Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

HYPO-CHLOR PRODUCT FAMILY

ECHA/BPC/321/2022

Adopted

3 March 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of HYPO-CHLOR PRODUCT FAMILY

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family:	**HYPO-CHLOR PRODUCT FAMILY**
Authorisation holder:	**Velltek Associates Inc. Europe**
Active substance common name:	**active chlorine released from sodium hypochlorite (CAS number sodium hypochlorite 7681-52-9)**
Product type:	**2**

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 20 December 2018, recorded in R4BP3 under case number BC-EF047438-44**,** the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 24 August 2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-42) and its Working Groups (WG-IV-2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product family was reached on 3 March 2022.

The BPC opinion was adopted by simple majority of the members present having the right to vote.

The opinion and the minority positions are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(1)(s).

The biocidal product family meets the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of HYPO-CHLOR PRODUCT FAMILY referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

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

General

France, as e-CA received an application from Veltek Associates Inc. Europe for union authorisation for the biocidal product family HYPO-CHLOR PRODUCT FAMILY.

The biocidal product family HYPO-CHLOR PRODUCT FAMILY contains 1.95% to 4.21% sodium hypochlorite releasing 0.25% to 0.5% active chlorine and is a product type 2 (PT2) intended to be used by professional users for the disinfection of hard non–porous surfaces of manufacturing facilities (medical device, pharmaceutical, biopharmaceutical and diagnostic industries).

The biocidal product family HYPO-CHLOR PRODUCT FAMILY as submitted by the applicant was composed of two Meta SPCs: products from Meta SPC 1 (HYPO-CHLOR 5.25%) are diluted in water before use and products from Meta SPC 2 (HYPO-CHLOR 0.25%; HYPO-CHLOR 0.25% NEUTRAL; HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL) are ready-to-use.

However, data submitted to support the shelf life of the Meta SPC were not deemed sufficient. Thus Meta SPC 1 cannot be proposed for authorisation. In addition, Meta SPC 2 as proposed by the applicant contained products with different classifications. As a result, Meta-SPC 2 as submitted by the applicant was split in two Meta-SPCs both containing ready to use products:

- Meta SPC 2A (HYPO-CHLOR 0.25% and HYPO-CHLOR 0.25% NEUTRAL);
- Meta SPC 2B (HYPO-CHLOR 0.52% and HYPO-CHLOR 0.52% NEUTRAL).

Physico-chemical properties

The physico-chemical properties of the biocidal product family HYPO-CHLOR PRODUCT FAMILY have been described and considered acceptable for the conditions of use detailed in the SPC.

For Meta SPC 1, the spray characteristics after long term storage is missing.

A shelf life for Meta SPC 1 cannot be determined as the content of active chlorine in the product decreased by more than 10% after storage and no efficacy test after storage was available for the tested product.

The shelf life of the Meta SPC 2A and 2B is set to 24 months. However, the long-term stability study is in progress for products in Meta SPC 2A and 2B and final results are required post authorisation for confirmatory purposes.

Meta SPC 2A is not classified as corrosive to metals.

Meta SPC 2B is classified as corrosive to metals with H290.

The analytical methods available are acceptable.

Efficacy

The products of the HYPO-CHLOR PRODUCT FAMILY biocidal product family have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 and EN 14885:2015 standard for the following uses:

- Meta SPC 1: Concentrate PT 2

Use 1: Disinfection of hard non-porous surfaces by immersion or with a mop/cloth/wipe/mechanical spray device without mechanical action, in clean conditions, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries (except the uses covered by the medical device regulation):

- bacteria, yeasts and fungi: 5% v/v, 8 min, room temperature
- viruses: 10% v/v, 20 min, room temperature
- bacterial spores: 10% v/v, 25 min, 5% v/v, 40 min, room temperature

No efficacy data have been submitted to demonstrate that products of Meta SPC 1 are still effective after 6 months (see above).

- Meta SPC 2A (0.25% active chlorine): Ready to use products PT 2

Use 1: Disinfection of hard non-porous surfaces by immersion or with a mop/cloth/wipe/mechanical spray device with non-mechanical action, in clean conditions, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries (except the uses covered by the medical device regulation):

- bacteria, yeasts and fungi: 8 min, room temperature;
- bacterial spores: 40 min, room temperature.

- Meta SPC 2B (0.47 to 0.50% active chlorine): Ready to use products PT 2

Use 1: Disinfection of hard non-porous surfaces by immersion or with a mop/cloth/wipe/mechanical spray device with non-mechanical action, in clean conditions, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries (except the uses covered by the medical device regulation):

- bacteria, yeasts and fungi: 8 min, room temperature;
- bacterial spores: 25 min, room temperature;
- viruses: 20 min, room temperature.

Human health

Products of HYPO-CHLOR PRODUCT FAMILY biocidal product family (Meta-SPC 2A and 2B) are not classified for human health, according to the CLP Regulation (EC) 1272/2008 and no substance of concern has been identified.

For the products of Meta-SPC 2A and 2B the risk is acceptable considering the local effects of sodium hypochlorite providing that the user wears a respiratory protective equipment (APF 4) during application and rinsing with compression sprayer (1-3 bars).

For bystanders (worker), the following RMM should be added “Do not be present in the treatment area during disinfection process by compression sprayer (1-3 bars). If it is necessary to be present, wear same RPE and PPE as the user.”

The presence of chlorate should also be taken into account in the systemic risk assessment. However, in the absence of harmonisation of the reference values for chlorate, no risk assessment can be performed. This should be adressed at the renewal of the active substance.

Disinfection by-products (DBP) risk assessment

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out.

The current guidance (Volume V, Guidance on Disinfection By-Products) should be completed in order to be applicable during the active substance renewal. ECHA and the member states will work actively to address these issues (e.g. data lacking and harmonised toxicological reference values).

Dietary risk assessment

The biocidal products are not intended for application on surfaces that are used for direct contact with food or feeding stuffs. Therefore, residues in food or feed are not expected.

Environment

Products of HYPO-CHLOR PRODUCT FAMILY biocidal product family are classified Aquatic chronic cat 3., H412, according to the CLP Regulation (EC) 1272/2008 for the environment and no substance of concern has been identified.

The risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance, sodium hypochlorite and chlorate formed during storage, leading to negligible emissions to the environment.

The risks linked to chlorate formed during storage are acceptable for all uses considering a semi-qualitative assessment for groundwater and surface water intended for the abstraction of drinking water.

Disinfection by-products (DBP) risk assessment

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out. The current ‘guidance’ (Volume V, Guidance on Disinfection By-Products) covering PT 2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.

Overall conclusion

The overall conclusions for HYPO-CHLOR PRODUCT FAMILY are reported for each use in the table below:

Meta SPC	Uses	Dose	Conditions of use	Conclusions
1	Disinfection of hard non-porous inanimate surfaces, materials and equipment.	Dilution: 5 to 10% v/v Contact time: 6 to 40 minutes	Industrial users Indoor	Not acceptable as no shelf life can be set
2A	Disinfection of hard non-porous inanimate surfaces, materials and equipment.	Ready to use Contact time: 8 to 40 minutes	Industrial users Indoor	Acceptable with RMM*
2B	Disinfection of hard non-porous inanimate surfaces, materials and equipment.	Ready to use Contact time: 8 to 40 minutes	Industrial users Indoor	Acceptable with RMM*

*Risk Mitigation Measures (RMMs) for Meta SPC 2A and 2B are the following:

- wear respiratory protection: min APF 4 for application and rinsing with compression sprayer (1-3 bars);
- it shall be ensured that the bystanders are not present in the treatment area during disinfection process by compression sprayer (1-3 bars). If it is necessary to be present, they have to wear same RPE and PPE as the user;
- ventilation rate has to be min 20/h for buffered products (only for HYPO-CHLOR® Neutral 0.25% and 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.

It is concluded that only Meta SPC 2A and 2B can be authorised.

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

The description of the biocidal product and of the structure of the family is available in the SPC.

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

c) Description of uses proposed to be authorised

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

d) Comparative assessment

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

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

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

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate uses, storage and transportation of the biocidal products.

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

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

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

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

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Description	**Due date**
Long term stability study for Meta SPC 2 (A and B).	No later than 6 months after the authorisation date.

It is noted that for the product family HYPO-CHLOR PRODUCT FAMILY the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the conditions under Article 19(1) on the basis of the existing data.

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