

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Contec Calcium Hypochlorite

ECHA/BPC/403/2023

Adopted

22 November 2023

BPC
BIOCIDAL PRODUCTS
COMMITTEE

Opinion of the Biocidal Products Committee

on the Union authorisation of the Contec Calcium Hypochlorite biocidal 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:	Contec Calcium Hypochlorite
Authorisation holder:	Contec Europe
Active substance(s) common name:	Active chlorine released from calcium hypochlorite (CAS 7778-54-3)
Product type(s):	PT 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 19 December 2018, recorded in R4BP3 under case number BC-LY047116-11, 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 17 July 2023. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-49) and its Working Groups (WG-III-2023). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product family was reached on 22 November 2023.

The BPC opinion was adopted by consensus. The opinion is 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 Contec Calcium Hypochlorite biocidal 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

The Contec Calcium Hypochlorite biocidal product family contains 5 biocidal products which are attributed to the following 3 meta SPCs:

Meta SPC	Biocidal products
1	Contec ProChlor Sterile Contec ProChlor
2	Contec CyChlor Sterile Contec CyChlor
3	Contec ProChlor V

All products contain the active substance active chlorine released from calcium hypochlorite (CAS number: 7778-54-3) and various non-active substances.

The relevant product type covered by the members of the Contec Calcium Hypochlorite biocidal product family is PT2.

AS content (%)	Substance of concern	User category	Use #	Use assessed	Use proposed to be authorised
0.2% active chlorine released from calcium hypochlorite	No substance of concern	professional	#1.1	PT2: Hard surface disinfection in cleanrooms by trigger spray and wipe Use Indoors	Yes
0.2% active chlorine released from calcium hypochlorite	No substance of concern	professional	#1.2	PT2: Hard surface disinfection in cleanrooms by wiping or mopping Use Indoors	Yes

AS content (%)	Substance of concern	User category	Use #	Use assessed	Use proposed to be authorised
0.06% active chlorine released from calcium hypochlorite	No substance of concern	professional	# 2.1	PT2: Hard surface disinfection in cleanrooms by trigger spray and wipe Use Indoors	Yes
0.06% active chlorine released from calcium hypochlorite	No substance of concern	professional	# 2.2	PT2: Hard surface disinfection in cleanrooms by wiping or mopping Use Indoors	Yes
0.2% active chlorine released from calcium hypochlorite	No substance of concern	professional	# 3.1	PT2: Hard surface disinfection in veterinary laboratories by trigger spray and wipe Use Indoors	Yes
0.2% active chlorine released from calcium hypochlorite	No substance of concern	professional	# 3.2	PT2: Hard surface disinfection in veterinary laboratories by pouring and subsequent wiping or mopping Use Indoors	Yes

The Biocidal Product Family (BPF) concerns a hard-surface disinfectant for cleanrooms and veterinary laboratories (PT2) with a concentration of active chlorine released from calcium hypochlorite of 0.06-0.20% to be applied by trigger spray, wiping or mopping. The product is used by professionals only.

Analytical methods and Physical Chemical Properties

All meta SPC are ready-to-use (RTU) formulations using active chlorine released from calcium hypochlorite as the active substance. Based on long term ambient storage stability studies a shelf-life of 12 months is supported in high density polyethylene (HDPE).

Storage conditions include: Keep away from direct sunlight. Protect from frost. Store at temperatures not exceeding 20°C.

With respect to the physical hazards the following classification and labelling is required:

Meta SPC 1 and 3 (ProChlor) are assigned H290 – May be corrosive to metals.

Meta SPC 2 (CyChlor) is assigned H290 – May be corrosive to metals.

A titration method is provided for the active substance active chlorine released from calcium hypochlorite and is considered sufficiently validated. In addition, the substance of concern, sodium chlorate, is supported by a validated ion chromatography method.

Efficacy

Efficacy tests (suspension and surface tests) were provided which showed efficacy against the following groups of target organisms indicated below with a shelf life of 12 months.

Meta SPC 1 (use 1 and use 2): Bacteria (including spores) and viruses

Meta SPC 2 (use 1 and use 2): Bacteria and yeasts-

Meta SPC 3 (use 1 and use 2): Bacteria, yeasts and viruses

Human Health

The BPF is not classified for human health risks. Dermal exposure of the professional user is considered acceptable because the product concentration of active chlorine released from calcium hypochlorite is below the limits for local effects. No adverse health effects are expected for the professional user or bystander during application by trigger spray with a minimum ventilation of 20 air changes per hour (ACH). No adverse health effects are expected for the professional user or bystander during application by wiping and mopping with a minimum ventilation of 40 ACH. Exposure of the general public is considered unlikely because the products are used in places that are not accessible for the general public

Dietary risk assessment

The products of all meta SPCs are intended for application to hard, non-porous surfaces not associated with food or feed areas. There is considered no likelihood of transfer of residues of chlorate or any other residue relating to the active substance to food or feed, and so there will be no exposure via the diet.

Risk assessment for animal health

Exposure to the active substance and chlorate from animals is not expected. No further consideration is necessary.

Environment

Following use of the products from the BPF, it is assumed that exposure of the STP via wastewater will occur due to rinsing and wet cleaning of the disinfected surfaces or equipment in cleanrooms (PT2) and veterinary laboratories (PT2), followed by subsequent indirect exposure of surface water (including sediment) and agricultural land (including groundwater) due to spreading of sewage sludge. Releases to wastewater may also occur due to rinsing or flushing of empty product containers with tap water. No marine or air exposure is anticipated based on the intended use of the products. Acceptable risk was demonstrated for all relevant environmental compartments following use of the products under worst-case assumptions. It is therefore concluded that use of the products from the BPF is acceptable.

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

The description of the biocidal products 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(s) 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 was not needed.

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 products in meta SPC 1, 2 and 3.

For the uses proposed for authorisation, 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 vertebrates¹;
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,

¹ Remove elements of "in particular ... vertebrates", if not relevant.

- 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 on non-target organisms,
- the impact of the biocidal product 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/biocidal product family

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

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