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Contents

[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.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1761

of 6 September 2023

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Mela Alto Adige / Südtiroler Apfel' (PGI))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected geographical indication 'Mela Alto Adige / Südtiroler Apfel' registered under Commission Regulation (EC) No 1855/2005 ([2]).

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* as required by Article 50(2)(a) of that Regulation ([3]).

(3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the product specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Mela Alto Adige / Südtiroler Apfel' (PGI) are hereby approved.

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*.

([1]) OJ L 343, 14.12.2012, p. 1.

([2]) Commission Regulation (EC) No 1855/2005 of 14 November 2005 supplementing the Annex to Regulation (EC) No 2400/96 as regards the entry of certain names in the Register of protected designations of origin and protected geographical indications (Mela Alto Adige or Südtiroler Apfel (PGI), Asperge des Sables des Landes (PGI), Pâtes d'Alsace (PGI), Jamón de Trevélez (PGI), Oliva Ascolana del Piceno (PDO)) (OJ L 297, 15.11.2005, p. 5).

([3]) OJ C 182, 24.5.2023, p. 20.

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

Done at Brussels, 6 September 2023.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1762

of 6 September 2023

registering a geographical indication of a spirit drink under Article 30(2) of Regulation (EU) 2019/787 of the European Parliament and of the Council ('Sárréti kökénypálinka')

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 ([1]), and in particular Article 30(2) thereof,

Whereas:

(1) Pursuant to Article 17(5) of Regulation (EC) No 110/2008 of the European Parliament and of the Council ([2]), the Commission has examined Hungary's application of 6 March 2019 for the registration of the name 'Sárréti kökénypálinka' as a geographical indication.

(2) Regulation (EU) 2019/787, which replaces Regulation (EC) No 110/2008, entered into force on 25 May 2019. Under Article 49(1) thereof, Chapter III of Regulation (EC) No 110/2008 on geographical indications is repealed with effect from 8 June 2019.

(3) After concluding that the application complied with Regulation (EC) No 110/2008, the Commission published the main specifications of the technical file in the *Official Journal of the European Union* ([3]) as required by Article 17(6) of that Regulation, in accordance with the first subparagraph of Article 50(4) of Regulation (EU) 2019/787.

(4) No notice of opposition has been received by the Commission under Article 27(1) of Regulation (EU) 2019/787.

(5) The name 'Sárréti kökénypálinka' should therefore be registered as a geographical indication,

HAS ADOPTED THIS REGULATION:

Article 1

The geographical indication 'Sárréti kökénypálinka' is hereby entered in the register. This Regulation grants the geographical indication 'Sárréti kökénypálinka' the protection referred to in Article 21 of Regulation (EU) 2019/787 in accordance with Article 30(4) of that Regulation.

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.

([1]) OJ L 130, 17.5.2019, p. 1.

([2]) Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

([3]) OJ C 182, 24.5.2023, p. 20.

Done at Brussels, 6 September 2023.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1763

of 12 September 2023

granting a Union authorisation for the biocidal product family 'Lactic acid Family – Quatchem' 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 14 April 2019, Arrow Regulatory (Ireland) Limited 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 'Lactic acid Family – Quatchem' of product-type 3, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Latvia had agreed to evaluate the application. The application was recorded under case number BC-WC050857-29 in the Register for Biocidal Products.

(2) 'Lactic acid Family – Quatchem' 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 3.

(3) On 16 May 2022, 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 13 December 2022, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'Lactic acid Family – Quatchem' 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 'Lactic acid Family – Quatchem' 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 5 January 2023, 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 'Lactic acid Family – Quatchem'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) ECHA opinion of 24 November 2022 on the Union authorisation of 'Lactic acid Family – Quatchem' (ECHA/BPC/371/2022), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0030143-0000 is hereby granted to Arrow Regulatory (Ireland) Limited for the making available on the market and use of the biocidal product family 'Lactic acid Family – Quatchem' subject to compliance with the terms and conditions set out in the Annex.

The Union authorisation is valid from 3 October 2023 to 30 September 2033.

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, 12 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Lactic acid Family - Quatchem

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0030143-0000

R4BP asset number: EU-0030143-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	Lactic acid Family - Quatchem

1.2. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Arrow Regulatory (Ireland) Limited
	Address	The Black Church St. Mary's Place, D07 P4AX Dublin Ireland
Authorisation number	EU-0030143-0000	
R4BP asset number	EU-0030143-0000	
Date of the authorisation	3 October 2023	
Expiry date of the authorisation	30 September 2033	

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

Name of manufacturer	Quat-Chem Ltd. A Neogen Company
Address of manufacturer	1-4 Sandfield Industrial Park, Dodgson Street, Rochdale, OL16 5SJ Lancashire United Kingdom
Location of manufacturing sites	1-4 Sandfield Industrial Park, Dodgson Street, Rochdale, OL16 5SJ Lancashire United Kingdom

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, 4206 AC Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46, 4206 AC Gorinchem Netherlands

Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S. A
Address of manufacturer	Z.I. et Portuaire, B.P. 32, FR-67390 Marckolsheim France
Location of manufacturing sites	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	4,0	4,0

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

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary 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
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	4,0	4,0

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	Wear protective gloves. Wear eye protection. Wash hands thoroughly after handling. IF IN EYES:Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. IF ON SKIN:Wash with plenty of water. If skin irritation occurs: Get medical advice. If skin irritation occurs: Get medical attention. Take off contaminated clothing. And wash it before reuse. Dispose of contents to hazardous or special waste collection point in accordance with national regulations. Dispose of container to hazardous or special waste collection point in accordance with national regulations.

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

4.1. **Use description**

Table 1.

Use # 1 – Use # 1.1 – Post milking teat disinfection – manual dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Yeasts Common name: Yeasts Development stage: -
Field(s) of use	Indoor Teat disinfection post-milking by manual dipping using a dip cup
Application method(s)	Method: Manual dipping using a dip cup Detailed description: Contact time for dipping at 30 °C in dirty conditions: - 5 minutes for bacteria and yeasts.
Application rate(s) and frequency	Application Rate: 5 to 10 ml per teat Dilution (%): RTU (Ready-to-use) product Number and timing of application: up to twice per day
Category(ies) of users	Professional
Pack sizes and packaging material	1 000 litre high density polyethylene (HDPE) container with HDPE closure; 200 litre plastic drum with HDPE closure; 25 litre HDPE keg with DIN 61 or equivalent HDPE screw cap; 5 litre HDPE keg with DIN 51 or equivalent HDPE screw cap.

4.1.1. *Use-specific instructions for use*

See general directions for use.

Product to be applied post-milking by use of a dipping cup.

Pre-clean teat with dry wipe, pour the product into the reservoir of the dip cup. When using a dip cup, the cup is applied to each teat in turn and the operator squeezes the product from the reservoir into the cup. The cup has a non-return value so any residual product cannot go back into the reservoir.

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.

4.2. **Use description**

Table 2.

Use # 2 – Use # 1.2 – Post milking teat disinfection - spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Yeasts Common name: Yeasts Development stage: -
Field(s) of use	Indoor Teat disinfection post-milking by using hand-held sprayer
Application method(s)	Method: Manual spraying using hand-held sprayer Detailed description: Contact time for spraying at 30 °C in dirty conditions: — 5 minutes for bacteria and yeasts.
Application rate(s) and frequency	Application Rate: 5 to 10 ml per teat Dilution (%): RTU product Number and timing of application: up to twice per day
Category(ies) of users	Professional
Pack sizes and packaging material	1 000 litre HDPE container with HDPE closure; 200 litre plastic drum with HDPE closure; 25 litre HDPE keg with DIN 61 or equivalent HDPE screw cap; 5 litre HDPE keg with DIN 51 or equivalent HDPE screw cap.

4.2.1. *Use-specific instructions for use*

See general directions for use.

Product to be applied post-milking by use of a hand-held sprayer.

Pre-clean teat with dry wipe, pour the product into the reservoir of the sprayer. The operator will spray each animal once after milking.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those bystanders wear the same type of PPE as the operator.

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** [1] **OF THE META SPC 1**

5.1. **Instructions for use**

See use-specific instruction for use of meta SPC 1.

Always read the label or leaflet before use.

The product must be brought to room temperature before use. The amount of product applied per teat is dependent upon the animal being treated. For large mammals (cows, camels) – up to 10 ml per teat, and for small mammals (sheep, goats) – up to 5 ml per teat. Make sure that the teats are fully covered with disinfectant. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing for at least 5 minutes).

5.2. **Risk mitigation measures**

The use of eye protection consistent with European standard EN ISO 16321 or equivalent during handling of the product is mandatory.

Avoid hand to eye transfer.

Wear protective chemical resistant gloves during product handling phase (nitrile gloves – classified under European standards EN ISO 374 or EN 455 or equivalent).

The full titles of the European standards indicated here are available under section 6.

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

IF ON SKIN: Immediately wash with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

[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 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.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

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.

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep out of reach of children.

Store in original container tightly closed.

Store between 0 °C and + 30 °C.

Shelf life: 24 months

6. **OTHER INFORMATION**

The full titles of the European standards referenced in section 5.2 'Risk mitigation measures' are :

EN ISO 16321 - Eye and face protection for occupational use

EN ISO 374 – Protective gloves against dangerous chemicals and microorganisms

EN 455 - Medical gloves for single use

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)	Synodex	Market area: EU
	Lactopost	Market area: EU
	Lactopost Y	Market area: EU
	Lactopost Plus	Market area: EU
	Lactopost Extra	Market area: EU
	Synodex Y	Market area: EU
	Synodex Extra	Market area: EU
	Synodex Plus	Market area: EU
	Udder X	Market area: EU
	Teat Care	Market area: EU
	Lacto Gold	Market area: EU
	Lacto Extra	Market area: EU
	Lactogold	Market area: EU
	Lacto Spray	Market area: EU

Authorisation number	EU-0030143-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	4,0

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

Trade name(s)	Laxsan	Market area: EU
	Hexsan	Market area: EU
	Lactopost R	Market area: EU
	Laxsan R	Market area: EU
	Hexfoam	Market area: EU
	Deosan LA1	Market area: EU
	Hexsan Extra	Market area: EU
	Hexsan Plus	Market area: EU
	Laxsan Plus	Market area: EU
	Laxsan Extra	Market area: EU
	Hexsan R	Market area: EU
	LA1	Market area: EU
	Condition Pink	Market area: EU

Authorisation number	EU-0030143-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	4,0

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)	PT03 - Veterinary hygiene (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	4,0	4,0

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. Contains peppermint oil. May produce an allergic reaction.
Precautionary statements	Wear protective gloves. Wear eye protection. Wash hands thoroughly after handling. IF IN EYES:Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. IF ON SKIN:Wash with plenty of water. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. Take off contaminated clothing.And wash it before reuse. Dispose of contents to hazardous or special waste collection point in accordance with national regulations. Dispose of container to hazardous or special waste collection point in accordance with national regulations.

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

4.1. **Use description**

Table 3.

Use # 1 – Use # 3.1 – Post milking teat disinfection – manual dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Yeasts Common name: Yeasts Development stage: -
Field(s) of use	Indoor Teat disinfection post-milking by manual dipping using a dip cup
Application method(s)	Method: Manual dipping using a dip cup Detailed description: Contact time for dipping at 30 °C in dirty conditions: — 5 minutes for bacteria and yeasts.
Application rate(s) and frequency	Application Rate: 5 to 10 ml per teat Dilution (%): RTU product Number and timing of application: up to twice per day
Category(ies) of users	Professional
Pack sizes and packaging material	1 000 litre HDPE container with HDPE closure; 200 litre plastic drum with HDPE closure; 25 litre HDPE keg with DIN 61 or equivalent HDPE screw cap; 5 litre HDPE keg with DIN 51 or equivalent HDPE screw cap.

4.1.1. *Use-specific instructions for use*

See general directions for use.

Product to be applied post-milking by use of a dipping cup.

Pre-clean teat with dry wipe, pour the product into the reservoir of the dip cup. When using a dip cup, the cup is applied to each teat in turn and the operator squeezes the product from the reservoir into the cup. The cup has a non-return value so any residual product cannot go back into the reservoir.

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.

4.2. **Use description**

Table 4.

Use # 2 – Use # 3.2 – Post milking teat disinfection - spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Yeasts Common name: Yeasts Development stage: -
Field(s) of use	Indoor Teat disinfection post-milking by using hand-held sprayer
Application method(s)	Method: Manual spraying using hand-held sprayer Detailed description: Contact time for spraying at 30 °C in dirty conditions: — 5 minutes for bacteria and yeasts.
Application rate(s) and frequency	Application Rate: 5 to 10 ml per teat Dilution (%): RTU product Number and timing of application: up to twice per day
Category(ies) of users	Professional

Pack sizes and packaging material	1 000 litre HDPE container with HDPE closure; 200 litre plastic drum with HDPE closure; 25 litre HDPE keg with DIN 61 or equivalent HDPE screw cap; 5 litre HDPE keg with DIN 51 or equivalent HDPE screw cap.

4.2.1. *Use-specific instructions for use*

See general directions for use.

Product to be applied post-milking by use of a hand-held sprayer.

Pre-clean teat with dry wipe, pour the product into the reservoir of the sprayer. The operator will spray each animal once after milking.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those bystanders wear the same type of PPE as the operators.

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** [2] **OF THE META SPC 2**

5.1. **Instructions for use**

See use-specific instruction for use of meta SPC 2.

Always read the label or leaflet before use.

The product must be brought to room temperature before use. The amount of product applied per teat is dependent upon the animal being treated. For large mammals (cows, camels) – up to 10 ml per teat, and for small mammals (sheep, goats) – up to 5 ml per teat. Make sure that the teats are fully covered with disinfectant. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing for at least 5 minutes).

5.2. **Risk mitigation measures**

The use of eye protection consistent with European standard EN ISO 16321 or equivalent during handling of the product is mandatory.

Avoid hand to eye transfer.

Wear protective chemical resistant gloves during product handling phase (nitrile gloves – classified under European standards EN ISO 374 or EN 455 or equivalent).

The full titles of the European standards indicated here are available under section 6.

[2] 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.

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

IF ON SKIN: Immediately wash with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

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.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

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.

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep out of reach of children.

Store in original container tightly closed.

Store between 0 °C and + 30 °C.

Shelf life: 24 months

6. **OTHER INFORMATION**

The full titles of the EN standards referred to in section 5.2 are the following:

EN ISO 16321 - Eye and face protection for occupational use

EN ISO 374 – Protective gloves against dangerous chemicals and micro-organisms

EN 455 - Medical gloves for single use

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)	Synoshield	Market area: EU
	Lactopost G	Market area: EU
	Synoshield P	Market area: EU
	Lactopost P	Market area: EU
	Synoshield G	Market area: EU
	Lactoshield	Market area: EU
	Lactoshield Plus	Market area: EU
	Lactoshield Extra	Market area: EU
	Synoshield Extra	Market area: EU
	Synoshield Plus	Market area: EU

	Lactopost Protect		Market area: EU		
	Udder Shield		Market area: EU		
	Teat Care		Market area: EU		
	Mint Lacto Plus		Market area: EU		
	Lacto Care G		Market area: EU		
	Lactosal		Market area: EU		
	Lacto Care P		Market area: EU		
	Previoshield		Market area: EU		
Authorisation number	EU-0030143-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	4,0

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1764

of 12 September 2023

granting a Union authorisation for the biocidal product family 'Oxy'Pharm H_2O_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 30 January 2017, OXY'PHARM 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 'Oxy'Pharm H_2O_2' of product-types 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-HC029658-43 in the Register for Biocidal Products.

(2) 'Oxy'Pharm H_2O_2' contains hydrogen peroxide as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 4.

(3) On 10 March 2022, 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 17 October 2022, the Agency submitted to the Commission its opinion ([2]), including the draft summary of the biocidal product characteristics ('SPC') of 'Oxy'Pharm H_2O_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 'Oxy'Pharm H_2O_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 31 October 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 'Oxy'Pharm H_2O_2'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) ECHA opinion of 14 June 2022 on the Union authorisation of 'Oxy'Pharm H_2O_2' (ECHA/BPC/358/2022), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0029752-0000 is granted to OXY'PHARM for the making available on the market and use of the biocidal product family 'Oxy'Pharm H_2O_2' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 3 October 2023 until 30 September 2033.

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 the Member States in accordance with the Treaties.

Done at Brussels, 12 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Oxy'Pharm H_2O_2

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

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0029752-0000

R4BP asset number: EU-0029752-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	Oxy'Pharm H_2O_2

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	OXY'PHARM
	Address	Rue Marcel Paul 829, 94500 Champigny-sur-Marne France
Authorisation number	EU-0029752-0000	
R4BP asset number	EU-0029752-0000	
Date of the authorisation	3 October 2023	
Expiry date of the authorisation	30 September 2033	

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

Name of manufacturer	OXY'PHARM
Address of manufacturer	Rue Marcel Paul, 829, 94500 Champigny-sur-Marne France
Location of manufacturing sites	Rue Marcel Paul, 829, 94500 Champigny-sur-Marne France

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

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Resource Efficiency GmbH
Address of manufacturer	Rellinghauser Straße 1—11, 45128 Essen Germany
Location of manufacturing sites	Evonik Industries AG / BL Active Oxygens, Untere Kanalstrasse 3, 79618 Rheinfelden 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
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	6,0	12,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0	0,0017

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	Oxy'Pharm H_2O_2 6%

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
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	6,0	6,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017	0,0017

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 serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wash hands thoroughly after handling. Avoid release to the environment. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Dispose of contents to hazardous or special waste collection point in accordance with national regulations. Dispose of container to hazardous or special waste collection point in accordance with national regulations.

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

4.1. **Use description**

Table 1

Use # 1 – Use #1.1: Hard surface disinfection by 6% Fogging Hydrogen Peroxide (FHP)

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: - Common name: Bacteria Development stage: -

	Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Tuberculosis bacilli Development stage: - Scientific name: - Common name: Viruses Development stage: - Scientific name: - Common name: Fungi Development stage: -
Field(s) of use	Indoor Room disinfection with fogging hydrogen peroxide (FHP) for rooms with volumes between 4-150 m^3. It involves disinfection of hard non-porous surfaces of equipment and material (excluding medical devices) present in the treated room: — Hospitals & clinics, — laboratories of research and analysis (including P3 laboratories and white rooms), — healthcare transport, — pharmaceutical industry, — industrial laundries, — dental surgery and implantology centres, — hotels, — schools, — day nurseries.
Application method(s)	Method: Fogging Detailed description: The product is a ready-to-use product that is placed in a device. That device automatically fogs the biocidal product, in the closed space/room to be disinfected, without any user or bystander present.
Application rate(s) and frequency	Application Rate: Bactericidal, yeasticidal, fungicidal, tuberculocidal and virucidal activity: 5 ml product/m^3 and 2 hours contact time. Treat a second time at 5 ml product/m^3 and 2 hours contact time. The second treatment takes place right after the first. The two treatments can be programmed in order to be carried out sequentially. Droplet size: 1-15µM Dilution (%): - Number and timing of application: Disinfect rooms and equipment as frequently as required by the hygiene protocol in place.

Category(ies) of users	Professional
Pack sizes and packaging material	1) High density polyethylene HDPE, white (non-transparent) bottle of 1 litre with a degassing screw cap. 2) HDPE, grey (non-transparent) single-use bottle of 2 litres. 3) HDPE, white (non-transparent) can of 5 litres (refill packaging). 4) HDPE, white (non-transparent) can of 20 litres.

4.1.1. *Use-specific instructions for use*

Surfaces must be cleaned before disinfection. The product is ready-to-use and should be used without dilution. The product is designed for equipment such as Nocospray/Bio-sanitizer/Sanofog/Nocomax/Nocomax Easy/Glosair. Read the instructions for use before use. Use according to the following protocols:

— Bactericidal, yeasticidal, fungicidal, tuberculocidal and virucidal activity: 5 ml product/m^3 and 2 hours contact time. Treat a second time at 5 ml product/m^3 and 2 hours contact time.

The second treatment takes place right after the first. The two treatments can be programmed in order to be carried out sequentially.

Droplet size: 1-15µM

Relative Humidity: 25 % - 75 %

Temperature: room temperature

Respect the advised contact time. The contact time starts when the required amount of product is present in the room.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

4.1.2. *Use-specific risk mitigation measures*

Please refer to general directions for use of this Meta SPC.

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*

First aid

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

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.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Likely direct or indirect effects

— causes serious eye irritation

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

Please refer to general directions for use of this Meta SPC.

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

Please refer to general directions for use of this Meta SPC.

5. **GENERAL DIRECTIONS FOR USE** [1] **OF THE META SPC 1**

5.1. **Instructions for use**

-

5.2. **Risk mitigation measures**

During the diffusion, keep the room closed and do not enter. Treatment must be conducted with no human or animals present.

All gaps present in the room (for example, window frames) from where fog may leak must be sealed before the diffusion.

Ensure that access to the fog-treated area is denied during the whole procedure with a warning sign.

No access to the treated area should be permitted until the concentration of hydrogen peroxide is ≤0,9 ppm (1,25 mg/m^3) or a lower relevant national reference value.

The professional user may enter the room only in emergency situations when the hydrogen peroxide level has dropped below 36ppm (50 mg/m^3) and must wear the following Personal Protective Equipment (PPE): Respiratory Protective Equipment (RPE) classified under EN 14387 or equivalent with an Assigned Protection Factor (APF) 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves classified under European Standard EN 374 or equivalent, eye protection consistent with European Standard EN ISO 16321 or equivalent, coverall). Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

A measuring device should be used to ensure that the concentration of hydrogen peroxide has decreased below 0,9 ppm or a lower relevant national reference value. Unprotected persons/animals may re-enter the treated room only after the hydrogen peroxide concentration in air decreases lower than 1,25 mg/m^3 (0,9 ppm) or a lower relevant national reference value.

Individual protective equipment:

Wear chemical resistant goggles consistent with European Standard EN ISO 16321 or equivalent as eye protection during mixing and loading of the product to the packaging that is directly used in the fogging device (such as Nocospray, Bio-sanitizer, Sanofog, Nocomax or Nocomax Easy).

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

-

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local regulations. Used product can be flushed to the municipal sewer or disposed of to the manure deposit depending on local regulations. Avoid release to an individual wastewater treatment plant.

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

— Shelf life: 2 years.

6. **OTHER INFORMATION**

The full titles of the EN standards mentioned in section 5.2 are listed below:

EN 374 – Protective gloves against dangerous chemicals and micro-organisms

EN ISO 16321 - Eye and face protection for occupational use

EN 14387 - Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking

[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.

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)	Nocolyse		Market area: EU		
	Glosair 400		Market area: EU		
Authorisation number	EU-0029752-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	6,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017

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

Trade name(s)	Nocolyse menthe		Market area: EU		
	Glosair 400 menthe		Market area: EU		
Authorisation number	EU-0029752-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	6,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017

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

Trade name(s)	Nocolyse nocodor		Market area: EU		
	Glosair 400 nocodor		Market area: EU		
Authorisation number	EU-0029752-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	6,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017

META SPC 2

1. **META SPC 2 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 2 identifier**

Identifier	Oxy'Pharm H_2O_2 12%

1.2. **Suffix to the authorisation number**

Number	1-2

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 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
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	12,0	12,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017	0,0017

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	May intensify fire; oxidiser Causes serious eye damage. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from clothing and other combustible materials. Avoid release to the environment. Wear eye protection.

	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. Immediately call a doctor. Dispose of contents to hazardous or special waste collection point in accordance with national regulations. Dispose of container to hazardous or special waste collection point in accordance with national regulations.

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

4.1. **Use description**

Table 2

Use # 1 – Use #2.1: Hard surface disinfection by 12% Fogging Hydrogen Peroxide (FHP)

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: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: bacterial spores Development stage: - Scientific name: - Common name: Tuberculosis bacilli Development stage: - Scientific name: - Common name: Viruses Development stage: - Scientific name: - Common name: Fungi Development stage: -
Field(s) of use	Indoor Room disinfection with FHP for rooms with volumes between 4-150 m^3. It involves disinfection of hard non-porous surfaces of equipment and material (excluding medical devices) present in the treated room: — Hospitals & clinics, — laboratories of research and analysis (including P3 laboratories and white rooms), — healthcare transport, — pharmaceutical industry, — industrial laundries, — dental surgery and implantology centres,

	— hotels, — schools, — day nurseries.
Application method(s)	Method: Fogging Detailed description: The product is a ready-to-use product that is placed in a device. That device automatically fogs the biocidal product, in the closed space/room to be disinfected, without any user or bystander present.
Application rate(s) and frequency	Application Rate: — Bactericidal, yeasticidal, fungicidal, sporicidal and virucidal activity: 3 ml product/m^3 and 2 hours contact time. Treat a second time at 3 ml product/m^3 and 2 hours contact time. — Tuberculocidal activity: 5 ml product/m^3 and 2 hours contact time. Treat a second time at 3 ml product/m^3 and 2 hours contact time. The second treatment takes place right after the first. The two treatments can be programmed in order to be carried out sequentially. Droplet size: 1-15 µm Dilution (%): - Number and timing of application: Disinfect rooms and equipment as frequently as required by the hygiene protocol in place.
Category(ies) of users	Professional
Pack sizes and packaging material	1) HDPE, white (non-transparent) bottle of 1 litre with a degassing screw cap. 2) HDPE, grey (non-transparent) single-use bottle of 2 litres. 3) HDPE, white (non-transparent) can of 5 litres (refill packaging). 4) HDPE, white (non-transparent) can of 20 litres.

4.1.1. *Use-specific instructions for use*

Surfaces must be cleaned before disinfection. The product is ready-to-use and should be used without dilution. The product is designed for equipment such as Nocospray/Bio-sanitizer/Sanofog/Nocomax/Nocomax Easy/Glosair. Read the instructions for use before use. Use according to the following protocols:

— Bactericidal, yeasticidal, fungicidal, sporicidal and virucidal activity: 3 ml product/m^3 and 2 hours contact time. Treat a second time at 3 ml product/m^3 and 2 hours contact time.

— Tuberculocidal activity: 5 ml product/m^3 and 2 hours contact time. Treat a second time at 3 ml product/m^3 and 2 hours contact time.

The second treatment takes place right after the first. The two treatments can be programmed in order to be carried out sequentially.

Droplet size: 1-15 µm

Relative humidity: 25% - 75%

Temperature: room temperature

Respect the contact time. The contact time starts when the required amount of product is present in the room.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

4.1.2. *Use-specific risk mitigation measures*

Please refer to general directions for use of this Meta SPC.

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*

First aid

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 ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: IF symptoms occur call a POISON CENTRE or a doctor.

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.

Likely direct or indirect effects

-

Causes serious eye irritation

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

Please refer to general directions for use of this Meta SPC.

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

Please refer to general directions for use of this Meta SPC.

5. **GENERAL DIRECTIONS FOR USE** [2] **OF THE META SPC 2**

5.1. **Instructions for use**

-

5.2. **Risk mitigation measures**

During the diffusion, keep the room closed and do not enter. Treatment must be conducted with no human or animals present.

All gaps present in the room (for example, window frames) from where fog may leak must be sealed before the diffusion.

[2] 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.

Ensure that access to the fog-treated area is denied during the whole procedure with a warning sign.

No access to the treated areas should be permitted until the concentration of hydrogen peroxide is ≤0,9 ppm (1,25 mg/m³) or a lower relevant national reference value.

The professional user may enter the room only in emergency situations when the hydrogen peroxide level has dropped below 36 ppm (50 mg/m³) and must wear the following PPE: RPE classified under EN 14387 or equivalent with APF 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves classified under European Standard EN 374 or equivalent, eye protection consistent with European Standard EN ISO 16321 or equivalent, coverall). Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

A measuring device should be used to ensure that the concentration of hydrogen peroxide has decreased below 0,9 ppm or a lower relevant national reference value. Unprotected persons/animals may re-enter the treated room only after the hydrogen peroxide concentration in air decreases lower than 1,25 mg/m³ (0,9 ppm) or a lower relevant national reference value.

Individual protective equipment:

Wear chemical resistant goggles consistent with European Standard EN ISO 16321 or equivalent as eye protection during mixing and loading of the product to the packaging that is directly used in the fogging device (such as Nocospray, Bio-sanitizer, Sanofog, Nocomax or Nocomax Easy).

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

-

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local regulations. Used product can be flushed to the municipal sewer or disposed of to the manure deposit depending on local regulations. Avoid release to an individual wastewater treatment plant.

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

— Shelf life: 2 years.

6. **OTHER INFORMATION**

The full titles of the EN standards referenced section 5.2 are:

EN ISO 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against dangerous chemicals and micro-organisms

EN 14387 - Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking

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)	Nocolyse One Shot	Market area: EU
	Nocolyse +	Market area: EU
	Glosair 600	Market area: EU

Authorisation number	EU-0029752-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	12,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017

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

Trade name(s)	Nocolyse One Shot menthe		Market area: EU		
	Nocolyse + menthe		Market area: EU		
	Glosair 600 menthe		Market area: EU		
Authorisation number	EU-0029752-0005 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	12,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017

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

Trade name(s)	Nocolyse One Shot nocodor		Market area: EU		
	Nocolyse + nocodor		Market area: EU		
	Glosair 600 nocodor		Market area: EU		
Authorisation number	EU-0029752-0006 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	12,0
Silver		Non-active substance	7440-22-4	231-131-3	0,0017

META SPC 3

1. **META SPC 3 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 3 identifier**

Identifier	Oxy'Pharm H_2O_2 7.9%

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (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
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	7,9	7,9

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

Formulation(s)	AL - Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3**

Hazard statements	Causes serious eye irritation.
Precautionary statements	Wash hands thoroughly after handling. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice.

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

4.1. **Use description**

Table 3

Use # 1 – Use #3.1: Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)

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: - Common name: Bacteria Development stage: - Scientific name: - Common name: yeasts Development stage: - Scientific name: - Common name: Bacterial spores Development stage: Scientific name: - Common name: Mycobacteria Development stage: - Scientific name: - Common name: Viruses Development stage: - Scientific name: - Common name: Fungi Development stage: -
Field(s) of use	Indoor Room disinfection with FHP for rooms with volumes between 4-150 m^3. It involves disinfection of hard non-porous surfaces of equipment and material (excluding medical devices) present in the treated room: — Hospitals & clinics, — laboratories of research and analysis (including P3 laboratories and white rooms), — healthcare transport, — pharmaceutical industry, — industrial laundries, — dental surgery and implantology centres, — transport vehicles — hotels, — restaurants, — schools, — day nurseries, — veterinary clinics.
Application method(s)	Method: Fogging Detailed description:

	The product is a ready-to-use product that is placed in a device. That device automatically fogs the biocidal product, in the closed space/room to be disinfected, without any user or bystander present.
Application rate(s) and frequency	Application Rate: — Bactericidal, yeasticidal, fungicidal, sporicidal, and virucidal activity: 5 ml product/m^3 and 2 hours contact time. — Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m^3 and 2 hours contact time. Droplet size: 1-15 µm Dilution (%): - Number and timing of application: Disinfect rooms and equipment as frequently as required by the hygiene protocol in place.
Category(ies) of users	Professional
Pack sizes and packaging material	1) HDPE, white (non-transparent) bottle of 1 litre with a degassing screw cap. 2) HDPE, grey (non-transparent) single-use bottle of 2 litres. 3) HDPE, white (non-transparent) can of 5 litres (refill packaging). 4) HDPE, white (non-transparent) can of 20 litres.

4.1.1. *Use-specific instructions for use*

Surfaces must be cleaned before disinfection. The product is ready-to-use and should be used without dilution. The product is designed for equipment such as Nocospray/Bio-sanitizer/Sanofog/Nocomax/Nocomax Easy/Glosair. Read the instructions for use before use. Use according to the following protocols:

— Bactericidal, yeasticidal, fungicidal, sporicidal, and virucidal activity: 5 ml product/m^3 and 2 hours contact time.

— Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m^3 and 2 hours contact time.

Droplet size: 1-15 µm

Relative humidity: 25 % - 75 %

Temperature: room temperature

Respect the contact time. The contact time starts when the required amount of product is present in the room.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

4.1.2. *Use-specific risk mitigation measures*

Please refer to general directions for use of this Meta SPC.

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*

First aid

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

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.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor

Likely direct or indirect effects

— Causes severe eye irritation

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

Please refer to general directions for use of this Meta SPC.

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

Please refer to general directions for use of this Meta SPC.

4.2. **Use description**

Table 4

Use # 2 – Use #3.3: Hard surface disinfection by Fogging Hydrogen Peroxide (FHP)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Bacterial spores Development stage: - Scientific name: - Common name: Mycobacteria Development stage: - Scientific name: - Common name: Viruses Development stage: - Scientific name: - Common name: bacteriophages Development stage: - Scientific name: - Common name: Fungi Development stage: -

Field(s) of use	Indoor Room disinfection with FHP disinfection of hard non-porous surfaces of equipment and material present in the treated room of a size between 4-150 m^3: — food industries, — central kitchens, — restaurants.
Application method(s)	Method: Fogging Detailed description: The product is a ready-to-use product that is placed in a device. That device automatically fogs the biocidal product, in the closed space/room to be disinfected, without any user or bystander present.
Application rate(s) and frequency	Application Rate: — Bactericidal, bacteriophagicidal, yeasticidal, fungicidal, sporicidal, and virucidal activity: 5 ml product/m^3 and 2 hours contact time. — Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m^3 and 2 hours contact time. Droplet size: 1-15 µm Dilution (%): - Number and timing of application: Disinfect rooms and equipment as frequently as required by the hygiene protocol in place.
Category(ies) of users	Professional
Pack sizes and packaging material	1) HDPE, white (non-transparent) bottle of 1litre with a de-gassing screw cap. 2) HDPE, grey (non-transparent) single-use bottle of 2 litres. 3) HDPE, white (non-transparent) can of 5 litres (refill packaging). 4) HDPE, white (non-transparent) can of 20 litres.

4.2.1. *Use-specific instructions for use*

Surfaces must be cleaned before disinfection. The product is ready-to-use and should be used without dilution. The product is designed for equipment such as Nocospray/Bio-sanitizer/Sanofog/Nocomax/Nocomax Easy/Glosair. Read the instructions for use before use. Use according to the following protocols:

— Bactericidal, bacteriophagicidal, yeasticidal, fungicidal, sporicidal and virucidal activity: 5 ml product/m^3 and 2 hours contact time.

— Mycobactericidal activity: 7 ml product/m^3 and 2 hours contact time.

droplet size: 1-15 µm

Relative humidity: 25 % - 75 %

Temperature: room temperature

Respect the contact time. The contact time starts when the required amount of product is present in the room. The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

4.2.2. *Use-specific risk mitigation measures*

Please refer to general directions for use of this Meta SPC.

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*

First aid

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

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.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor

Likely direct or indirect effects

— Causes severe eye irritation

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

Please refer to general directions for use of this Meta SPC.

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

Please refer to general directions for use of this Meta SPC.

5. **GENERAL DIRECTIONS FOR USE** [3] **OF THE META SPC 3**

5.1. **Instructions for use**

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5.2. **Risk mitigation measures**

During the diffusion, keep the room closed and do not enter in. Treatment must be conducted with no human or animals present.

All gaps present in the room (for example, window frames) from where fog may leak must be sealed before the diffusion.

Ensure that access to the fog-treated area is denied during the whole procedure with a warning sign.

No access to the treated areas should be permitted until the concentration of hydrogen peroxide is ≤0,9 ppm (1,25 mg/m^3) or a lower relevant national reference value.

The professional user may enter the room only in emergency situations when the hydrogen peroxide level has dropped below 36ppm (50 mg/m^3) and must wear the following PPE: RPE classified under EN 14387 or equivalent with APF 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves classified under European Standard EN 374 or equivalent, eye protection consistent with European Standard EN ISO 16321 or equivalent, coverall). Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

[3] 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.

A measuring device should be used to ensure that the concentration of hydrogen peroxide has decreased below 0,9 ppm or a lower relevant national reference value. Unprotected persons/animals may re-enter the treated room only after the hydrogen peroxide concentration in air decreases lower than 1,25 mg/m³ (0,9 ppm) or a lower relevant national reference value.

Individual protective equipment:

Wear chemical resistant goggles consistent with European Standard EN ISO 16321 or equivalent as eye protection during mixing and loading of the product to the packaging that is directly used in the fogging device (such as Nocospray, Bio-sanitizer, Sanofog, Nocomax or Nocomax Easy).

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

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local regulations. Used product can be flushed to the municipal sewer or disposed of to the manure deposit depending on local regulations. Avoid release to an individual wastewater treatment plant.

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

— Shelf life: 2 years.

6. **OTHER INFORMATION**

The full titles of the EN standards referenced in section 5.2 are:

EN ISO 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

EN 14387 - Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking

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)	Nocolyse Food		Market area: EU		
	Glosair 500		Market area: EU		
Authorisation number	EU-0029752-0007 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	7,9

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