

COMMISSION IMPLEMENTING REGULATION (EU) 2023/708**of 20 March 2023****granting a Union authorisation for the biocidal product family ‘HYPO-CHLOR Product Family’ 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 20 December 2018, Veltek Associates Inc. Europe submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for a Union authorisation of a biocidal product family named ‘HYPO-CHLOR Product Family’ 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-EF047438-44 in the Register for Biocidal Products.
- (2) ‘HYPO-CHLOR Product Family’ contains active chlorine released from sodium hypochlorite 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-type 2.
- (3) On 24 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⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘HYPO-CHLOR 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 ‘HYPO-CHLOR 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 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 ‘HYPO-CHLOR Product Family’.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 3 March 2022 on the Union authorisation of the biocidal product family ‘Hypo-Chlor product family’ (ECHA/BPC/321/2022), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

- (8) In its opinion, the Agency recommends that the authorisation holder conducts a long-term ambient storage stability test for products in meta-SPC 2A and 2B in the commercial packaging in which the products are to be made available on the market, as a condition in the authorisation. The test should address the relevant physical, chemical and technical properties of the products, both prior to and after storage, to confirm a shelf life of 24 months. 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 'HYPO-CHLOR Product Family' 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 has been granted does not affect the conclusion on the fulfilment of the condition under Article 19(1), point (d), of that Regulation based on the 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-0028423-0000 is granted to Veltek Associates Inc. Europe for the making available on the market and use of the biocidal product family 'HYPO-CHLOR Product Family' 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 20 April 2023 until 31 March 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, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

TERMS AND CONDITIONS (EU-0028423-0000)

The authorisation holder shall conduct a long-term ambient storage stability test for products in meta SPC 2A and 2B in the commercial packaging in which they will be made available on the market. The long-term ambient storage stability test shall address the relevant physical, chemical and technical properties of the products both prior to and after storage in accordance with section 2.6.4 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 a shelf life of 24 months.

By 20 October 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

HYPO-CHLOR Product Family

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

Authorisation number: EU-0028423-0000

R4BP asset number: EU-0028423-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	HYPO-CHLOR Product Family
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1.2. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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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 asset number	EU-0028423-0000	
Date of the authorisation	20 April 2023	
Expiry date of the authorisation	31 March 2033	

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

Name of manufacturer	Veltek Associates, Inc.
Address of 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	Active chlorine released from sodium hypochlorite
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Name of manufacturer	Univar USA Inc.
Address of 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 (%)	
					Min	Max
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

Formulation(s)	AL – Ready to use
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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 2A
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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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
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	2,0

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

Formulation(s)	AL – Ready to use
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

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 1

4.1. Use description

Table 1

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

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: Bacterial cells Scientific name: Yeast species Common name: Yeasts Development stage: Cellular yeasts Scientific name: Fungi Common name: Fungi Development stage: Fungi

	<p>Scientific name: Bacterial spores Common name: Bacterial spores Development stage: Bacterial spores</p>
Field(s) of use	<p>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.</p>
Application method(s)	<p>Method: Mop, cloth, wipe, immersion or spraying (compression sprayer 1-3 bars or trigger spray). Detailed description: Only trigger spray for buffered products.</p>
Application rate(s) and frequency	<p>Application Rate: Ready to use. Dilution (%): - Number and timing of application: Apply as necessary. Contact time: — Bactericidal, yeasticidal and fungicidal treatment: 8 minutes. — Sporicidal treatment: 40 minutes. Room temperature Clean conditions</p>
Category(ies) of users	Industrial
Pack sizes and packaging material	<p>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</p>

4.1.1. Use-specific instructions for use

- Do not use more than 35 ml/m²

4.1.2. Use-specific risk mitigation measures

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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*

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

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 L 117, 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.

⁽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 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

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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)	HYPO-CHLOR NEUTRAL 0,25 %		Market area: EU		
Authorisation number	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

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

Trade name(s)	HYPO-CHLOR 0,25 %		Market area: EU		
Authorisation number	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	2,0

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC 2B
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1.2. **Suffix to the authorisation number**

Number	1-2
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1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
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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
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 2**

Formulation(s)	AL – Ready to use
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

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 2

4.1. Use description

Table 2

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	-
Target organism(s) (including development stage)	<p>Scientific name: Bacterial spores Common name: Bacterial spores Development stage: Bacterial spores</p> <p>Scientific name: Bacteria Common name: Bacteria Development stage: Bacterial cells</p> <p>Scientific name: Yeast species Common name: Yeasts Development stage: Cellular yeasts</p> <p>Scientific name: Fungi Common name: Fungi Development stage: Fungi</p>
Field(s) of use	<p>Indoor</p> <p>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).</p> <p>Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries without mechanical action.</p> <p>Only clean room for buffered products</p>
Application method(s)	<p>Method: Mop, cloth, wipe, immersion or spraying (compression sprayer 1-3 bars or trigger spray).</p> <p>Detailed description: Only trigger spray for buffered products.</p> <p>See instructions for use for further detail.</p>
Application rate(s) and frequency	<p>Application Rate: Ready to use.</p> <p>Dilution (%): Not applicable</p> <p>Number and timing of application: Apply as necessary.</p> <p>Contact time:</p> <ul style="list-style-type: none"> — Bactericidal, yeasticidal and fungicidal treatment: 8 minutes — Sporicidal treatment: 40 minutes <p>Room temperature</p> <p>Clean conditions</p>

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*

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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*

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

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

^(?) 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.

5.2. 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 2

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	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

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

Trade name(s)	HYPO-CHLOR NEUTRAL 0,52 %		Market area: EU		
Authorisation number	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