Biocidal Products Committee (BPC)

Opinion on the Union authorisation of

Pal IPA Product Family

ECHA/BPC/223/2019

Adopted

28 February 2019

Opinion of the Biocidal Products Committee

on the Union authorisation of Pal IPA 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: Pal IPA Product Family

Authorisation holder: Pal International Limited

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 29 June 2016, recorded in R4BP3 under case number BC-DY025578-07, 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 22 August 2018. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-29) and its Working Groups (WG VII 2018). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the Union authorisation of the biocidal product family was reached on 28 February 2019.

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 may be expected to fulfil 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 Pal IPA 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 Pal IPA Product Family consists of products containing the active substance propan-2-ol (70 % v/v; 62.9 % w/w) for disinfection of hard surfaces in products types 2 and 4. No substances of concern were identified in the biocidal product family.

The biocidal product family (BPF) consists of a single meta SPC containing a single product format for which the following use has been assessed:

- Application method: Wiping;
- Formulation type: RTU impregnated wipe;
- Users: Professionals;
- PT 2 use: Disinfection of hard surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications;
- PT 4 use: Disinfection of hard surfaces in industrial food and feed preparation areas.

There are two different types of wipe. Polypropylene wipes and polyester wipes, all of different sizes.

Physico-chemical properties

The physical, chemical and technical properties for Pal IPA Product Family are acceptable for the liquid formulation supplied to the user as impregnated wipe products. For the majority of properties data on the liquid formulation alone can be extrapolated to the impregnated wipes as the liquid formulations are identical. Therefore 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. These data can be extrapolated to support the impregnated RTU wipe products. An accelerated storage stability study was conducted on the impregnated RTU wipes; however, the active ingredient content was not reported. Therefore, a long-term storage test at ambient temperature for wipes in their commercial packaging has been requested. The formulation can be considered similar to an aqueous based formulation due to the main component being an aliphatic alcohol; therefore, extrapolation between packaging types is acceptable. In addition, propan-2-ol is known to have good resistance to a range of plastics. Therefore a shelf life of 2 years is supported for the BPF.

An ambient temperature storage stability study, run to GLP, remains in progress. Packaging suitability will also be assessed following long-term storage.

A low temperature storage stability study showed no significant change in the liquid product following storage at 0°C for seven days.

Based on expert consideration of the composition, Pal IPA Product Family is considered not to be explosive, oxidising, self-reactive, self-heating or corrosive to metals. The flash point was measured to be 21.0°C therefore the product family is classified as category 2 flammable liquid.

Efficacy

The efficacy of the BPF is demonstrated for use at a concentration of 70 % v/v (62.9 % w/w) propan-2-ol with a contact time of 1 minute for bacteria and myobacteria and 3 minutes for yeast. The amount of product in one wipe is 1.7 – 7.5 ml (0.93 – 4.12 g propan-2-ol). One wipe can treat a surface of 1 – 1.5 m^2.

Sufficient data were provided to demonstrate that the BPF is efficacious against bacteria, mycobacteria and yeast with a 1 minute contact time for bacteria and mycobacteria and 3 minutes contact time for yeast. However, efficacy against viruses and fungi is not supported.

Human health

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

- Eye irritation cat. 2 - H319: Causes serious eye irritation.
- STOT SE 3 - H336: May cause drowsiness or dizziness.
- EUH066: Repeated exposure may cause skin dryness or cracking.

The active substance assessment for propan-2-ol informs that the AEC for professional users of 52.6 ppm for 8 hours/day (converted to a systemic AEL of 17.9 mg/kg bw/d) also sufficiently covers local irritant effects in the eyes/airways. As such additional risk mitigation measures for local effects is not required.

Professional users are exposed through disinfection of small surfaces in industrial/manufacturing cleanrooms, private and public health areas e.g. hospitals (PT2) and professional food preparation settings (PT4).

Secondary exposure may also occur for members of the general public in healthcare environments e.g. hospital.

Professional user risk assessment

No combined exposure scenarios have been identified for professional users. It is not expected that a professional user would use the products in multiple settings in the same day.

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

- Routine disinfection of small surfaces by trigger spray and RTU wipes e.g. a technician performs routine dsinfection of equipment and work stations as part of their working procedures in industrial/manufacturing cleanrooms (PT2): Acceptable exposure without PPE.
- Disinfection of surfaces in private and public health areas e.g. hospital (PT2): Acceptable exposure without PPE.
- Disinfection of small surfaces in professional food preparation settings e.g. canteen/kitchen setting (PT4): Acceptable exposure without PPE.
- Disinfection of small surfaces in industrial professional food preparation settings e.g. food processing industry (PT4): Acceptable exposure without PPE.

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

- Bystander inhalation of volatilised residues during disinfection in industrial/ manufacturing cleanrooms (PT2): Acceptable exposure without PPE.
- Bystander exposure to volatilised residues during disinfection in professional food preparation setting (PT4): Acceptable exposure without PPE.

On the basis that acceptable exposure has been identified for all professional user scenarios without PPE, no additional RMMs are required.

General public risk assessment

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

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

- Bystander inhalation of volatised residues during disinfection in healthcare environments e.g. hospital: Acceptable exposure without PPE.

Disinfection wipes are intended for small scale use to disinfect small surfaces which have frequent contact e.g. door handles, visitor's chair and realistically patient's rooms are likely to be disinfected once a day or after patient discharge. However, where areas (>1 m^2) are required for disinfection and given the associated P-phrases triggered by the classification of the BPF (P261: Avoid breathing vapours, and P271: Use only outdoors or in a well-ventilated area) users should consider appropriate risk mitigation measures for exposed bystanders; such as ensuring the room is well ventilated prior to entry.

The following use specific risk mitigation measure is recommended:

When performing disinfection in areas where members of the public may be present, persons should be prevented from entering the room until the room has been well ventilated.

Consumer risk assessment

Dietary exposure is not envisaged. The formulation of the products of the family is similar to the representative formulation considered at active substance approval and therefore the same conclusion is applicable. No residues in food or feed are expected to arise from the use of the product in the family (PT 4) due to the high vapour pressure of the active substance (5780 Pa at 25°C).

Environment

The environmental risk assessment for the BPF has followed the agreements made within the active substance assessment and assumed a 90 % loss to air and 10 % loss to drain following application for a number of scenarios.

As a protective approach for the aquatic compartment, the scenario for the use of propan-2-ol in a brewery has also been considered although this is not one of the uses proposed by the applicant. This is an extreme worst-case situation and acceptable risks to the environment were still predicted for this use.

The highest proposed application rate of 7.5 ml per wipe per m² daily for a 70 % propan-2-ol product has been used in the risk assessment to cover the use of the BPF. It is noted that this is an extreme worst case as it has been assumed that all of the liquid is removed from the largest available wipe over a surface multiple times during the day.

In conclusion, even using a number of worst case assumptions, acceptable uses to the environment have been demonstrated for the BPF for the proposed use as RTU wipes under PT 2 and PT 4.

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;
- the BPF is efficacious against bacteria, mycobacteria and yeast with 1 minute contact time for bacteria and mycobacteria and 3 minutes contact time for yeast;
- no unacceptable risks are identified for professional users, 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 / 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 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 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

It is proposed that Pal IPA Product Family shall be authorised, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Description	Due date
Long term storage tests at ambient temperature for wipes in their commercial packaging.	July 2021

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Annex I: Draft Summary of Product Characteristics