Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Contec Hydrogen Peroxide Biocidal Product Family

ECHA/BPC/298/2021

Adopted

29 November 2021


ECHA
EUROPEAN CHEMICALS AGENCY

Opinion of the Biocidal Products Committee

on the Union authorisation of
Contec Hydrogen Peroxide 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 Hydrogen Peroxide Biocidal Product Family**
Authorisation holder:	**Contec Europe**
Active substance common name:	**Hydrogen Peroxide (CAS number 7722-84-1)**
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 3 December 2020[1], recorded in R4BP3 under case number BC-PP063133-29, 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 26 May 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-41) and its Working Groups (WG III 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

[1] An opinion of the BPC on a previous submission of Contec Hydrogen Peroxide (ECHA/BPC/248/2020) is available at: https://echa.europa.eu/opinions-on-union-authorisation/bpc. The current application is a resubmission based on updated data and assessments.

Adoption of the BPC opinion

Rapporteur: Slovenia

The BPC opinion on the Union authorisation of the biocidal product family was reached on 29 November 2021.

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 Hydrogen Peroxide 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

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The biocidal product family Contec Hydrogen Peroxide Biocidal Product Family includes products containing 6.67% active substance hydrogen peroxide. The products are ready-to-use liquids for hard surface disinfection (PT 2) in isolators and in Restricted Access Barrier Systems (RABS) positioned in cleanrooms and for hard surface disinfection (PT 2) in cleanrooms for the control of bacteria, yeasts and fungi. They are intended to be used by professional users only and are not intended for use in healthcare.

No substances of concern were identified in the biocidal product family.

The biocidal product family consists of a single meta SPC for which the following uses have been assessed:

1. Application by trigger spray onto a suitable cleanroom wipe to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS);
2. Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the inner surface of isolators and Restricted Access Barrier Systems (RABS);
3. Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms;
4. Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms.

Physico-chemical properties

The physical, chemical and technical properties for Contec Hydrogen Peroxide biocidal product family have been adequately characterised.

The storage stability data for the Contec Hydrogen Peroxide biocidal product family support the claim of a 2-year shelf life. The following storage conditions have been defined:

- Store in a dry well-ventilated area and protect from damage and direct sunlight;
- Store in properly designed bulk storage tanks or in original vented container;
- Keep container tightly closed;
- Do not freeze;
- Do not store at temperature above 30 °C.

With regard to physical hazards, the products are not classified.

The analytical method for the determination of hydrogen peroxide in the biocidal product family has been validated and therefore is available.

Efficacy

The Contec Hydrogen Peroxide Biocidal Product Family has shown sufficient efficacy in accordance with the requirements of the Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C) for the hard surface disinfection of non-porous surfaces in isolators and in Restricted Access Barrier Systems (RABS) positioned in cleanrooms and for hard surface disinfection of non-porous surfaces in cleanrooms (PT2) in areas other than healthcare.

Four intended uses of ready-to-use liquid products in a single meta SPC 1 were demonstrated as efficacious against target organisms bacteria, yeasts and fungi with bactericidal activity expressed in 15 minutes, yeasticidal and fungicidal activity expressed in 30 minutes contact time at room temperature.

For the efficacious use of the products in the biocidal product family a professional user has to ensure that the entire surface to be disinfected is visibly wet for the contact time, not more than 50 ml product/m² is used and distribution of the biocidal product is uniform and that visibly soiled surfaces are cleaned prior to the disinfection.

Hydrogen peroxide has been intensively used as a disinfectant and preservative for more than 3 decades and such use has not led to the development of significant resistance levels among field populations. In addition, genetically inherited resistance is not expected when the products are used as recommended.

Human health

The Contec Hydrogen Peroxide Biocidal Product Family is classified as follows according to the harmonized classification and the information provided for the active substance:

- Eye Irrit. 2: H319 - Causes serious eye irritation.

Professional user risk assessment

Risk assessment for local effects was performed for dermal and inhalation routes of exposure. Based on the risk assessment, it is concluded that no adverse health effects are expected for the professional user as a result of the application of the Contec Hydrogen Peroxide Biocidal Product Family in accordance with the labelling instructions and by applying general and use-specific risk mitigation measures as stated in the SPC.

General public and consumers risk assessment

The biocidal product family is intended to be used only in controlled professional cleanroom environments. There is no risk for general public or consumers via residues in food.

Environment

According to the CLP criteria the product is not classified for environmental hazards.

Acceptable levels of risk to all environmental compartments have been demonstrated for the proposed uses of the BPF. No risk mitigation measures are considered necessary from an environmental fate and behaviour perspective.

Overall conclusion

It is concluded that the evaluation has shown that sufficient data have been provided to support authorisation of the Contec Hydrogen Peroxide Biocidal Product Family. When using the products belonging to the Contec Hydrogen Peroxide Biocidal Product Family according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health nor to the environment.

An overview of the proposed authorised uses is presented below.

Overview of proposed authorised uses

Uses	**User**	**Target organisms**	**Use conditions : risk mitigations measures**
Use #1 Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of isolators and Restrictive Access Barrier Systems (RABS) positioned in cleanrooms	Professional	Bacteria, yeasts and fungi	• Avoid hand to eye transfer. • Used wipes must be disposed in a closed container.
Use #2 Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of isolators and Restrictive Access Barrier Systems (RABS) positioned in cleanrooms	Professional	Bacteria, yeasts and fungi	
Use #3 Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms	Professional	Bacteria, yeasts and fungi	• The product must only be applied for disinfection of small surfaces. • The use of eye protection during handling of the product is mandatory. • For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied. • Used wipes must be disposed in a closed container.

Use #4 Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms	Professional	Bacteria, yeasts and fungi	• Pouring of product shall be done in ventilated rooms only (with min. 3 air exchange/h). • The use of eye protection during handling of the product is mandatory. • For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied. • Used wipes must be disposed in a closed container. • If the product is applied by wiping, the disinfection must be limited to small area. • When using the product with a mop to disinfect floors or other large surfaces in cleanrooms, additional risk mitigation measures must be in place: o Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory for the professional user and all other personnel within the room. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). o All personnel must leave the room after mopping. o Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before personnel are permitted to enter into treated areas after large surface disinfection. Monitor the air concentration and ensure that the limit value (1.25 mg/m^3) is not exceeded when personnel re-enter the area.

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 assessments 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 hydrogen peroxide 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 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 family

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised[2], for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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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.