

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of SOPURCLEAN BPF

ECHA/BPC/227/2019

Adopted

26 June 2019

Opinion of the Biocidal Products Committee

on the Union authorisation of SOPURCLEAN BPF

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 : SOPURCLEAN BPF

Authorisation holder : SOPURA

Active substance common name: octanoic acid and decanoic acid

Product type: 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 28 August 2015, recorded in R4BP3 under case number BC-PJ019489-22, 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 15 December 2017. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-31) and its Working Groups (WG-II 2019). 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 SOPURCLEAN BPF was reached on 26 June 2019.

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

Detailed BPC opinion and background

1. Overall conclusion

SOPURCLEAN BPF 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).

SOPURCLEAN BPF 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 SOPURCLEAN BPF 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 SOPURCLEAN BPF.

General

SOPURCLEAN BPF consists of products divided into 4 Meta SPCs and containing 2 active substances: octanoic acid used at the concentration range 1.10 – 2.70 % w/w and decanoic acid used at the concentration range 0.3 – 1.50 % w/w. All the biocidal products within the entire SOPURCLEAN BPF are soluble concentrates (SL) to dilute in tap water.

The following non-active substances were identified as substances of concern (SoC) for Human Health : sulfuric acid, propionic acid, phosphoric acid, nitric acid, methane sulfonic acid, glycolic acid, lactic acid and citric acid. They were considered as SoC based on the fact that they were either Skin Corr. 1A or Eye Damage 1 (sulfuric acid, propionic acid, phosphoric acid, nitric acid, methane sulfonic acid, glycolic acid, STOT SE 3 (propionic acid, methane sulfonic acid), Acute inhal 3 (nitric acid) or biocidal active substance (lactic acid, citric acid).

The biocidal products within the entire SOPURCLEAN BPF are either combined cleaning-disinfectants or disinfectants intended to be used as PT 4 "Food and feed area" biocidal products by professionals/industrial users only in various food & feed industries.

Products in the family can be used for:

Meta SPC 1 : combined cleaning-disinfectants for:

- CIP (cleaning in place) with circulation;
- Soaking/dipping for small stainless steel connections, valves.

Meta SPC 2 : combined cleaning-disinfectants or disinfectants for:

- CIP (cleaning in place) with circulation;
- Spraying of surfaces (conveyors, external machines, inside of cold storages/freezers);
- Soaking/dipping for small stainless steel connections, valves;

- Manual disinfection of surfaces (with wiping/mopping only after the relevant contact time).

Meta SPC 3 : combined cleaning-disinfectants for CIP (cleaning in place) with circulation.

Meta SPC 4 : combined cleaning-disinfectants for CIP (cleaning in place) with circulation.

The 4 Meta SPC have been defined based on differences in hazard properties between products, differences in uses and differences in active substance concentrations. The differences and common parts are further explained in the table below.

Table 1. Meta SPC overview

Meta SPC	Products	Properties of Meta SPC
1	Septacid BN Septacid BN PS Sopurclean BN Sopurclean BN PS Sopurcip EC	Hazard properties / Classification: - Skin Corrosion Cat.1A (H314) - Metal Corrosion Cat.1 (H290)
2	Sopurclean NR	Hazard properties / Classification: - Skin Corrosion Cat.1A (H314) - Metal Corrosion Cat.1 (H290) - STOT SE 3 (H335)
3	Sopurclean OP-N	Hazard properties / Classification: - Skin Corrosion Cat.1A (H314) - Metal Corrosion Cat.1 (H290) - Acute Toxicity Cat. 4 (H332) = Different Meta SPC compared to Meta SPC 1 as a result of the difference in hazard properties and a different set of uses. All information relevant to Meta SPC 1 is relevant to this Meta SPC 3.
4	Sopurclean CIP OP	Hazard properties / Classification: - Skin Corrosion Cat.1A (H314) - Metal Corrosion Cat.1 (H290) - STOT SE 3 (H335) = Different Meta SPC compared to Meta SPC 1 as a result of the difference in hazard properties and a different set of uses. All information relevant to Meta SPC 1 is relevant to this Meta SPC 4.

Physico-chemical properties

Products included in the SOPURCLEAN BPF are limpid, colourless liquids with a vinegar or an aromatic odour with a pH < 2. After 12 weeks at +40 °C, the appearance of the biocidal products and the container remained unchanged. All the products are stable during accelerated storage and a low temperatures (+0°C during 48 h). The concentrated and diluted products are also stable.

All the products included in the SOPURCLEAN BPF have a relative density between 1.104 and 1.288 kg/L (at +20°C), a surface tension between 28.4 and 55.1 mN/m (at +20°C at 1 g/L) and a pure viscosity lower than 15.1 mPa/s (which also depends on the T°C considered). For the products of Meta SPC 1; 3 & 4, ≤ 10mL foam persisted after 1 minute when tested according to CIPAC MT47.2 (0 mL for products of Meta SPC2).

All products of the Sopurclean BPF are packed in HD-PE (high density polyethylene) which has a high resistance to light. The shelf life is 12 months at +20°C for all products of the Sopurclean BPF. All products of the Sopurclean BPF must be stored below +30°C. There is no evaluation for the physical or chemical compatibility of the product because products of the SOPURCLEAN BPF are not intended to be used with other products. The products of the Sopurclean BPF are not explosive, neither flammable nor combustible. They do not have a flashpoint below +130°C. They are not oxidising. However, they are corrosive to metals.

Efficacy

All the products of the SOPURCLEAN BPF are intended to have bactericidal and yeasticidal activity.

Meta SPC 1; 3 and 4: Product SOPURCIP EC as tested product. For disinfection by either CIP (products of Meta SPC1; 3 and 4) or soaking/dipping procedures (products of Meta SPC1) without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the product SOPURCIP EC, when diluted at 1.5 % (v/v), in hard water, possesses bactericidal and yeasticidal activity in 15 minutes at +4°C and above, up to +20-25°C.

Meta SPC 2: Product SOPURCLEAN NR as tested product. For disinfection by CIP, soaking/dipping, spraying and manual disinfection procedures without prior cleaning of the items (even if a pre-rinsing is always recommended and usually performed by the users), the product *SOPURCLEAN NR*, when diluted at 1 % (v/v), in hard water, possesses bactericidal and yeasticidal activity in 15 minutes at +4°C (and above, up to +20-25°C).

About the SOPURCLEAN BPF it is noted that :

- All the products of the SOPURCLEAN BPF can be used in various food & feed industries.
- In case of outbreaks caused by *Pediococcus damnosus*, the products of Meta SPC1; 3 and 4 must be used at 2% and the products of Meta SPC2 at 1.5%.
- For disinfection procedures in slaughterhouses, a cleaning step (with a cold alkaline solution) before disinfection is always mandatory.
- Disinfection procedures by dipping (for products of Meta SPC1 and 2): the dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.
- Disinfection by CIP procedures (with circulation): in case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.
- In order to guarantee efficacy of future products in Meta SPC 1, any new product must contain sufficient amounts of acids to yield a pH ≤ 2 at the use dilution of 1.5%.
- In order to guarantee efficacy of future products in Meta SPC 1, any new product with a total active substance concentration below 3%, and with co-formulant levels different from those in SopurCIP EC, will need to be introduced by a change application and supported by new efficacy data.

It can be concluded that all products in the SOPURCLEAN BPF are efficacious, when used in accordance with the use instructions mentioned above and proposed in the SPC.

Human health

A qualitative risk assessment of the potential local effects has been made for all 4 Meta SPCs.

- Meta SPC1: Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, mixing & loading (M&L), the application and the post-application phases, the risk is considered acceptable for:

- Scenario 1 – CIP;
- Scenario 3 – Soaking baths.

Secondary exposure is not relevant.

- Meta SPC2: Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, the M&L, the application, and the post-application phases, the risk is considered acceptable for:

- Scenario 1 – CIP;
- Scenario 2 – Spraying systems low pressure;
- Scenario 3 – Soaking baths;
- Scenario 4 – Manual cleaning.

Secondary exposure is not relevant.

- Meta SPC3: Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, the M&L, the application, and the post-application phases, the risk is considered acceptable for:

- Scenario 1 – CIP.

Secondary exposure is not relevant.

- Meta SPC4: Based on the arguments of the acceptability and non-acceptability of the risk during primary exposure, the M&L, the application, and the post-application phases, the risk is considered acceptable for:

- Scenario 1 – CIP.

- Risk for the general public: The biocidal products of the SOPURCLEAN BPF are not sold to non-professionals. Possible residues in food and beverages are very low and of no concern. Human exposure of the general public is considered not relevant.

All products of the SOPURCLEAN BPF have a pH < 2 and cause severe burns to skin and eyes. This results in classification of the different products as Corrosive Cat 1A, H314 (weight of evidence evaluation). Respective classification and labelling is appropriate and sufficient to address the acute hazard for all products present in Meta SPC 1 and Meta SPC 2. For the product in Meta SPC 3 an additional hazard category is to be added for acute inhalation toxicity Cat. 4, H332 (based on presence of nitric acid). For the product in Meta SPC 4 an additional hazard category is to be added for systemic toxicity, single exposure (STOT SE) Cat. 3, H335. Based on the above mentioned hazard properties of the biocidal products, it is required that the professionals use appropriate PPE: coverall, gloves, goggles and face shield in case there is potential for splashes (for all the products of the SOPURCLEAN BPF).

- Indirect exposure via food:

Due to the nature of both active substances no quantitative dietary risk assessment was carried out. Furthermore, presence of relevant amounts of residues of the application solution in food or feed is not expected. Minimal residues of the application solution in food or feed are unlikely to cause local effects due to the expected high dilution rate in food. Both active substances are approved active substances for plant protection products. No MRLs are set for both active substances under Regulation (EU) No 396/2005. No specific needs to set a MRL was identified for SOPURCLEAN BPF.

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

Environment

Two formulated products containing the highest concentration of active substances - i.e. Septacid BN and Sopurclean NR – are used in the risk assessment as worst-case representatives of the SOPURCLEAN BPF: The emission estimations have been calculated for the whole SOPURCLEAN BPF, i.e. for an octanoic acid concentration of 2.7% and a decanoic acid concentration of 1.5% as a worst-case situation.

In addition, two new tests on the products SOPURCLEAN CIP OP (1.8% of octanoic acid and 1.2% decanoic acid) and SOPURCLEAN CIP LF (octanoic acid 5%) have been submitted showing that increasing the octanoic acid concentration from 1.5% to 2.7% (min. and max. range of octanoic acid within the BPF) does not impair the sewage treatment plant functioning. None of the biocidal products contained in the SOPURCLEAN BPF require an environmental classification or labelling.

The environmental exposure assessment has been performed in accordance with the Emission Scenario Document for Product Type 4 (Disinfectants used in food and feed areas)¹ as well as the Guidance on the Biocidal Product Regulation (ECHA, 2015)² and the EUSES Background report (EC 2004)³ and is based on information relating to the Intended Use (Chapter 3 of this document) and confidential information available in the respective CAR of the active substances. The environmental exposure assessment was conducted for the local scale only.

In the Emission Scenario Document for Product Type 4 (ESD for PT 4) the environmental release pathway for substances used as disinfectants in food, drink and milk industries is described. The main emission pathway to the environment is assumed to be the waste water. Based on the physico-chemical properties of the active substances, it is expected that the emissions will primarily affect the aquatic compartment.

No unacceptable risk to the environment is expected from the use of SOPURCLEAN BPF products, neither for the aquatic compartment, nor for the terrestrial compartment. No unacceptable risk of secondary poisoning through the aquatic or the terrestrial food chain is to be expected from the products of the SOPURCLEAN BPF.

No exceedance of the groundwater limit is expected from the SOPURCLEAN BPF and the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

¹ JRC scientific and technical reports (2011). Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas.

² ECHA (2015) Guidance on Biocidal Products Regulation: Volume IV Environment Part B Risk Assessment (active substances), Version 1.0. European Chemicals Agency, Helsinki, Finland. Available via <https://echa.europa.eu/>

³ EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via <http://ecb.jrc.ec.europa.eu/euses/>.

Overall conclusion

The evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the SOPURCLEAN BPF. When using the products belonging to the SOPURCLEAN BPF 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 SOPURCLEAN BPF 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 description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

Both active substances decanoic acid and octanoic acid contained in SOPURCLEAN BPF 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 SOPURCLEAN BPF 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 SOPURCLEAN BPF have been evaluated.

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

The physico-chemical properties of SOPURCLEAN BPF 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. SOPURCLEAN BPF is sufficiently effective;
2. SOPURCLEAN BPF has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. SOPURCLEAN BPF 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. SOPURCLEAN BPF 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 the biocidal product family

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

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Annex I : Draft Summary of Product Characteristics