

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

perform-IPA

ECHA/BPC/245/2020

Adopted

5 March 2020

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product family perform-IPA

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: perform-IPA

Authorisation holder: Schülke und Mayr GmbH

Active substance common name: Propan-2-ol

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 19 April 2016, recorded in R4BP3 under case number BC-AB023095-72, 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 accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

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 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.

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 perform-IPA 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 consists of products containing the active substance Propan-2-ol (63.1% w/w; 70% v/v) for disinfection of clean non-porous surfaces, which are not used for direct contact with food or feeding stuffs (PT 02) and for disinfection of clean non porous-surfaces in food and feed area (PT 04). No substances of concern are identified. For a co-formulant concerns were identified with respect to its endocrine-disrupting properties.

The biocidal product family consists of eight meta SPCs with ready-to-use liquids (meta SPCs 1, 3, 7) and ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8). The user categories are professional (including industrial) user (meta SPCs 1 - 8) and non-professional user (meta SPC 6).

The following uses have been assessed:

meta SPC 1 :

- Use 1: Disinfection of surfaces - spraying
- Use 2: Disinfection of surfaces - wiping
- Use 3: Disinfection of surfaces with food and feed contact - spraying
- Use 4: Disinfection of surfaces with food and feed contact - wiping

meta SPC 2 :

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact – wiping

meta SPC 3 :

- Use 1: Disinfection of surfaces - spraying
- Use 2: Disinfection of surfaces - wiping
- Use 3: Disinfection of surfaces with food and feed contact - spraying
- Use 4: Disinfection of surfaces with food and feed contact - wiping

meta SPC 4 :

- Use 1: Disinfection of surfaces – wiping
- Use 2: Disinfection of surfaces with food and feed contact - wiping

meta SPC 5 :

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact - wiping

meta SPC 6 :

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact - wiping

meta SPC 7 :

- Use 1: Disinfection of surfaces - spraying
- Use 2: Disinfection of surfaces - wiping
- Use 3: Disinfection of surfaces with food and feed contact - spraying
- Use 4: Disinfection of surfaces with food and feed contact - wiping

meta SPC 8 :

- Use 1: Disinfection of surfaces - wiping
- Use 2: Disinfection of surfaces with food and feed contact – wiping

Physico-chemical properties

The products within the family are colourless and have an alcoholic odour. The pH of the products within the family ranges from approximately 7.2 to 7.7, the density is around 0.876 g/cm³.

The products (ready-to-use liquids) of meta SPC 1, 3 and 7 have a shelf-life of 36 months, whereas products (ready-to-use wipes) of meta SPC 2, 4, 5, 6 and 8 have a shelf-life of 24 months.

According to the CLP criteria, the individual products of the BPF, and thus the BPF itself, need to be classified with regard to physical hazards as follows:

- Flam. Liq. 2; (Flammable liquids, hazard category 2);
- H225: Highly flammable liquid and vapour.

The analytical methods for detection and identification for the BPF are deemed acceptable.

Efficacy

Proven efficacy for disinfection of non-porous surfaces by spraying with ready-to-use liquids (meta SPCs 1, 3, 7):

- PT2 and PT4: bactericidal (including tuberculocidal) and yeasticidal efficacy within a contact time of 1 minute under clean conditions at 20°C;
- PT4: virucidal efficacy within a contact time of 2 minutes under clean conditions at 20°C.

Proven efficacy for disinfection of non-porous surfaces by wiping with ready-to-use liquids (meta SPCs 1, 3, 7) or ready-to-use wipes (meta SPCs 2, 4, 5, 6, 8):

- PT2 and PT4: bactericidal (including tuberculocidal) efficacy within a contact time of 5 minutes under clean conditions at 20°C;
- PT2 and PT4: yeasticidal efficacy within a contact time of 1 minute under clean conditions at 20°C;
- PT4: virucidal efficacy within a contact time of 2 minutes under clean conditions at 20°C.

It can be concluded that products of the BPF show sufficient bactericidal and yeasticidal activity as substantiated according to European Standards (EN) in PT2 and PT4. Furthermore, the products show sufficient virucidal activity in PT4.

Resistance is not reported or known at the time being. Hence, with regard to efficacy, the requirements for the authorisation of the BPF have been met.

To ensure the efficacy of the products, the following instructions for use are defined in the SPC:

- Clean the surface carefully before use. Remove excess water from the surface before disinfection, if appropriate;
- Make sure to wet surfaces completely.

Human health

Professional user/ industrial user

Meta SPC 1 (ready to use solution) represents worst case for meta SPC 2, 5, 6, 7 and 8 (wipes). The exposure assessment for professional/industrial users for biocidal products of meta SPC 2, 5, 6, 7 and 8 is covered by the exposure assessment for biocidal products of meta SPC 1.

Meta SPC 3 (ready to use solution) represents worst case for meta SPC 4 (wipes). The exposure assessment for professional / industrial users for biocidal products of meta SPC 4 is covered by the exposure assessment for biocidal products of meta SPC 3.

Meta SPC 1

The exposure assessments are based on model assumptions.

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional/industrial users resulting from the intended uses 'Small surface disinfection in patient rooms (PT02)', 'Small surface disinfection in laboratory and biotechnology (PT02)', 'Small surface disinfection in kitchens and canteens (PT04)' as wells as 'Disinfection of food processing machinery (PT04)' and secondary exposure with the biocidal products covered by meta SPC 1 is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100% after TIER 1 consideration.

The local toxicity profile of the active substance propan-2-ol is also considered. The active substance propan-2-ol has eye irritating properties and therefore leads to classification of the biocidal products covered by meta SPC 1 with H319 (Causes serious eye irritation). In addition, the biocidal products covered by meta SPC 1 has to be labelled with EUH066 (Repeated exposure may cause skin dryness or cracking). Therefore a qualitative risk

assessment for local effects regarding skin and eye contact is necessary. The allocated hazard category according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015) is “low”.

Based on the systemic and qualitative risk assessment for local effects regarding occupational safety, there are no objections against the aforementioned intended uses taking into account the restriction of the application rate to 25 ml/m² and the use only for disinfection of small surfaces. Based on the local effects to eyes it is recommended to use eye protection for refilling and for disinfection of food processing machinery for ready-to-use liquids only. For ready-to-use wipes a labelling advice to avoid contact to eyes is required.

Meta SPC 3

The exposure assessments are based on model assumptions.

Based on the systemic risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional/industrial users resulting from the intended uses ‘Small surface disinfection in patient rooms (PT02)’, ‘Small surface disinfection in laboratory and biotechnology (PT02)’, ‘Small surface disinfection in kitchens and canteens (PT04)’ as wells as ‘Disinfection of food processing machinery (PT04)’ and secondary exposure with the biocidal products covered by meta SPC 3 is unlikely since the respective risk characterisation consistently yields exposure-to-AEL ratio of less than 100% after TIER 1 consideration. Based on the systemic and qualitative risk assessment for local effects regarding occupational safety, there are no objections against the aforementioned intended uses taking into account the restriction of the application rate to 25 ml/m² and the use only for disinfection of small surfaces. Based on the local effects to eyes it is recommended to use eye protection for refilling and for disinfection of food processing machinery for ready-to-use liquids only. For ready-to-use wipes a labelling advice to avoid contact to eyes is required.

Non-Professional user and general public

No human health risk from use of biocidal products for Meta-SPC 6 by non-professional users was identified if the biocidal products are used as intended. To avoid excessive use the typical application rate in a simple form easily understandable for the non-professional user has to appear on the label (e.g. Use one wipe per m² surface). In addition, the biocidal product has to be stored out of the reach of children since the unattended use/misuse of the biocidal product by smaller children may result in human health hazards.

Human health hazard based on the classification of the biocidal product as Eye Irrit. 2, H319 and STOT SE 3, H336 can be sufficiently controlled by the corresponding precautionary statements. In addition, a labelling advice to avoid contact to eyes is required.

No human health risk was identified for secondary exposure of the general public (adults and older children) resulting from professional and non-professional use of the biocidal product family. This includes combined exposure to PT02 and PT04. However, for smaller children (toddlers) a risk was identified, if they enter treated areas immediately after application. Safe re-entry is only possible after adequate ventilation. An appropriate labelling is required. The following labelling has to be included which contains also measures to avoid potential risks for children and pets: “Keep children and pets away from rooms where disinfection is taking place.” and “Provide adequate ventilation before children and pets enter treated rooms”.

Dietary exposure/ Consumer risk assessment

For the intended uses of the biocidal product family, due to its high vapour pressure, dietary exposure to humans can be excluded.

Environment

As concluded in the product assessment report no unacceptable risks for the environment are to be expected from the use of the biocidal products in the meta-SPCs of the biocidal product family "Perform-IPA", the conditions for granting a union authorisation are formally met.

The products in the biocidal product family "Perform-IPA" containing Propan-2-ol are intended for disinfection of non-porous surfaces indoor only, therefore there will be no direct exposure of the environment. However, the application of products part of the BPF "Perform-IPA" used for disinfection can result in indirect exposure via STP. The assessment demonstrated an acceptable risk for all environmental compartments. No risk mitigation measures are necessary.

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 propan-2-ol 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 use(s) 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;
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/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.

For the co-formulant identified as potentially having ED properties, a process under REACH will be triggered by the eCA (DE) in line with paragraph 31(b) of the note CA-March18-Doc.7.3.b-final entitled "The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation".