long-term Union-wide DUC trend. The Commission also observes that the determined costs for the charging zone have not been reduced to a sufficient extent in view of ensuring consistency with the Union-wide performance targets.
- (45) In addition, the Commission did not find, based on the elements and justifications provided in the revised draft FABEC performance plan, that the significant deviation from the long-term Union-wide DUC trend could be exclusively attributed to additional costs incurred for the achievement of the local capacity performance targets.
- (46) Furthermore, the Commission notes that the revised draft FABEC performance plan does not set out major structural measures which would mitigate the planned cost increases over RP3 and contribute to cost-efficiency over the medium and long term.

- (47) The Commission has therefore decided to initiate the detailed examination set out in Article 15(3) of Implementing Regulation (EU) 2019/317 in respect of the cost-efficiency performance targets for the Belgium-Luxembourg *en route* charging zone,

HAS ADOPTED THIS DECISION:

Article 1

The following cost-efficiency performance targets proposed for the Belgium-Luxembourg *en route* charging zone, contained in the revised draft RP3 performance plan established at functional airspace block level by Belgium, Germany, France, Luxembourg, and the Netherlands give rise to doubts in respect of their consistency with the Union-wide performance targets:

KEY PERFORMANCE AREA OF COST-EFFICIENCY

Determined unit cost of *en route* air navigation services

<i>En route</i> charging zone of Belgium-Luxembourg	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Revised draft <i>en route</i> cost-efficiency targets , expressed as determined <i>en route</i> unit cost (in real terms in 2017 prices)	81,78 EUR	83,26 EUR	189,52 EUR	104,47 EUR	94,18 EUR	89,87 EUR

Article 2

1. The detailed examination procedure set out in Article 15(3) of Implementing Regulation (EU) 2019/317 is hereby initiated with regard to the cost-efficiency performance targets referred to in Article 1.
2. In order to support the further assessment of the performance targets referred to in Article 1, Belgium, Germany, France, Luxembourg, and the Netherlands shall provide, upon request by the Commission, relevant additional data and information with regard to the elements set out in the Annex to this Decision.

Article 3

This Decision is addressed to the Kingdom of Belgium, the Federal Republic of Germany, the French Republic, the Grand Duchy of Luxembourg, and the Kingdom of the Netherlands.

Done at Brussels, 24 October 2022.

For the Commission
Adina-Ioana VĂLEAN
Member of the Commission

ANNEX

NON-EXHAUSTIVE LIST OF ELEMENTS FOR FURTHER ANALYSIS IN RESPECT OF THE COST-EFFICIENCY PERFORMANCE TARGETS FOR THE BELGIUM-LUXEMBOURG EN ROUTE CHARGING ZONE

- (1) Measures invoked by Belgium and Luxembourg in order to justify the observed deviations from Union-wide cost-efficiency trends on the grounds of additional costs for the achievement of capacity targets;
 - (2) Complexity of the provision of air navigation services in the charging zone, and its evolution over time;
 - (3) Detailed assumptions and parameters underlying the determined costs of skeyes and MUAC, for each year of RP3 and broken down per cost category and service;
 - (4) Service units recorded and forecasted in the charging zone, broken down per ANSP;
 - (5) Distribution of the MUAC costs and service units between the Brussels sector and the other sectors within the MUAC area of responsibility;
 - (6) Capacity planning of skeyes and MUAC including with regard to the planned number of ATCOs, ATCO training, and planned investments in fixed assets;
 - (7) Cost allocation between *en route* and terminal services, and between services in the scope of the performance plan and other services;
 - (8) 'DISPO' pre-retirement scheme for air traffic controllers in Belgium;
 - (9) Cross-border service provision arrangements with neighbouring countries, and their operational and financial impact;
 - (10) Costs charged to airspace users in RP2 in respect of postponed or delayed investments in fixed assets.
-

COMMISSION DECISION (EU) 2022/2256**of 15 November 2022****on the initiation of the detailed examination of certain performance targets contained in the revised draft performance plan for the third reference period submitted at functional airspace block level by Switzerland pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council***(notified under document C(2022) 8076)***(Only the German, French and Italian texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Agreement between the European Community and the Swiss Confederation on Air Transport ⁽¹⁾,

Having regard to Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) ⁽²⁾, and in particular Article 11(3) point (c), second paragraph, thereof,

Having regard to Commission Implementing Regulation (EU) 2019/317 of 11 February 2019 laying down a performance and charging scheme in the single European sky and repealing Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 ⁽³⁾, and in particular Article 15(1) and (3) thereof,

Whereas:

- (1) Pursuant to Article 10 of Implementing Regulation (EU) 2019/317, Member States are to draw up, either at national level or at the level of functional airspace blocks ('FABs'), binding performance targets for each reference period of the performance scheme for air navigation services and network functions. Those performance targets are to be consistent with the Union-wide targets adopted by the Commission for the reference period concerned.
- (2) Union-wide performance targets for the third reference period ('RP3') were originally set out in Commission Implementing Decision (EU) 2019/903 ⁽⁴⁾. As those Union-wide performance targets and the draft RP3 performance plans subsequently submitted in October 2019 by the Member States and Switzerland were drawn up before the outbreak of the COVID-19 pandemic in March 2020, they did not take account of the considerable reduction in air traffic due to the measures taken by the Member States and third countries to contain the pandemic.
- (3) In response to the impact of the COVID-19 pandemic on the provision of air navigation services, exceptional measures for RP3, which derogate from the provisions of Implementing Regulation (EU) 2019/317, were set out in Commission Implementing Regulation (EU) 2020/1627 ⁽⁵⁾. The Commission adopted, on 2 June 2021, Implementing Decision (EU) 2021/891 ⁽⁶⁾ setting revised Union-wide performance targets for RP3. On that basis, the Member States and Switzerland submitted to the Commission, in October 2021, draft performance plans containing revised performance targets for RP3.

⁽¹⁾ OJ L 114, 30.4.2002, p. 73.

⁽²⁾ OJ L 96, 31.3.2004, p. 1.

⁽³⁾ OJ L 56, 25.2.2019, p. 1.

⁽⁴⁾ Commission Implementing Decision (EU) 2019/903 of 29 May 2019 setting the Union-wide performance targets for the air traffic management network for the third reference period starting on 1 January 2020 and ending on 31 December 2024 (OJ L 144, 3.6.2019, p. 49).

⁽⁵⁾ Commission Implementing Regulation (EU) 2020/1627 of 3 November 2020 on exceptional measures for the third reference period (2020-2024) of the single European sky performance and charging scheme due to the COVID-19 pandemic (OJ L 366, 4.11.2020, p. 7).

⁽⁶⁾ Commission Implementing Decision (EU) 2021/891 of 2 June 2021 setting revised Union-wide performance targets for the air traffic management network for the third reference period (2020-2024) and repealing Implementing Decision (EU) 2019/903 (OJ L 195, 3.6.2021, p. 3).

- (4) Commission Implementing Decision (EU) 2022/780 ⁽⁷⁾ analysed certain performance targets contained in the draft performance plan for RP3 submitted by Switzerland, established jointly at the level of the Functional Airspace Block Europe Central ('FABEC'), together with Belgium, Germany, France, Luxembourg, and the Netherlands ('Member States part of FABEC'). The Commission found that the cost-efficiency performance targets for the Belgium-Luxembourg *en route* charging zone were not consistent with the Union-wide performance targets and issued recommendations for the revision of those targets.
- (5) In response to Russia's war of aggression against Ukraine, which started on 24 February 2022, the Union has imposed restrictive measures which prohibit Russian air carriers, any Russian-registered aircraft and any non-Russian-registered aircraft which is owned or chartered, or otherwise controlled by any Russian natural or legal person, entity or body, from landing in and taking off from, or overflying the territory of the Union. Those restrictive measures and the counter-measures adopted by Russia have led to changes in air traffic in European airspace. Certain Member States have been severely affected by the changes in the number of overflights in the airspace under their responsibility. However, at Union-wide level, the observed impact on the number of flights has been limited in contrast with the sharp reduction of air traffic across Europe which resulted from the outbreak of the COVID-19 pandemic.
- (6) Switzerland, together with the Member States part of FABEC, submitted, on 13 July 2022, a revised draft FABEC performance plan for RP3 ('revised draft FABEC performance plan') for assessment by the Commission.
- (7) The performance review body, assisting the Commission in the implementation of the performance scheme pursuant to Article 11(2) of Regulation (EC) No 549/2004, has submitted to the Commission a report containing its advice on the assessment of the revised draft FABEC performance plan.
- (8) In accordance with Article 15(1) of Implementing Regulation (EU) 2019/317, the Commission has assessed the consistency of the FAB performance targets contained in the revised draft FABEC performance plan on the basis of the assessment criteria laid down in point 1 of Annex IV to that Implementing Regulation, and taking account of local circumstances. In respect of each key performance area and the related performance targets, the Commission has complemented its assessment by reviewing the elements set out in point 2 of Annex IV to that Implementing Regulation.
- (9) The Eurocontrol STATFOR base traffic forecast published in June 2022 takes account of the changed circumstances referred to in recital (5). Based on that forecast, the Commission notes that Switzerland and the Member States part of FABEC are not foreseen to experience major changes in air traffic flows over RP3 as a result of Russia's war in Ukraine. Therefore, those changed circumstances do not directly impact the performance targets contained in the revised draft FABEC performance plan or the assessment of those targets in respect of their consistency with the Union-wide performance targets.
- (10) On the basis of the assessment referred to in recital (8), the Commission has found that the performance targets directly applicable to the air navigation service providers operating in the airspace of Switzerland are consistent with the Union-wide performance targets. Therefore, no related findings are set out in this Decision.

⁽⁷⁾ Commission Implementing Decision (EU) 2022/780 of 13 April 2022 on the inconsistency of certain performance targets contained in the draft functional airspace block performance plan submitted by Switzerland pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period and setting out recommendations for the revision of those targets (OJ L 139, 18.5.2022, p. 218).

- (11) However, in its Decision (EU) 2022/2255 ⁽⁸⁾, the Commission has concluded, in respect of the revised draft FABEC performance plan, that the cost-efficiency performance targets proposed for the Belgium-Luxembourg *en route* charging zone continue to give rise to doubts as to their consistency with the Union-wide performance targets. The Commission has therefore decided to initiate the detailed examination laid down in Article 15(3) of Implementing Regulation (EU) 2019/317 in respect of those performance targets.
- (12) Therefore, Switzerland should be notified that the Commission will initiate the detailed examination set out in Article 15(3) of Implementing Regulation (EU) 2019/317 in respect of the performance targets referred to in recital (11), which are contained in the revised draft FABEC performance plan jointly adopted by the Member States part of FABEC and Switzerland,

HAS ADOPTED THIS DECISION:

Article 1

The detailed examination procedure set out in Article 15(3) of Implementing Regulation (EU) 2019/317 is hereby initiated with regard to the cost-efficiency performance targets referred to in Article 1 of Decision (EU) 2022/2255.

Article 2

This Decision is addressed to the Swiss Confederation.

Done at Brussels, 15 November 2022.

For the Commission
Adina-Ioana VĂLEAN
Member of the Commission

⁽⁸⁾ Commission Decision (EU) 2022/2255 of 24 October 2022 on the initiation of the detailed examination of certain performance targets contained in the revised draft performance plan for the third reference period submitted at functional airspace block level by Belgium, Germany, France, Luxembourg, and the Netherlands pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council (see page 71 of this Official Journal).

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2019/1383 of 8 July 2019 amending and correcting Regulation (EU) No 1321/2014 as regards safety management systems in continuing airworthiness management organisations and alleviations for general aviation aircraft concerning maintenance and continuing airworthiness management*(Official Journal of the European Union L 228 of 4 September 2019)*

On page 32, in Annex I, point (59), in the amendment to point (b) of Appendix VIII to Annex I to Regulation (EU) No 1321/2014:

for: ‘(59) in Appendix VIII, point (b)(9) is deleted.’,

read: ‘(59) in Appendix VIII, point (b) is amended as follows:

(i) point (b)(9) is deleted;

(ii) the third sentence is replaced by the following:

“The criteria 1 to 8 cannot be overridden by less restrictive instructions issued in accordance with ‘M.A.302(d) Maintenance Programme’.”.

Corrigendum to Council Decision (EU) 2022/1975 of 13 October 2022 on the position to be taken on behalf of the European Union within the Trade Committee established by the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part as regards the amendment of Annexes 10-A and 10-B to the Agreement

(Official Journal of the European Union L 271 of 19 October 2022)

1. Page 7, recital 10, point (b):

- for:* '(b) Having reviewed the geographical indications of the EU protected in the Agreement and in light of Commission Regulation (EU) 2019/674 of 29 April 2019 amending Annex III to Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks(16), the EU requested on November 2020 the removal of the name 'Polish Cherry' from Annex 10-B to the Agreement, in accordance with Article 10.25.3(b), as it ceased to be protected in the EU.'
- read:* '(b) Having reviewed the geographical indications of the EU protected in the Agreement and in light of Commission Regulation (EU) 2019/674 of 29 April 2019 amending Annex III to Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks(16), the EU requested in November 2020 the removal of the name 'Polish Cherry' from Annex 10-B to the Agreement, in accordance with Article 10.25.3(b), as it ceased to be protected in the EU.'

2. Page 7, footnote 15:

- for:* '(15) 대한민국정부 관보 제20163호 별권1 (official gazette 20163, separate volume 1), 2021.1.6, p. 4.'
- read:* '(15) 대한민국정부 관보 제20163호 별권1 (official gazette 20163, separate volume 1), 2022.1.6, p. 4.'

3. Page 9, Article 2, point (6):

- for:* '(6) removal of the geographical indications 'Seosan Garlic (서산마늘)', 'Muan White Lotus Tea (무안백련차)' and 'Cheongyang Powdered Hot Pepper (청양고춧가루)', 'Yeoju Sweet Potato (여주고구마)' from the list of geographical indications of Korea in Part B of Annex 10-A to the Agreement; and'
- read:* '(6) removal of the geographical indications 'Seosan Garlic (서산마늘)', 'Muan White Lotus Tea (무안백련차)', 'Cheongyang Powdered Hot Pepper (청양고춧가루)' and 'Yeoju Sweet Potato (여주고구마)' from the list of geographical indications of Korea in Part B of Annex 10-A to the Agreement; and'
-

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN