



Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

IPA Family 1

ECHA/BPC/316/2022

Adopted

1 March 2022



Opinion of the Biocidal Products Committee

on the Union authorisation of IPA Family 1

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:	IPA Family 1
Authorisation holder:	Ecolab Deutschland GmbH
Active substances common name:	Propan-2-ol (CAS number 67-63-0)
Product types:	PT 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 10 June 2016, recorded in R4BP3 under case number BC-HN024859-20, 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 25 August 2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-42) and its Working Groups (WG-IV-2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: the Netherlands

The BPC opinion on the Union authorisation of the biocidal product family IPA Family 1 was reached on 1 March 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 IPA Family 1 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 biocidal product family (BPF) IPA Family 1 contains the active substance propan-2-ol (30-65% w/w) for disinfection of surfaces in cleanrooms and non-food and food contact surfaces by professional users. No substances of concern are identified.

Proposed uses

The following 5 uses were proposed by the applicant:

Use #1.1 (metaSPC 1.1) - disinfection of surfaces (including gloves) in cleanrooms by trigger spraying or pouring, wiping and mopping;

Use #2.1 (metaSPC 1.2) 1/2 disinfection of surfaces (including gloves) in cleanrooms by wiping with pre-wetted wipes;

Use #3.1 (metaSPC 1.3) 1/2 disinfection of surfaces (including gloves) in cleanrooms by aerosol;

Use #4.1 (metaSPC 1.4) 1/2 disinfection of non-food and food contact surfaces in e.g., commercial kitchens, bathrooms by pre-wetted wipes;

Use #5.1 (metaSPC 1.5) - disinfection of non-food and food contact surfaces in e.g., commercial kitchens, bathrooms by trigger spraying.

The following uses are considered to be acceptable:

Use#1.1 (metaSPC 1.1) - disinfection of surfaces in cleanrooms by trigger spraying or mopping;

Use #2.1 (metaSPC 1.2) 1/2 disinfection of surfaces in cleanrooms by wiping with pre-wetted wipes;

Use #3.1 (metaSPC 1.3) 1/2 disinfection of surfaces in cleanrooms by aerosol;

Use #4.1 (metaSPC 1.4) 1/2 disinfection of non-food and food contact surfaces in e.g., commercial kitchens, bathrooms by pre-wetted wipes;

Use #5.1 (metaSPC 1.5) - disinfection of non-food and food contact surfaces in e.g., commercial kitchens, bathrooms by trigger spraying.

For the uses #1.1, #2.1 and # 3.1, glove disinfection cannot be authorized because of the practical implications for efficacy and human toxicology.

The outcome of the assessment for the biocidal product family IPA Family 1 is described below.

Physico-chemical properties

The family consists of 5 meta SPCs, including wipes, aerosols and ready to use liquids, with and without trigger sprayer.

Sufficient data were provided to address the physical and chemical properties and to determine suitable storage conditions. The products within the family have a shelf-life of 2 years and should be stored at temperatures between 0 °C to 25 °C, away from direct sunlight.

The MMAD (Mass Median Aerodynamic Diameter) of droplets was determined before storage for the trigger spray packaging of meta-SPCs 1.1 and 1.5 and the aerosol of meta-SPC 1.3. No data were available on the MMAD after storage. Since the composition is simple consisting mainly of propan-2-ol and water and is stable during storage, no change in MMAD after storage is expected. Hence, it is acceptable that the MMAD after storage is not provided.

For the aerosol packaging of meta-SPC 1.3, only accelerated storage stability data are available. Therefore, a provisional shelf life of 2 years is considered acceptable, but a long-term ambient storage stability study is still required, as providing accelerated storage stability data does not negate the need to generate ambient storage data. These data will need to be provided post-authorisation. For meta-SPC 1.3 therefore the following is proposed: a shelf-life study is required with the Klercide 70/30 IPA Aerosol, at least addressing: packaging stability, spray characteristics and internal pressure before and after storage to support the read-across to Klercide 70/30 IPA.

All products within the family are flammable. The aerosols are category 1 flammable aerosols while the other products are classified as category 2 or 3 flammable liquids. The products are not auto-flammable, explosive or oxidising and are not corrosive to metals.

An adequate GC method is available to determine the content of propan-2-ol in the product.

Efficacy

Products in meta-SPC 1.1; meta-SPC 1.2 and meta-SPC 1.3 are intended for disinfection of hard surfaces in cleanrooms in life sciences industry (PT2) and are applied by trigger spraying or mopping (meta-SPC 1.1), wiping with pre-wetted wipes (meta-SPC 1.2) and aerosol spraying (meta-SPC 1.3). The products are intended for use against bacteria, yeast, fungi and enveloped viruses under clean conditions. Efficacy against bacteria, yeast, fungi and enveloped viruses at the claimed contact times is supported by relevant tests according to the European Standards (EN1276, EN1650, EN13697, EN16615 and EN14476). Considering the practical implications with claimed contact times (5-15 minutes) the intended disinfection of gloves on hands cannot be authorized. The long contact times are not feasible in practice

as the product evaporates quickly and hands inside the gloves cannot be used for 5-15 minutes, so altogether efficacy cannot be guaranteed for the claimed contact time.

Products in meta-SPC 1.4 are intended for disinfection of non-food and food contact surfaces (PT2 and PT4) by wiping with pre-wetted wipes. The products are intended for use against bacteria and yeast under clean conditions. Efficacy against bacteria at the claimed contact time is supported by relevant tests according to the European Standards (EN1276, EN13697, EN16615). Efficacy against yeast at the claimed contact time (15 minutes) is supported by tests according to the European Standards EN1650 and EN13697.

Products in meta-SPC 1.5 are intended for disinfection of non-food and food contact surfaces (PT2 and PT4) by trigger spray. The products are intended against bacteria and yeast under clean and dirty conditions. Efficacy against bacteria and yeast at the claimed contact time (30 seconds) is supported by relevant tests according to the European Standards (EN1276, EN1650, EN13697).

Human health

Based on the active substance content, all meta SPCs of the BPF IPA Family 1 are 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.

Risk assessment

Due to the high volatility of propan-2-ol, inhalation of vapour is the major route for exposure for the professionals. The calculation of exposure to vapour depends on many different parameters such as room size, ventilation rate of the room, application rate, product amount applied in a room, and disinfection frequency. The applications in cleanrooms were evaluated using parameters either from HEAd hoc recommendation no.15 or in some cases more conservative parameters from the applicant's information are used.

It is concluded that the glove disinfection (Use included in #1.1-3.1) in cleanrooms cannot be authorised, because of the practical implications for efficacy and human toxicology, which is based on the following:

considering that the dosing of 3 mL of the product to be applied on gloves, it can be calculated that propan-2-ol evaporates in 64 sec (calculation is included in scenario 6). This does not meet the claimed contact time for efficacy (5-15 min leave-on time) (meta-SPC 1.1, 1.2 and 1.3);

metaSPC 1.2 (impregnated wipes) contain 2.5-35 mL/wipe. It is not explained how the amount of product on the glove can be restricted to be in line with the dosing instructions of 3 mL/glove.

The active substance assessment for propan-2-ol informs that the AEC (Acceptable Exposure Concentration) for professional users of 52.6 ppm for 8 hours/day (converted to a systemic

AEL (Acceptable Exposure Level) of 17.9 mg/kg bw/d) also sufficiently covers local irritant effects in the eyes/airways.

The risk for professional users is considered acceptable during mixing and loading, and disinfection by wiping or spraying. The predicted levels of exposure are lower than the AEL.

However, the exposure of the unprotected professional users exceeds the AEL during the application by mopping (Scenario 5, Tier 1). Therefore, during mopping gloves and respiratory protection equipment (RPE) are needed. Furthermore, eye protection is required during mopping based on the local risk assessment.

Considering the local risk assessment for wiping or spraying applications, no eye protection is considered necessary. However, the contact with eyes should be avoided.

Combined exposure scenarios as spraying with wiping or mixing/loading with mopping are considered acceptable. No human health risk from use of biocidal product (PT 2 and 4) was identified for unprotected professionals from the application by wiping or trigger/aerosol spraying, and for protected professionals (gloves, eye protection and RPE of protection factor 10) from the application by mopping.

Regarding secondary exposure of the bystanders (professionals present in the same room) from inhalation of volatilised residues the following conclusions can be drawn:

during mopping (Use #1.1) unprotected personnel should not be present in the room. The following risk mitigation measure should be included: unprotected personnel should not be present in the room during disinfection by mopping;

for the other secondary exposure scenarios acceptable exposure has been identified for all professional user scenarios without gloves or RPE (respiratory protective equipment). No other additional RMMs (risk management measures) are required either.

No risk has been identified for secondary exposure of the general public (relevant for metaSPC 1.4 and 1.5., PT 2 uses).

Dietary exposure

The IPA Family 1 products are an aqueous solution of up to 65 % propan-2-ol. Products of the BPF are not used directly on food or feed, but the use includes disinfection of food contact surfaces in e.g., commercial kitchen, catering, food processing, food retail and canteen, which could potentially lead to transfer of residues onto food. However, due to its high vapour pressure, the active substance evaporates completely within the time of application of the products, so that no transfer from treated surfaces to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore, dietary exposure to humans from the use of the products of the BPF can be excluded, when the products are used in accordance with the use instructions specified in the SPC.

Environment

The use of propan-2-ol in PT 2 and PT 4 does not pose an unacceptable risk to the local STP, surface water, sediment and the terrestrial environment including groundwater. The sum of

the PEC/PNEC (Predicted Environmental Concentration; Predicted No Effect Concentration) values for all uses are also <1 for these compartments demonstrating an acceptable risk.

Primary poisoning of birds and mammals is not expected for the intended uses. Based on the low estimated BCF (Bioconcentration Factor) values in aquatic and terrestrial indicator species, propan-2-ol is not expected to accumulate in the environment. The risk of secondary poisoning via ingestion of contaminated food by birds or mammals is therefore negligible.

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/biocidal product 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

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised¹ for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC and the following condition.

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

Description	Due date
A shelf-life study with the Klercide 70/30 IPA Aerosol, at least addressing: packaging stability, spray characteristics and internal pressure before and after storage.	10 months after the granting of the authorisation

It is noted that for the biocidal product family the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the conditions under Article 19(1) on the basis of the existing data.

oOo

¹ 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.