

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family

AWPF Calcium Hypochlorite BPF

ECHA/BPC/289/2021

Adopted

6 October 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of AWPf Calcium Hypochlorite BPF

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: AWPf Calcium Hypochlorite BPF

Authorisation holder: Innovative Water Care Europe SAS

Active substance common name: Active chlorine released from calcium hypochlorite (CAS number calcium hypochlorite 7778-54-3)

Product types: PT 2, 4 and 5

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 13/12/2018, recorded in R4BP3 under case number BC-WK046289-14, 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 23/06/2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-40) and its Working Groups (WG-II-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 6 October 2021.

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

The opinion and the minority position including their grounds 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(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 AWPf Calcium Hypochlorite BPF 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

The biocidal product family AWPf Calcium Hypochlorite BPF consists of products containing 62 to 100 % of the active substance Active chlorine released from calcium hypochlorite. Products are to be used for the disinfection of swimming pools and spas (PT 2), disinfection of equipments associated with drinking water for human consumption (PT 4) and disinfection of drinking water (PT 5).

The biocidal product family (BPF) is composed of 4 Meta-SPCs. The structuring of the BPF into Meta-SPCs is based on the formulation (tablets or granules) of the products, intended uses and the mode of application.

The following non-active substance is identified as a substance of concern for Meta-SPC 3 and 4: calcium dihydroxide (hydrated lime) as it is an approved active substance for PT 2 and 3 and is present in the products of Meta-SPC 3 and 4 in concentrations above 0.1 %.

The following intended claims were assessed:

Users	Meta-SPC	Uses
Professional	1, 2 and 3	Use # 1 – PT 2 - Disinfection of swimming pools and spas
Non-professional	1, 2, 3 and 4	Use # 2 – PT 2 - Disinfection of swimming pools and spas
Professional	1, 2 and 3	Use # 3 – PT 4 - Disinfection of equipment, containers, pipework associated with drinking water for human consumption by filling/CIP with circulation

Users	Meta-SPC	Uses
Professional	1, 2 and 3	Use # 4 – PT 5 - Disinfection of drinking water for human consumption in public distribution systems and portable devices
Industrial	1, 2 and 3	Use # 5 – PT 5 - Disinfection of drinking water for human consumption in public distribution systems and portable devices (automated feeder)

Physico-chemical properties

Products of the AWPf Calcium Hypochlorite biocidal product family are water soluble granules (SG) formulations (from Meta-SPC 1 and Meta-SPC 2) and water-soluble tablets (ST) formulations (Meta-SPC 3 and Meta-SPC 4).

Physico chemical studies were provided and cover the whole AWPf Calcium Hypochlorite biocidal product family. Based on these results, the stability of the products within the biocidal product family is demonstrated. A shelf life of 12 months can be granted for all formulations.

In addition, no specific concern is expected from physico-chemical properties of the products.

To set the shelf life of the Meta-SPC 4, a read across with Meta-SPC 3 has been made, based on similar formulation type (water-soluble tablets (ST)) and composition. In order to confirm this shelf life, a long-term storage study (12 months) in commercial packaging at ambient temperature is required post-authorisation within two years.

Physico-chemical hazards have also been assessed for water soluble granules formulations (from Meta-SPC 1 and Meta-SPC 2) and for water-soluble tablets formulations (Meta-SPC 3 and Meta-SPC 4) which cover the whole AWPf Calcium Hypochlorite biocidal product family. Products are neither flammable nor auto-flammable. They have no explosive properties and are not classified as corrosive to metals. They are classified as Oxidising Solids 2.

A validated analytical method for the determination of active chlorine and chlorate in the AWPf Calcium Hypochlorite biocidal product family is available.

Analytical method is available, in the Competent Authority Report of the active substance "Active chlorine released from calcium hypochlorite" (January 2017) and validated for the determination of residues of active chlorine and the relevant metabolite chlorate in drinking water. An analytical method for the determination of the relevant metabolite chlorate in food/feed of animal origin is under review at EU level.

Efficacy

The AWPf Calcium Hypochlorite product family has shown a sufficient efficacy in accordance with the requirements of the Efficacy guidance Vol II Part B/C for the following uses and application rates:

Meta-SPC 1, 2, 3 and 4

- Use # 1 and use # 2: Disinfection of swimming pools and spas – PT 2 – professional and non-professional users:

- For swimming pool disinfection:
 - For maintenance application, against bacteria (including *Legionella pneumophila*) and virus: between 1 and 3 mg/L of available chlorine in water;
 - For shock treatment, against bacteria (including *L. pneumophila*) and virus: 10 mg/L of available chlorine in water with a contact time of 10 minutes.
- For spas disinfection:
 - For maintenance application, against bacteria (including *L. pneumophila*) and virus: between 2.5 and 4 mg/L of available chlorine in water,
 - For shock treatment, against bacteria (including *L. pneumophila*) and virus: 10 mg/L of available chlorine in water with a contact time of 10 minutes.

As no acceptable simulated use test or field has been provided against algae, the efficacy against this target organism is not demonstrated.

Meta-SPC 1, 2 and 3

- Use # 3: Disinfection of equipment, containers, pipework associated with drinking water for human consumption by filling (CIP) with circulation – PT 4
 - Against bacteria: 100 mg/L of available chlorine in water, clean conditions (0.3 g/L BSA), 12 hours, 20 °C.

As no efficacy data has been provided to support the use against virus and no acceptable simulated use test or field has been provided against algae, the efficacy against these target organisms is not demonstrated.

Meta-SPC 1, 2 and 3

- Use # 4 and 5: Disinfection of drinking water for human consumption in public distribution systems and portable devices – PT 5
 - For primary disinfection, against bacteria and virus: between 3 and 5 mg/L of available chlorine in water.

As no acceptable efficacy data (representative of the conditions of use) has been provided to support the efficacy for this use against algae, the efficacy against algae is not demonstrated.

Some member states including France, after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount (claimed by the applicant as "*Secondary disinfection: 0.2-0.5 mg/L available chlorine (residual)*") has been considered as covered by the primary disinfection.

Resistance

Although sensitivity of target species to active chlorine is variable, development of acquired resistance is not expected. No management strategy is considered necessary as acquired resistance to active chlorine has not been reported and is not expected to be developed due to the reactive nature and unspecific mode of action of active chlorine.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations of use for the biocidal products proposed in the SPC have to be

implemented.

Human health

AWPF Calcium Hypochlorite biocidal product family is classified as follows according to the harmonized classification of active substance as:

- Acute tox. 4;
- Skin corr. 1B;
- Eye damage 1.

The risk is acceptable for all uses for the Meta-SPC 1, 2 and 3 for professional and industrial users considering the application of risk mitigation measures (RMM) and personal protective equipment (PPE) or respiratory personal equipment (RPE). For mixing and loading task: RPE APF20 at minimum, gloves, eye protection, protective clothing and closed footwear. For post application task in contact with solid: gloves, eye protection, protective clothing and closed footwear. For post-application task (in contact with concentrated stock solution): gloves, chemical goggles, protection coverall and face shield. No PPE/RPE is needed for mixing and loading task (small scale – packaging \leq 10 kg) using a scoop, plier or similar to transfer the product. It should be specified that the tool should have a handle and should not be in contact with the product (should not be stored inside the packaging).

The risk is acceptable for all uses for the four Meta-SPC for non-professional users considering the application of risk mitigation measures listed below and the use of a scoop, plier or similar, to transfer the product for mixing and loading task. For mixing and loading task: "*Washing of hands after use and washing of face/eye after accidental exposure*". For post application task in contact with solid: "*Wait for the complete dissolution of the product before working on the floating device, dosing pump or the skimmer*". As for professional and industrial users, the tool (scoop, plier or similar) should have a handle and should not be in contact with the product (should not be stored inside the packaging).

The risk is acceptable for all uses for the four Meta-SPC for general public considering the application of the following risk mitigation measures: for Meta-SPC 1, 2 and 3: "*Treatment must be made in absence of bathers for shock treatment and until complete dissolution of the product for direct application for maintenance treatment*" and "*Do not allow entrance to the pool until the concentration decreases back to 3 mg/L of available chlorine for swimming pools and 4 mg/L of available chlorine for spas or to national chlorine limit*".

Products of Meta-SPC 3 and 4 contain calcium dihydroxide. Calcium dihydroxide is a substance of concern: a risk assessment taking into account calcium dihydroxide has been performed. The risk is acceptable considering human health.

Indirect exposure via food

Due to the high reactivity of chlorine species, chlorine species degrade very rapidly. Hence, residue formation (other than chlorate) is assumed to be negligible for aqueous solutions of chlorine. Conversely, chlorate residues, a stable metabolite is considered relevant for dietary exposure from the uses of this active substance as drinking water disinfectant.

Disinfection of drinking water with calcium hypochlorite would not lead to a concentration of chlorate that will exceed the parametric values set by the Drinking Water Directive (Directive

(EU) 2020/2184). There is no concern for the general public from indirect exposure via drinking water or food to either available chlorine or chlorate. The product user should control the chlorination levels (chlorine, chlorates) to ensure that trigger values from the Drinking Water Directive are not exceeded. Moreover, for food commodities, the concentration of chlorate present in food should not exceed the Maximum Residue Levels values set by Regulation (EU) 2020/749¹.

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).

Environment

AWPF Calcium Hypochlorite biocidal product family is classified as follows according to the harmonized classification of active substance as:

- Aquatic Acute cat. 1.

Risks are acceptable for all environmental compartments considering a qualitative assessment leading to negligible emissions to the environment for:

- Disinfection of public and private swimming pools and spas (Meta-SPC 1, 2, 3 and 4) considering that only the pools that are connected to sewage system are covered in this dossier;
- Disinfection of equipment, containers, pipework associated with drinking water for human consumption by filling/CIP (Meta-SPC 1, 2 and 3);
- Disinfection of drinking water for human consumption (Meta-SPC 1, 2 and 3).

No substance of concern is identified in Meta-SPC 1, 2, 3 and 4.

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 provide for a harmonised DBP assessment.

Overall conclusion

According to the assessment performed for the biocidal product family AWPF Calcium

¹ Commission Regulation (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products.

Hypochlorite BPF, the overall conclusion for the following uses considering the appropriate instruction of uses and risk mitigation measures as indicated in the SPC, is as follows:

Meta-SPC	User	Uses	Conclusions
1, 2 and 3	Professional	Use # 1 – PT 2 - Disinfection of swimming pools	Acceptable considering <ul style="list-style-type: none"> - Treatment against bacteria (including <i>L. pneumophila</i>) and virus - Maintenance treatment - 1 to 3 mg/L of available chlorine in water - Shock treatment - 10 mg/L of available chlorine in water
			Not acceptable <ul style="list-style-type: none"> - application against algae (efficacy not demonstrated)
		Use # 1 – PT 2 - Disinfection of spas	Acceptable considering <ul style="list-style-type: none"> - Treatment against bacteria (including <i>L. pneumophila</i>) and virus - Maintenance – 2.5 to 4 mg/L of available chlorine in water - Shock treatment - 10 mg/L of available chlorine in water
			Not acceptable <ul style="list-style-type: none"> - For the treatment against algae (efficacy not demonstrated)
1 and 2	Non-professional	Use # 2 – PT 2 - Disinfection of swimming pools and spas	Acceptable considering <ul style="list-style-type: none"> - Treatment against bacteria (including <i>L. pneumophila</i>) and virus - Shock treatment - 10 mg/L of available chlorine in water
			Not acceptable <ul style="list-style-type: none"> - For the treatment against algae (efficacy not demonstrated)
3	Non-professional	Use # 2 – PT 2 - Disinfection of swimming pools and spas	Acceptable considering <ul style="list-style-type: none"> - Treatment against bacteria (including <i>L. pneumophila</i>) and virus - Maintenance treatment - 1 to 3 mg/L of available chlorine in water - Shock treatment - 10 mg/L of available chlorine in water
			Not acceptable <ul style="list-style-type: none"> - For the treatment against algae (efficacy not demonstrated)

Meta-SPC	User	Uses	Conclusions
		Use # 2 – PT 2 - Disinfection of spas	<p>Acceptable considering</p> <ul style="list-style-type: none"> - Treatment against bacteria (including <i>L. pneumophila</i>) and virus - Maintenance – 2.5 to 4 mg/L of available chlorine in water - Shock treatment - 10 mg/L of available chlorine in water <p>Not acceptable</p> <ul style="list-style-type: none"> - For the treatment against algae (efficacy not demonstrated)
4	Non-professional	Use # 2 – PT 2 - Disinfection of swimming pools and spas	<p>Acceptable considering</p> <ul style="list-style-type: none"> - Treatment against bacteria (including <i>L. pneumophila</i>) and virus - Maintenance treatment - 1 to 3 mg/L of available chlorine in water - Shock treatment - 10 mg/L of available chlorine in water <p>Not acceptable</p> <ul style="list-style-type: none"> - For the treatment against algae (efficacy not demonstrated)
		Use # 2 – PT 2 - Disinfection of spas	<p>Acceptable considering</p> <ul style="list-style-type: none"> - Treatment against bacteria (including <i>L. pneumophila</i>) and virus - Maintenance – 2.5 to 4 mg/L of available chlorine in water <p>Not acceptable</p> <ul style="list-style-type: none"> - For the treatment against algae (efficacy not demonstrated)
1, 2 and 3	Professional	Use # 3 – PT 4 - Disinfection of equipment, containers, pipework associated with drinking water for human consumption by filling/CIP with circulation	<p>Acceptable considering</p> <ul style="list-style-type: none"> - Treatment against bacteria - 100 mg/L of available chlorine in water <p>Not acceptable</p> <ul style="list-style-type: none"> - For the treatment against algae and virus (efficacy not demonstrated)
1, 2 and 3	Professional	Use # 4 – PT 5 - Disinfection of drinking water for human consumption in	<p>Acceptable considering</p> <ul style="list-style-type: none"> - Treatment against bacteria and virus – 3 to 5 mg/L of available chlorine in water

Meta-SPC	User	Uses	Conclusions
		public distribution systems and portable devices	
1, 2 and 3	Industrial	Use # 5 – PT 5 - Disinfection of drinking water for human consumption in public distribution systems and portable devices (automated feeder)	<p>Not acceptable</p> <ul style="list-style-type: none"> - For the treatment against algae (efficacy not demonstrated)

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.

The existing harmonised classification for calcium hypochlorite (ATP01: H302 and H314) was applied in the frame of this product assessment. It is noted that the recommendation for revising the harmonised classification and labelling of calcium hypochlorite as described in the BPC opinion has not been followed, as a formal process under the CLP has not been initiated yet.

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 calcium 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 use, storage and transportation of the biocidal product.

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;
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 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 biocidal product family shall be authorised² 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 storage study (12 months) on a Meta-SPC 4 product in commercial packaging at ambient temperature is required.	Not later than two years after the authorisation date.

It is noted that for the product family AWPf Calcium Hypochlorite BPF 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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² 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.