

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

PeridoxRTU Product Family

ECHA/BPC/247/2020

Adopted

5 March 2020

Opinion of the Biocidal Products Committee

on the Union authorisation of PeridoxRTU 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: PeridoxRTU Product Family

Authorisation holder: Contec Europe

Active substance common name: Peracetic acid

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 26 September 2017, recorded in R4BP3 under case number BC-EM034155-45, 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 27 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 and the draft SPC were finalised accordingly¹.

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

Adoption of the BPC opinion

Rapporteur: Belgium

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

The BPC opinion was adopted by consensus. The opinion is 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 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 PeridoxRTU 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 PeridoxRTU Product Family consists of products containing the active substance peracetic acid. The formulated active substance contains 0.23 % peracetic acid. The product is for disinfection of hard surfaces in cleanrooms in product type 2. Two substances of concern were identified in the biocidal product family: hydrogen peroxide (for human health and environment) and acetic acid (for human health only).

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

Meta SPC 1

Use 1

- Application method: trigger spray onto a suitable cleanroom wipe followed by application to a surface;
- Formulation type: trigger spray;
- Users: professionals;
- Use: disinfection of hard surfaces in cleanrooms.

Use 2

- Application method: pour into a container then apply to surfaces using a suitable cleanroom mop or wipe;
- Formulation type: RTU solution;
- Users: professionals;
- Use: disinfection of hard surfaces in cleanrooms.

Physico-chemical properties

The physical, chemical and technical properties for PeridoxRTU 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 12 weeks at 40°C and showed no adverse interactions between the liquid formulation and the HDPE packaging. Acceptable storage data were also submitted relating to storage for 12 months at ambient temperature. Therefore, a shelf life of 12-months is supported for the BPF.

Based on the results of UN Test C.1 the product is assigned the hazard "H290: May be corrosive to metals".

Based on expert consideration of the composition, PeridoxRTU Product Family is considered not to be flammable, explosive, oxidising, self-reactive or self-heating.

The detection and identification of peracetic acid, hydrogen peroxide and acetic acid in the biocidal product family has been performed by HPLC-UV analytical method validated in accordance with the relevant guidance.

Efficacy

The efficacy of the BPF is demonstrated for use at a concentration of 0.23 % w/w peracetic acid.

Meta SPC 1

Use #1: The application rate for application by a wipe is 50 ml/m². For this application method a contact time of 2 min is required for bacteria. A contact time of 3 min is required for bacterial spores, fungi and yeast.

Use #2: The application rate is 50 ml/m². For this application method a contact time of 2 min is required for bacteria. A contact time of 3 min is required for bacterial spores, fungi and yeast.

Sufficient data were provided to demonstrate that the BPF is efficacious against bacteria, fungi, yeast, bacterial spores in clean conditions at room temperature.

Human health

Based on a pH of 1.72, the BPF should be classified:

- Skin Corr. 1A - H314: Causes severe skin burns and eye damage.

The active substance assessments for peracetic acid and hydrogen peroxide informs that the AEC for professional users is 0.5 mg/m³ and 1.25 mg/m³, respectively. Exposure above these levels was modelled for users of the product. The risk to professional users was demonstrated to be acceptable when gloves and eye protection were modelled to be worn and increased ventilation rates are considered.

Professional user risk assessment

Primary exposure has been considered for a professional user using a trigger spray, pouring the product into a container and also through disinfection of surfaces using a dry wipe or mop.

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

When taking into account primary exposure from the use of products from the PeridoxRTU Product Family the following conclusions can be drawn:

- Spraying of the product onto a wipe: gloves, coveralls and eye protection must be worn when handling the product and the product must only be applied for disinfection of small surfaces;
- Pouring of the product into a suitable container and apply to the surface using a suitable cleanroom mop or wipe: gloves, coveralls and eye protection must be worn when handling the product.

When taking into account secondary exposure from the use of products from the PeridoxRTU Product Family the following conclusions can be drawn:

- Exposure when a professional bystander re-enters a treated area after disinfection through spraying onto a wipe: acceptable exposure without PPE;
- Exposure when a professional bystander re-enters a treated area after disinfection through mopping/wiping: acceptable exposure without PPE.

When taking into account exposure scenarios for products from the PeridoxRTU Product Family, the following conclusions can be drawn:

The risk to professional users is demonstrated to be acceptable when protective gloves and coveralls and eye protection are worn and with an increased ventilation rate for Use #1 and Use #2.

The following risk mitigation measures are required for Use #1:

- Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information);
- A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
- A ventilation rate of at least 20/hr is mandatory when handling the product;
- The product must only be applied for disinfection of small surfaces.

The following risk mitigation measures are required for Use #2:

- Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information);
- A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);

- Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV) during product application. A minimum ventilation rate of 100 air change per hour is mandatory;
- 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 surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

In addition, given it can be expected that the product still evaporates from the used wipe after the product is distributed on the surface by wiping, the following use instructions should be added to the product label: "Used wipes must be disposed in a closed container".

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 peracetic acid via the diet is not expected for the proposed use of PeridoxRTU Product Family in cleanrooms.

Environment

The PeridoxRTU Product Family contains peracetic acid as the active substance at 0.23 % w/w plus hydrogen peroxide as "substance of concern" at 4.4 % w/w (in line with agreement reached at BPC-M-20-2017 under agenda item 8.2). The BPF is assigned the hazard: harmful to aquatic life with long lasting effects.

With a product density of 1.022 g/ml at 20 °C the product application rate of 50 ml/m² used in the environmental risk assessment is equivalent to 51.10 g/m². In line with the respective PT 1 - 6 evaluations for both peracetic acid and hydrogen peroxide, rapid degradation of both compounds during transit in sewer systems / drains and in a STP was taken into account within the emissions assessment.

Acceptable levels of risk to all environmental compartments (air, STP, surface water, sediment, soil, groundwater and non-target biota) 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;
- the BPF is efficacious against bacteria, fungi, yeast and bacterial spores at the stipulated contact times of 2 min for bacteria, 3 min for fungi, bacterial spores and yeast;
- risks to professional users are acceptable provided that suitable PPE (gloves, coveralls and eye protection) are worn and increased ventilation rates are ensured;

- no unacceptable risks are identified for the general public or the environment;

the BPC considers that using the products belonging to this 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 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 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 peracetic acid 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 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 PeridoxRTU Product Family shall be authorised for the uses described under section 2.1 of this opinion, subject to compliance with the proposed draft SPC.

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