

Summary of product characteristics for a biocidal product family

Family name: HYPO-CHLOR Product Family

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

Authorisation number: EU-0028423-0000

R4BP 3 asset reference number: EU-0028423-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

HYPO-CHLOR Product Family

1.2. Product type(s)

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

1.3. Authorisation holder

Name and address of the authorisation holder

Name	Veltek Associates Inc. Europe
Address	Rozengaard 1940 8212DT Lelystad Netherlands

Authorisation number

EU-0028423-0000

R4BP 3 asset reference number

EU-0028423-0000

Date of the authorisation

20/04/2023

Expiry date of the authorisation

31/03/2033

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Veltek Associates, Inc.

Address of the manufacturer

15 Lee Blvd. PA19355 Malvern United States

Location of manufacturing sites

15 Lee Blvd. PA19355 Malvern United States

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

Active substance	1391 - Active chlorine released from sodium hypochlorite
Name of the manufacturer	Univar USA Inc.
Address of the manufacturer	532 E. Emaus Street Pennsylvania 17057 Middleton United States
Location of manufacturing sites	532 E. Emaus Street Pennsylvania 17057 Middleton United States

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 (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,25 - 0,5
Sodium hypochlorite	Sodium hypochlorite	Non-active substance	7681-52-9	231-668-3	1,95 - 4,21

2.2. Type(s) of formulation

AL - Ready to use

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 2A

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

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

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,25 - 0,25
Sodium hypochlorite	Sodium hypochlorite	Non-active substance	7681-52-9	231-668-3	1,95 - 2

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

Formulation(s)

AL - Ready to use

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep only in original packaging.
Avoid release to the environment.
Absorb spillage to prevent material damage.
Store in container with a resistant inner liner.
Dispose of contents to according to the local regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Disinfectant, bactericidal, fungicidal and sporicidal use - Meta SPC 2A

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: Bacterial cells Scientific name: Yeast species Common name: Yeasts Development stage: Cellular yeasts Scientific name: Fungi Common name: Fungi Development stage: Fungi Scientific name: Bacterial spores Common name: Bacterial spores Development stage: Bacterial spores
Field(s) of use	Indoor For the disinfection of hard non-porous inanimate surfaces materials and equipment which are not used for direct contact with food or feeding stuffs (except for medical sector and except uses covered by Regulation (EU) 2017/745 on medical devices). Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries without mechanical action. Only clean room for buffered products.
Application method(s)	Method: Mop, cloth, wipe, immersion or spraying (compression sprayer 1-3 bars or trigger spray). Detailed description: Only trigger spray for buffered products.
Application rate(s) and frequencies	Application Rate: Ready to use. Dilution (%): - Number and timing of application: Apply as necessary. Contact time: - Bactericidal, yeasticidal and fungicidal treatment: 8 minutes. - Sporocidal treatment: 40 minutes. Room temperature Clean conditions
Category(ies) of users	Industrial

Pack sizes and packaging material

High density polyethylene (HDPE) bottle 100 ml to 10 litres (in some packaging sizes the triggers are supplied but not attached to the bottle)
HDPE SimpleMix bottle 473 ml and 3,79 litres with a smaller low density polyethylene (LDPE) bottle inside
HDPE drum 200 litres

4.1.1 Use-specific instructions for use

- Do not use more than 35 ml/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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Comply with the instructions for use.
- Use the product within a maximum of 24h after adding the buffer solution (only for HYPO-CHLOR® Neutral 0,25%) in order to ensure efficacious use.
- Inform the authorisation holder if the treatment is ineffective.
- Clean carefully the surfaces before application of the product.
- Apply only on non-porous surfaces.
- For mop/cloth/wipe applications, apply (spray/pour) the product onto the surface to be disinfected and then use a cloth/mop/wipe in order to have a uniform distribution of the product on the surface.
- Make sure to wet surfaces completely with the product. Allow product to take effect for the required contact time.
- After contact time, rinse surfaces. Allow surface to air dry or wipe dry.
- The use for the disinfection of instruments and materials covered by Regulation (EU) 2017/745 of the European Parliament and of the Council is not concerned by this authorisation.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L117, 5.5.2017, p.1).

- Products should not be used in conjunction with acids or ammonia.
- For trigger spray (buffered products), apply only on small surfaces.

5.2. Risk mitigation measures

- Wear respiratory protection: minimum APF 4 for application and rinsing with compression sprayer (1-3 bars).
- Ensure that bystanders are not present in the treatment area during the disinfection process by compression sprayer (1-3 bars). If it is necessary for bystanders to be present, they shall wear the same RPE and PPE as the user.
- Ventilation rate shall be minimum 20/h for buffered products (only for HYPO-CHLOR® Neutral 0,25%)
- Avoid all unnecessary exposure.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

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

- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- Keep the container or label available.

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...) or 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

- Do not store above 30°C.
- Protect from frost.
- Protect from direct sunlight.
- Shelf life: 24 months

6. Other information

7. Third information level: individual products in the meta SPC

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

Trade name(s)	HYPO-CHLOR NEUTRAL 0,25%	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	EU-0028423-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,25
Sodium hypochlorite	Sodium hypochlorite	Non-active substance	7681-52-9	231-668-3	1,95

Trade name(s)	HYPO-CHLOR 0,25%	Market area: EU
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Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0028423-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,25
Sodium hypochlorite	Sodium hypochlorite	Non-active substance	7681-52-9	231-668-3	2

1. Meta SPC administrative information**1.1. Meta SPC identifier**

Meta SPC 2B

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,47 - 0,5
Sodium hypochlorite	Sodium hypochlorite	Non-active substance	7681-52-9	231-668-3	3,92 - 4,21

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

Formulation(s)

AL - Ready to use

3. Hazard and precautionary statements of the meta SPC

Hazard statements

May be corrosive to metals.
Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep only in original packaging.
Avoid release to the environment.
Absorb spillage to prevent material damage.
Store in container with a resistant inner liner.
Dispose of contents to according to the local regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Disinfectant, bactericidal, fungicidal and sporicidal use - Meta SPC 2B

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

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Target organism(s) (including development stage)

Scientific name: Bacterial spores
Common name: Bacterial spores
Development stage: Bacterial spores

Scientific name: Bacteria
Common name: Bacteria
Development stage: Bacterial cells

Scientific name: Yeast species
Common name: Yeasts
Development stage: Cellular yeasts

Scientific name: Fungi
Common name: Fungi
Development stage: Fungi

Field(s) of use

Indoor

For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs(except for medical sector).
Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries without mechanical action.
Only clean room for buffered products

Application method(s)

Method: Mop, cloth, wipe, immersion or spraying (compression sprayer 1-3 bars or trigger spray).
Detailed description:
Only trigger spray for buffered products.
See instructions for use for further detail.

Application rate(s) and frequencies

Application Rate: Ready to use.
Dilution (%): Not applicable
Number and timing of application:
Apply as necessary.

Contact time:

- Bactericidal, yeasticidal and fungicidal treatment: 8 minutes
- Sporocidal treatment: 40 minutes

Room temperature
Clean conditions

Category(ies) of users

Industrial

Pack sizes and packaging material

High density polyethylene (HDPE) bottle 100 ml to 10 litres (in some packaging sizes the triggers are supplied but not attached to the bottle)
HDPE SimpleMix bottle 473 ml and 3,79 litres with a smaller low density polyethylene (LDPE) bottle inside LDPE bottle inside.
HDPE drum 200 litres

4.1.1 Use-specific instructions for use

- Do not use more than 35 ml/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

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

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4.1.5 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

5.1. Instructions for use

- Comply with the instructions for use.
- Use the product within a maximum of 24h after adding the buffer solution (only for HYPO-CHLOR® Neutral 0,52%) in order to ensure efficacious use.
- Inform the authorisation holder if the treatment is ineffective.
- Clean carefully the surfaces before application of the product.
- Apply only on non-porous surfaces.
- For mop/cloth/wipe applications, apply (spray/pour) the product onto the surface to be disinfected and then use a cloth/mop/wipe in order to have a uniform distribution of the product on the surface.
- Make sure to wet surfaces completely with the product. Allow product to take effect for the required contact time.
- After contact time, rinse surfaces. Allow surface to air dry or wipe dry.
- The use for the disinfection of instruments and materials covered by Regulation (EU) 2017/745 of the European Parliament and of the Council is not concerned by this authorisation.
- Products should not be used in conjunction with acids or ammonia.
- For trigger spray (buffered products), apply only on small surfaces

5.2. Risk mitigation measures

5.2. Risk mitigation measures

- Wear respiratory protection: minimum APF 4 for application and rinsing with compression sprayer (1-3 bars).
- Ensure that bystanders are not present in the treatment area during the disinfection process by compression sprayer (1-3 bars). If it is necessary for bystanders to be present, they shall wear the same RPE and PPE as the user.
- Ventilation rate shall be minimum 20/h for buffered products (only for HYPO-CHLOR® Neutral 0,52%)
- Avoid all unnecessary exposure.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock

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

- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- Keep the container or label available.

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...) or 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: 24 months.
- Protect from direct sunlight.
- Protect from frost.
- Do not store above 30°C

6. Other information

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7. Third information level: individual products in the meta SPC

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

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

Trade name(s)

HYPO-CHLOR 0,52%

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0028423-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,5
Sodium hypochlorite	Sodium hypochlorite	Non-active substance	7681-52-9	231-668-3	4,21

Trade name(s)

HYPO-CHLOR NEUTRAL 0,52%

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0028423-0004 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite		Active Substance			0,47

Sodium hypochlorite	Sodium hypochlorite	Non-active substance	7681-52-9	231-668-3	3,92
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