Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Oxy'Pharm H_2O_2

ECHA/BPC/358/2022

Adopted

28 September 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of Oxy'Pharm H_2O_2 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:	**Oxy'Pharm H_2O_2**
Authorisation holder:	**OXY'PHARM**
Active substance common name:	**hydrogen peroxide (CAS number 7722-84-1)**
Product types:	**2 and 4**

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 30 January 2017, recorded in R4BP3 under case number BC-HC029658-43, 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 10 March 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-44) and its Working Groups (WG II2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: the Netherlands (NL)

The BPC opinion on the Union authorisation of the biocidal product family was reached on 28 September 2022.

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(1)(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 **Oxy'Pharm H2O2** 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 Oxy'Pharm H_2O_2 biocidal product family includes the following 3 meta-SPC's:

Meta-SPC 1: Oxy'Pharm H_2O_2 6%;

Meta-SPC 2: Oxy'Pharm H_2O_2 12%;

Meta-SPC 3: Oxy'Pharm H_2O_2 7.9%.

All products contain the active substance hydrogen peroxide and various non-active substances. One ingredient (silver) is identified as a substance of concern (SoC) as Indicative Occupational Exposure Limit Values are available for human health and the concentration silver shall classify the products for its environmental hazards. All products are used by professional users.

Physico-chemical properties

All products in the biocidal product family are clear colourless liquids. All products are stable during 2 years based on long term shelf life data.

The products included in Meta-SPC 2 are classified as oxidising liquids category 3. Further, it can be concluded that the products of the "Oxy'Pharm H2O2" BPF do not cause any additional physical hazards for which they would need to be classified according to Regulation (EC) 1272/2008.

The method for quantification of hydrogen peroxide (HPLC-UV) was validated so as to comply with the guidance document SANCO/3030/99 rev.4 (11/07/00) and was proven to have sufficient analytical qualities. For the substance of concern silver no validated analytical method is required as the concentration of this component is not expected to change during storage.

Efficacy

The product assessment report contained 5 uses divided over three meta-SPCs (see table below). All uses are applied by fogging hydrogen peroxide. Uses # 1.1, # 2.1, # 3.1, and # 3.3 were sufficiently supported by efficacy testing for bacteria, including mycobacteria, bacterial spores, yeasts, fungi, viruses and bacteriophages with a contact time of 2 hours. However, use # 3.2 is currently not substantiated well enough by efficacy testing for authorisation because appropriate efficacy tests on a porous surface are missing.

Human health

A risk assessment has been performed for applying Oxy'Pharm H2O2 using FHP at concentrations of 6%, 7.9% and 12% H_2O_2. Based on the risk assessment performed for the active substance, hydrogen peroxide, no unacceptable risks have been found when using appropriate risk mitigation measures (RMM). Unprotected person/animals may re-enter the treated room only after the hydrogen peroxide concentration in air decreases to lower than 1.25 mg/m^3 (0.89 ppm). When the concentration of hydrogen peroxide is still above the AEC of 0.89 ppm (i.e. 1.25 mg/m^3), RPE (respiratory protection equipment) is required for professionals entering the treated room in case of an emergency.

Therefore the following RMMs are proposed:

During the diffusion, keep the room closed and do not enter in. Treatment should be conducted with no human or animals present. All gaps present in the room (e.g. window frame) from where fog may leak should be sealed beforehand. Ensure that access to the fog-treated area is denied during the whole procedure with a warning sign.

Treated areas may not be entered until the concentration of hydrogen peroxide is ≤0.9 ppm (1.25 mg/m^3).

The professional user may enter the room only in emergency situations when the hydrogen peroxide level has dropped below 36ppm (50 mg/m^3) wearing mandatory the following PPE: RPE with APF 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves, eye protection, coverall). A measuring device should be used to ensure that the concentration of hydrogen peroxide has decreased below 0.9 ppm. Unprotected person/animals may re-enter the treated room only after the hydrogen peroxide concentration in air decreases lower than 1.25 mg/m^3 (0.9 ppm)

Meta-SPC 1 and Meta-SPC 2 contain silver which is found to be a substance of concern (SoC). For those Meta-SPC's and relevant scenarios a risk assessment of the inhalatory exposure to the SoC silver has been performed with the Indicative Occupational Exposure Limit Values (IOELV). A dermal exposure assessment is not needed due to the absence of a skin notation[1]. No unacceptable risks are found due to inhalatory exposure to this SoC, and therefore the Meta-SPCs with silver (i.e. Meta-SPC1 and Meta-SPC 2) and relevant uses (i.e. Use # 1.1 – Hard surface disinfection by 6% Fogging Hydrogen Peroxide; Use #2.1 – Hard surface disinfection by 12% Fogging Hydrogen Peroxide) can be authorised.

Environment

Regarding the active substance hydrogen peroxide, no unacceptable environmental risks have been found. However, Meta-SPC 1 and Meta-SPC 2 contain silver (Ag) which is assigned as a substance of concern (SoC). The accompanied risks have been assessed

[1] The IOELV for silver does not have a skin notation, which indicates that dermal systemic exposure does not need to be considered.

quantitatively based on the available emission scenarios and the harmonised list of endpoints taken from the silver core dossier from 2017.

Unacceptable risks to the environment are found in meta-SPC 1 as the SoC silver in products intended for surface disinfection by fogging (use #1.1). Although silver is also present in meta SPC 2 in the same concentration (use #2.1), no risk has been identified as the products requires more dilution and consequently to lower silver concentration in the diluted solution. However, as proposed by the applicant, removal of the sporicidal claim lowers the final dose from 12 (7+5 mL/m³) to 10 mL/m³ (5+5 mL/m³) which results in acceptable risks while still fulfilling the basic claim against bacteria and yeast. Consequently, application of the biocidal products within the family is acceptable provided that the sporicidal claim will be removed from use #1.1.

Overall conclusion:

The overall conclusion of the assessment is that the uses #1.1 (Hard surface disinfection by 6% Fogging Hydrogen Peroxide (FHP)), #2.1 (Hard surface disinfection by 12% Fogging Hydrogen Peroxide (FHP)), #3.1 (Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)) and #3.3 (Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)) may be authorised with the RMMs suggested above.

Use #3.2 (Porous Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)) may not be authorised as efficacy on porous surface has not been demonstrated.

PT	Use	Authorised uses	Concerned Meta SPC
02	Hard surface disinfection by 6% Fogging Hydrogen Peroxide (FHP)	Use # 1.1 (sporicidal claim not included)	1
	Hard surface disinfection by 12% Fogging Hydrogen Peroxide (FHP)	Use # 2.1	2
	Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)	Use # 3.1	3
03	Porous Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)	Use # 3.2 (not authorised)	3
04	Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)	Use # 3.3	3

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 **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 was not needed.

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 use 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 or unnecessary suffering and pain for vertebrates;
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.