Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Contec Hydrogen Peroxide

ECHA/BPC/248/2020

Adopted

5 March 2020

Opinion of the Biocidal Products Committee

on the Union authorisation of Contec Hydrogen Peroxide

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

Applicant: Contec Europe

Active substances common name: Hydrogen Peroxide

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 25 January 2017, recorded in R4BP3 under case number BC-VJ029379-17, 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 28 August 2019. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-34) and its Working Groups (WG V 2019). Revisions agreed upon were presented and the draft PAR was finalised accordingly[1].

[1] The application was submitted to the UK in 2017. As a consequence of the Brexit, Slovenia took over as the evaluating Competent Authority as of 1 February 2020.

Adoption of the BPC opinion

Rapporteur: Slovenia

The BPC opinion on the Union authorisation of the biocidal product family was reached on 5 March 2020.

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 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 does not meet the conditions laid down in Article 19(1)(b)(i) of Regulation (EU) No 528/2012 and therefore shall not be authorised. The detailed grounds for the overall conclusion are described in the PAR.

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 consists of a product containing the active substance hydrogen peroxide at a concentration of 6.67%. The product is for disinfection of non-porous hard surfaces by professionals in cleanrooms in product type 2. No substances of concern were identified in the biocidal product family.

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

Use 1

- Application method: spraying on a wipe and wiping;
- Formulation type: trigger spray;
- Users: professionals;
- Use: disinfection of non-porous hard surfaces in cleanrooms with a minimum ventilation rate of 20 air changes per hour.

Use 2

- Application method: pouring and mopping or wiping;
- Formulation type: RTU solution;
- Users: professionals;
- Use: disinfection of non-porous hard surfaces in cleanrooms with a minimum ventilation rate of 140 air changes per hour.

Physico-chemical properties

The physical, chemical and technical properties for Contec Hydrogen Peroxide biocidal product family are acceptable for the liquid formulation supplied to the user as trigger spray and RTU product. The data provided are sufficient to support the BPF requested.

Accelerated storage data for the liquid formulation alone were acceptable after 18 weeks at 30°C and showed no adverse interactions between the liquid formulation and the HDPE packaging. Acceptable storage data were also submitted relating to storage for 24 months at ambient temperature.

Therefore, a shelf life of 2 years is supported for the BPF.

Based on expert consideration of the composition, Contec Hydrogen Peroxide Family is considered not to be flammable, explosive, oxidising, self-reactive or self-heating. Insufficient information was available to evaluate the corrosivity to metals.

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

Efficacy

The efficacy of the BPF was not demonstrated for use at a concentration of 6.67 % w/w hydrogen peroxide.

Efficacy data were provided to demonstrate that the BPF is efficacious against bacteria, fungi (including yeast and molds), bacterial spores and fungal spores in clean conditions at room temperature. However, inconsistencies were noted with phase 2 step 1 (suspension test) and phase 2 step 2 (surface test) studies performed according to the older and newer version of EN norms. Either the validation criteria or the pass criteria of the norms were not achieved in the submitted studies and therefore it was concluded that efficacy was not demonstrated.

Basic bactericidal and yeasticidal activity of the product in BPF was not demonstrated neither with phase 2 step 1 nor with phase 2 step 2 studies.

Human health

Based on the active substance content, the BPF is classified for:

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

For hydrogen peroxide the AEC for inhalation exposure for professional users is 1.25 mg/m^3. Based on the classification, professional users must wear eye protection when handling the product. Wearing protective chemical gloves is recommended.

Professional user risk assessment

Primary exposure has been considered for professional users performing surface disinfection by trigger spraying onto a wipe and subsequent disinfection of surfaces with the wipe, for professional users pouring the product from a container and also through disinfection of surfaces using a dry wipe or mop in cleanrooms.

Secondary exposure has been modelled for professionals re-entering an area treated by mopping/wiping or spraying in cleanrooms.

When taking into account primary exposure from the use of products from the Contec Hydrogen Peroxide BPF the following conclusions can be drawn:

- Pouring of the product from a 5 L bottle into a suitable container where wipes or a mop is saturated with the product: eye protection must be worn when applying the product. Acceptable risk if PPE is worn.
- Disinfection of hard surfaces using trigger sprayer and wiping: eye protection must be worn when applying the product. Acceptable risk if PPE is worn.
- Disinfection of hard surfaces using a wipe or mop: eye protection must be worn when applying the product.

When taking into account secondary exposure from the use of products from the Contec Hydrogen Peroxide family the following conclusions can be drawn:

- Exposure when a professional bystander re-enters a treated area after disinfection through pouring and mopping/wiping: Acceptable risk without PPE/RPE when a minimum ventilation of 140 air change per hour is ensured. Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) during product application and before operatives are permitted to enter into treated areas after large surface disinfection. Where necessary, setting a waiting period of sufficient duration is required to allow time for the removal of airborne residues.
- Exposure when a professional bystander re-enters a treated area after disinfection through spraying and wiping: acceptable risk without PPE when a minimum ventilation of 20 air change per hour is ensured.

When taking into account the risk assessment for products from the Contec Hydrogen Peroxide family the following PPE phrase is mandatory:

- Wear eye protection when applying the product.

The following use-specific risk mitigation measures are mandatory:

- for Use 1 professional spaying/wiping:
  - A minimum ventilation rate of 20/hr is mandatory for cleanrooms where the product is applied.

- for Use 2 professional pouring and mopping or wiping:
  - Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) during product application.
  - Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after large surface disinfection. Where necessary, setting a waiting period of sufficient duration to allow time for the removal of airborne residues.
  - A minimum ventilation rate of 140/hr is mandatory for cleanrooms where the product is applied.

General public risk assessment

The BPF is not intended for use by the general public therefore no primary exposure scenarios have been identified.

The BPF is intended for use in controlled professional cleanroom environments. As such no general public bystander exposure scenarios are foreseen.

Consumer risk assessment

Exposure to hydrogen peroxide via the diet is not expected for the proposed use of Contec Hydrogen Peroxide biocidal product in cleanrooms.

Environment

Two application rates have been considered, a worst-case value of 7.34%[2] hydrogen peroxide has been modelled for application rates of 50 ml/m^2 for the trigger spray and 80 ml/m^2 for pouring and mopping or wiping.

Acceptable levels of risk to all environmental compartments have been demonstrated for the proposed uses of the BPF.

Overall conclusion

To summarise, taking all information into consideration and noting that:

- physical, chemical and technical properties of the BPF are considered to be acceptable except for the endpoint corrosivity to metals where more information is required;
- the BPF is not efficacious against bacteria, fungi (including yeast and molds), bacterial spores and fungal spores at the stipulated contact times of 5 min for bacteria and yeast, 15 min for fungi, bacterial spores and fungal spores;
- risks to professional users are acceptable provided that suitable PPE (eye protection) is worn and increased ventilation rates are ensured;
- no unacceptable risks are identified for the general public or the environment,

the BPC considers that the products belonging to this biocidal product family are not efficacious and that using these products will not present an unacceptable risk to human and animal health nor the environment.

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 PAR.

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

c) Description of uses applied for

The uses claimed in the application and their assessment are described in the PAR.

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 applied for

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.

[2] This value is higher than the concentration of hydrogen peroxide of 6.67% indicated above. The value of 7.34% was originally indicated in the application and therefore used for the assessment. As using this value did not lead to unacceptable risks for the environment it was considered unnecessary to carry out an assessment with a value of 6.67% as this would lead to the same conclusion.

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 uses applied for, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is not 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 applied forshall not be authorised.

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

As the conditions of Article 19(1)(b)(i) are not met it is proposed that the biocidal product family Contec Hydrogen Peroxide family shall not be authorised because it was not demonstrated that the biocidal product family is sufficiently effective.

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