Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family

SOPUROXID

ECHA/BPC/279/2021

Adopted

4 March 2021

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SOPUROXID

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: **SOPUROXID**

Authorisation holder: **SOPURA**

Active substance common name: **Peracetic acid**

Product type: **2, 3 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 1 September 2017, recorded in R4BP3 under case number BC-KV033704-17, the evaluating Competent Authority (Belgium) 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 2020. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-38) and its Working Groups (WG-IV 2020). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur : Belgium

The BPC opinion on the Union authorisation of the biocidal product family SOPUROXID was reached on 4 March 2021.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

SOPUROXID 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).

SOPUROXID meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of SOPUROXID 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 SOPUROXID.

General

SOPUROXID consists of products divided into 4 Meta SPCs and containing one active substance : peracetic acid used at the concentration range 3.20 – 15.00 % w/w.

All the biocidal products within the entire family are soluble concentrates (SL) to dilute in tap water. They are intended to be used only by professional and industrial users. One substance of concern was identified in the biocidal product family: sulfuric acid (for human health only).

SOPUROXID is composed of 4 meta-SPCs:

- Meta-SPC 1 and 4 present similar uses, but with different concentrations of the active substance (5% for Meta-SPC 1 and 15% for Meta-SPC 4);
- Meta-SPC 2 covers application by fogging;
- Meta-SPC 3 covers application by foaming.

This means that uses in Meta-SPC 2 and 3 have dedicated scenarios while for most uses in Meta-SPC 1 and 4, the same scenario can be used with an adaptation for the difference in concentration.

The biocidal products within the entire family are disinfectants for PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*), PT3 (*Veterinary Hygiene*) and PT4 (*Food & feed Area*) with the following uses as considered:

META SPC 1 (with products *Sopuroxid 5* and *Sopuroxid 5C*) **& META SPC 4** (with products *Sopuroxid 15* and *Oxypur CS*).

PT 2	**DISINFECTANTS AND ALGAECIDES NOT INTENDED FOR DIRECT APPLICATION TO HUMANS OR ANIMALS**
Use	
1	Disinfection of surfaces in industrial, public and healthcare/non-medical areas - manual treatment (mopping)
2	Disinfection of surfaces in industrial, public and healthcare/non-medical areas - manual treatment (spraying)
3	CIP in the pharmaceutical and cosmetic industry
4	Surface disinfection in greenhouses by spraying with personal enclosure (in absence of plants - for general hygiene purpose only)
5	Surface disinfection in greenhouses by spraying without personal enclosure (in absence of plants - for general hygiene purpose only)
6	Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)
7	Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)
8	Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)
9	Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)

PT 3	**VETERINARY HYGIENE**
Use	
10	Disinfection of animal housing by low-pressure manual spraying – spraying with personal enclosure
11	Disinfection of animal housing by low-pressure manual spraying – spraying without personal enclosure
12	Disinfection of boots in footbaths in animal housing/husbandries
13	Disinfection of equipment by dipping

PT 4	**FOOD AND FEED AREA**
Use	
14	Automated spraying closed systems (aseptic filling of crown corks, cheese moulds and food crates in the food and beverage industry) – automatic spraying (closed room)
15	Disinfection of equipment in the food and beverage industry by immersion
16	CIP and disinfection of heat and ion exchangers, membrane filters and returnable and non-returnable glass and PET bottles in the food and beverage industry
17	Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure
18	Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure
19	Disinfection of surfaces and equipment by low pressure spraying, manually
20	Disinfection of surfaces and equipment by low pressure spraying, automatically
21	Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)
22	Disinfection of inner surfaces (pipelines, tanks, vessels) by CIP
23	Disinfection of water used for rinsing of recycled items during the washing process

META SPC 2 (with product *Sopuroxid 3.2*).

PT 2	DISINFECTANTS AND ALGAECIDES NOT INTENDED FOR DIRECT APPLICATION TO HUMANS OR ANIMALS
Use	
1	Room disinfection by fogging - In industrial, public and health care areas (pharmaceutical and cosmetic industry)
2	Room disinfection by fogging - In agriculture & horticulture areas (in absence of plants - for general hygiene purpose only)

PT 3	VETERINARY HYGIENE
Use	
3	Room disinfection by fogging – In animal housing

PT 4	FOOD AND FEED AREA
Use	
4	Room Disinfection by fogging – In storage rooms with special device in storage cellar or room

META SPC 3 (with product *Acidofoam CF*).

PT 2	DISINFECTANTS AND ALGAECIDES NOT INTENDED FOR DIRECT APPLICATION TO HUMANS OR ANIMALS
Use	
1	Disinfection of surfaces in industrial, public and health care areas – foam application on surfaces
2	Disinfection of surfaces and agriculture/horticulture equipment by foaming, manually (in absence of plants - for general hygiene purpose only)
3	Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (in absence of plants - for general hygiene purpose only)
4	Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (closed rooms) (in absence of plants - for general hygiene purpose only)

PT 3	VETERINARY HYGIENE
Use	
5	Disinfection of animal housing by foaming – foaming with personal enclosure
6	Disinfection of animal housing by foaming – foaming without personal enclosure

PT 4	FOOD AND FEED AREA
Use	
7	Disinfection of surfaces by foaming with personal enclosure
8	Disinfection of surfaces by foaming without personal enclosure

Physico-chemical properties

Products included in SOPUROXID are limpid, colourless liquids with a vinegar odour with a pH <2. The density of the products is 1.108 – 1.235 g/ml. The volume of foam does not exceed 60 ml after 1 minute, except for meta-SPC 3 (intended for foaming application) and meta-SPC 2 (fogging use does not trigger concerns regarding the mode of application and this parameter). The rinsed residue is higher than the threshold and can be explained by surface tension. In order to avoid hazardous situations during waste disposal, safe waste disposal instructions are to be respected for all products of the biocidal product family (BPF). The surface tension of the products at the highest in use concentration is in the range of 65 to 69 mN/m, except for the foaming product (meta-SPC 3), where it is 24.1

mN/m. The viscosity of all products is 3.7 – 4.8 mPa.s at 20 °C and 3.4 - 4.8 mPa.s at 40°C. An evaluation for the physical or chemical compatibility of the product is not considered necessary because products of SOPUROXID are not intended to be used with other products.

After 12 weeks at +30°C, the appearance of the biocidal products and the container remained unchanged and the variation of the concentration of peracetic acid is within the allowed range. All the products are stable during low temperature tests. The products also show stable dilutions as no separated material is observed at the highest in use concentration.

The proposed shelf life is 6 months for all meta-SPCs. In addition, the following risk mitigation measure (RMM) is recommended for meta-SPCs 1, 2 and 3 : “do not store at temperatures higher than +30 °C”. For meta-SPC 4 the following RMM is recommended: “store at ambient temperature”. The products are to be packaged in HDPE packagings.

Concerning physical hazards:

- Based on the results of UN Test C.1 and long term experience of the applicant in handling and use, all the products of SOPUROXID are corrosive to metals;
- Based on exceptional case UN3149 described in CLP regulation products of meta-SPCs 1, 2 and 3 are oxidising liquids, category 2 and organic peroxides, category G;
- Based on testing provided by the applicant in line with CLP requirements concerning flammable liquid and organic peroxide products of meta-SPC 4 are considered as flammable liquids, category 3 and organic peroxides, category F;
- Based on expert consideration of the composition, none of the other physical hazards is of relevance in this product family.

The detection and identification of peracetic acid and hydrogen peroxide in the biocidal product family has been performed by oxido-reduction titration by $KMnO_4$, KI and $Na_2S_2O_3$. The detection and identification of acetic acid in the biocidal product family has been performed by HPLC-DAD analytical method.

Acceptable analytical methods for the determination of peracetic acid, hydrogen peroxide and acetic acid in the biocidal product have been provided.

Efficacy

The target organisms for this BPF include vegetative bacteria, yeasts (fungi for one use only), viruses (including bacteriophages) and spore-forming bacteria relevant to the products’ areas of use and in-use conditions.

The product *Acidofoam CF* (3.2 % PAA) has been chosen as the representative product for the majority of efficacy testing of the SOPUROXID products, since it has the lowest concentration active substance compared to the other products of the family. Efficacy tests performed according to “suspension” and “surface” standards have been submitted: Phase 2/Step 1 efficacy tests (mandatory for products intended to be used for CIP with circulation procedures and water stream disinfection, and Phase 2/Step 1 and Step 2 efficacy tests (mandatory for products intended to be used for soaking, spraying, fogging, foaming and manual cleaning procedures).

Detailed function, field of use, application rates and contact times of the products are described in the Efficacy part of the PAR and described in the section *# 2.1.4.” Authorized use(s)*” but also summurised below :

Meta SPC-1 (5% PAA)
Meta SPC-4 (15% PAA)

PT 2	DISINFECTANTS AND ALGAECIDES NOT INTENDED FOR DIRECT APPLICATION TO HUMANS OR ANIMALS	
Use		**Use conditions granted**
1	Disinfection of surfaces in industrial, public and healthcare/non-medical areas - manual treatment (mopping)	On hard/non-porous surfaces with prior cleaning: • **HEALTHCARE / non-medical areas** Active against bacteria and yeasts 0.048% PAA - 5 min - at Room Temperature • **Use other than in HEALTHCARE** Active against bacteria and yeasts 0.048% PAA - 15 min - Efficient use temperature from +4°C up to room temperature.
2	Disinfection of surfaces in industrial, public and healthcare/non-medical areas - manual treatment (spraying)	
3	CIP in the pharmaceutical and cosmetic industry	On hard/non-porous surfaces with prior cleaning: Active against bacteria and yeasts 0.032% PAA - 15 min - Efficient use temperature from +4°C up to room temperature.
4	Surface disinfection in greenhouses by spraying with personal enclosure (in absence of plants - for general hygiene purpose only)	On hard/non-porous surfaces with prior cleaning: Active against bacteria and yeasts 0.048% PAA - 60 min
5	Surface disinfection in greenhouses by spraying without personal enclosure (in absence of plants - for general hygiene purpose only)	
6	Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)	
7	Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)	
8	Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)	
9	Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)	

PT 3	VETERINARY HYGIENE	
Use		**Use conditions granted**
10	Disinfection of animal housing by low-pressure manual spraying – spraying with personal enclosure	On hard/non-porous surfaces with prior cleaning: Active against bacteria, yeasts and viruses 0.064% PAA - 60 min
11	Disinfection of animal housing by low-pressure manual spraying – spraying without personal enclosure	
12	Disinfection of boots in footbaths in animal housing/husbandries	
13	Disinfection of equipment by dipping	

PT 4	FOOD AND FEED AREA	
Use		**Use conditions granted**
14	Automated spraying closed systems (aseptic filling of crown corks, cheese moulds and food crates in the food and beverage industry) – automatic spraying (closed room)	On hard/non-porous surfaces with prior cleaning - Active against bacteria and yeasts: 0.048% PAA - 15 min - Efficient use temperature from +4°C up to room temperature. - Active against bacteria (including bacterial spores) and yeasts: 0.064% PAA - 60 min - Efficient use temperature from +4°C up to room temperature. For additional activity against viruses (including bacteriophages): the product should be used at room temperature.
15	Disinfection of equipment in the food and beverage industry by immersion	
16	CIP and disinfection of heat and ion exchangers, membrane filters and returnable and non-returnable glass and PET bottles in the food and beverage industry	
17	Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure	
18	Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure	
19	Disinfection of surfaces and equipment by low pressure spraying, manually	
20	Disinfection of surfaces and equipment by low pressure spraying, automatically	
21	Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)	
22	Disinfection of inner surfaces (pipelines, tanks, vessels, …) by CIP	
23	Disinfection of water used for rinsing of recycled items during the washing process	In clean conditions: Active against bacteria and yeasts 0.008% PAA - 15 min - +20°C

META SPC 2 (3.2% PAA)

PT 2	DISINFECTANTS AND ALGAECIDES NOT INTENDED FOR DIRECT APPLICATION TO HUMANS OR ANIMALS	
Use		**Use conditions granted**
1	Room disinfection by fogging - In industrial, public and healthcare/non-medical areas (pharmaceutical and cosmetic industry)	On hard/non-porous surfaces without prior cleaning: Active against bacteria (including bacterial spores) and yeasts 5.6 mL/m3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at room temperature
2	Room disinfection by fogging - In agriculture & horticulture areas (in absence of plants - for general hygiene purpose only)	On hard/non-porous surfaces with prior cleaning: Active against bacteria (including bacterial spores) and yeasts 5.6 mL/m3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at room temperature

PT 3	VETERINARY HYGIENE	
Use		**Use conditions granted**
3	Room disinfection by fogging – In animal housing	Active against bacteria (including bacterial spores) and yeasts 5.6 mL/m3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at room temperature

PT 4	FOOD AND FEED AREA	
Use		**Use conditions granted**
4	Room disinfection by fogging – In storage rooms with special device in storage cellar or room	On hard/non-porous surfaces without prior cleaning: Active against bacteria (including bacterial spores) and yeasts 5.6 mL/m3 (product diluted at 40% => 1.28% PAA) – 2h contact time (after fogging) - at room temperature

META SPC 3 (3.2% PAA)

PT 2	DISINFECTANTS AND ALGAECIDES NOT INTENDED FOR DIRECT APPLICATION TO HUMANS OR ANIMALS	
Use		**Use conditions granted**
1	Disinfection of surfaces in industrial, public and healthcare/non-medical areas – foam application on surfaces	On hard/non-porous surfaces with prior cleaning: • **HEALTHCARE / non-medical areas** Active against bacteria and yeasts 0.048% PAA - 5 min - at room temperature • **Use other than in HEALTHCARE** Active against bacteria and yeasts 0.048% PAA - 15 min - Efficient use temperature from +4°C up to room temperature**.**
2	Disinfection of surfaces and agriculture/horticulture equipment by foaming, manually (in absence of plants - for general hygiene purpose only)	On hard/non-porous surfaces with prior cleaning: Active against bacteria and yeasts 0.048% PAA - 60 min
3	Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (in absence of plants - for general hygiene purpose only)	
4	Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (closed rooms) (in absence of plants - for general hygiene purpose only)	

PT 3	VETERINARY HYGIENE	
Use		**Use conditions granted**
5	Disinfection of animal housing by foaming – foaming with personal enclosure	On hard/non-porous surfaces with prior cleaning: Active against bacteria, yeasts and viruses 0.064% PAA - 60 min
6	Disinfection of animal housing by foaming – foaming without personal enclosure	

PT 4	FOOD AND FEED AREA	
Use		**Use conditions granted**
7	Disinfection of surfaces by foaming with personal enclosure	On hard/non-porous surfaces with prior cleaning: - Active against bacteria and yeasts 0.048% PAA - 15 min - Efficient use temperature from +4°C up to room temperature.
8	Disinfection of surfaces by foaming without personal enclosure	- Active against bacteria (including bacterial spores), yeasts and viruses (including bacteriophages) : 0.064% PAA - 60 min - at room temperature

It can be concluded that all products in SOPUROXID are efficacious, when used in accordance with the use instructions as proposed in the SPC.

Human health

One non-active substance (i.e. sulfuric acid) was identified as a substance of concern (SoC) for human health based on the fact that it was Skin Corr. 1A (H314) in the product SOPUROXID 5C (from meta-SPC 1).

SOPUROXID is composed of 4 meta-SPCs : meta-SPC 1 and 4 present similar uses, but with different concentrations in the initial product. Meta-SPC 2 covers uses and disinfection by fogging and Meta-SPC 3 covers application by foaming. This means that uses in meta-SPC 2 and 3 have dedicated scenario while for most uses in meta-SPC 1 and 4 the same scenario can be used, with an adaptation for the difference in concentration.

As the uses of the products from SOPUROXID are restricted to professional users, their potential exposure has been theroughly assessed. The use of the products are safe pending particular conditions. The risk mitigation measure for all uses includes the wearing of coverall, gloves and glasses. It also includes the uses of respiratory protection with varying degrees of protection depending on the uses.

Primary exposure was taken into account with two main route of exposure: dermal exposure an inhalatory exposure. Secondary exposure was also assessed to take into account reentry into treated area. The inhalatory exposure plays an especially important role in the assessment given the high volatility of peracetic acid and hydrogen peroxide.

Safe use can be achieved through the use of technical measures such as ventilation, automatic application, personal enclosure, and the use of PPE such as gloves, RPE, coverall. To offer a safe use in regards to secondary exposure, monitoring of the level of peracetic acid and hydrogen peroxide must be performed to allow re-entry only when the amount present in the air fall below the AEC valume of 0.5 mg/m^3 for peracetic acid and 1.25 mg/m^3 for hydrogen peroxide.

As none of the product from SOPUROXID are intended for use by non-professional users, no primary exposure were performed for this category. Since many of the uses are intended to be performed in controlled and professional environment, it is not foreseen that those uses could lead to a secondary exposure to the general public. As for the other uses, secondary exposure is avoided through restriction of access to treated area, including warning signals and closing access to the area. Given the volatility and low stability of peracetic acid and hydrogen peroxide, combined with the restriction of access, no secondary exposure of the general public is expected. In a similar way, no exposure to peracetic acid or hydrogen peroxide is expected through food, as those two molecules react with organic matter and decompose quickly.

It can be concluded that all products in SOPUROXID will not present an unacceptable risk to human health when used in accordance with the use instructions proposed in the SPC.

Environment

No unacceptable effect to the environment is expected from SOPUROXID, neither for the Sewage Treatment Plant, nor for aquatic compartment or for the terrestrial compartment. Moreover no unacceptable risk of secondary poisoning trough the aquatic or the terrestrial food chain is to be expected from the products of SOPUROXID. No unacceptable risk to the groundwater is expected from SOPUROXID and the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

It can be concluded that all products in SOPUROXID will not present an unacceptable risk to environment, when used in accordance with the use instructions proposed in the SPC.

Overall conclusion

The evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of SOPUROXID. When using the products belonging to SOPUROXID 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 to 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 SOPUROXID is available in the SPC.

The hazard and precautionary statements of SOPUROXID according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance peracetic acid contained in SOPUROXID do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates for substitution.

Therefore, a comparative assessment of SOPUROXID in accordance with Article 23 of the BPR 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 SOPUROXID have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substances in SOPUROXID are met.

The physico-chemical properties of SOPUROXID 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. SOPUROXID is sufficiently effective;
2. SOPUROXID has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. SOPUROXID 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. SOPUROXID 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 intended uses, described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of SOPUROXID

It is proposed that SOPUROXID 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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