

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

INTEROX Biocidal Product Family 1

ECHA/BPC/295/2021

Adopted

13 October 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of INTEROX Biocidal Product 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:	INTEROX Biocidal Product Family 1
Authorisation holder:	Solvay Chemicals International S.A.
Active substance common name:	Hydrogen peroxide
Product types:	PT 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 25 January 2017, recorded in R4BP3 under case number BC-WX029254-02, 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 21 April 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-40) and its Working Groups (WG II 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Finland

The BPC opinion on the Union authorisation of the biocidal product family was reached on 13 October 2021.

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(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 INTEROX Biocidal Product 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 INTEROX Biocidal Product Family 1 consists of products containing the active substance hydrogen peroxide (13 - 49.9 %) for disinfection in PT 2, PT 3 and PT 4. No substances of concern were identified in the biocidal product family.

The biocidal product family (BPF) consists of 9 meta SPCs for which the following professional uses has been assessed:

Meta SPC 1:

- Surface disinfection of closed spaces by aerosolised hydrogen peroxide, PT 2

Meta SPC 2, meta SPC 3:

- Surface disinfection of closed spaces by aerosolised hydrogen peroxide, PT 2
- Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP), PT 2

Meta SPC 4:

- Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP), PT 4

Meta SPC 5:

- Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP), PT 4
- Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP), PT 4

Meta SPC 6, meta SPC 7:

- Surface disinfection in food and feed processing by liquid application, PT 4
- Disinfection of distribution and storage systems for drinking water, PT 4

Meta SPC 8, meta SPC 9:

- Surface disinfection by liquid application in industrial and institutional areas, PT 2
- Disinfection of surfaces associated with animal housing by spraying, PT 3

Physico-chemical properties

The products in the biocidal product family INTEROX Product Family 1 are clear, colourless liquids with acidic pH showing no surface active properties.

With regard to physical hazards, the products containing 25 to 49.9% (w/w) hydrogen peroxide are classified as oxidizing, category 2 (Ox. Liq. 2; H272: May intensify fire; oxidiser) (Meta SPC 2-9) and products containing 13% (w/w) hydrogen peroxide are classified as oxidizing, category 3 (Ox. Liq. 3; H272: May intensify fire; oxidiser) (Meta SPC 1).

The products are stable in HDPE packaging, which has been demonstrated by accelerated storage test, low temperature stability test and long-term storage stability studies. The shelf-life for the biocidal product family is 12 months at ambient temperature.

The validated analytical methods for determination of the active substance and impurities in the products as well as the relevant monitoring methods for the active substance are acceptable.

Efficacy

The meta SPCs 1-9 were shown to be efficacious against the following target organisms in the following uses:

Meta SPC 1:

- Surface disinfection of closed spaces by aerosolised hydrogen peroxide, PT 2
 - bacteria - bacterial spores - fungi - yeasts - viruses

Meta SPC 2, meta SPC 3:

- Surface disinfection of closed spaces by aerosolised hydrogen peroxide, PT 2
 - bacteria - bacterial spores - fungi - yeasts - viruses
- Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP), PT 2
 - bacteria - bacterial spores – fungi – yeasts - viruses

Meta SPC 4:

- Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP), PT 4
 - bacterial spores

Meta SPC 5:

- Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP), PT 4
 - bacterial spores
- Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP), PT 4
 - bacterial spores

Meta SPC 6, meta SPC 7:

- Surface disinfection in food and feed processing by liquid application, PT 4
 - bacteria - bacterial spores - yeasts - fungi - viruses
- Disinfection of distribution and storage systems for drinking water, PT 4
 - bacteria - bacterial spores - yeasts - fungi - viruses

Meta SPC 8, meta SPC 9:

- Surface disinfection by liquid application in industrial and institutional areas, PT 2
 - bacteria - bacterial spores - yeasts - fungi - viruses
- Disinfection of surfaces associated with animal housing by spraying, PT 3
 - bacteria - yeasts - fungi - viruses

Hydrogen peroxide concentrations shown to be efficacious ranged from 9.5% to 49% (w/w) depending on the use and the target organism.

Human health

Human health classification of the products according to CLP mixture rules is based on the content of hydrogen peroxide and pH values. Each Meta SPC in the biocidal product family is classified as follows:

Meta SPC 1:

- Eye Dam. 1; H318: Causes serious eye damage;

Meta SPC 2, 5, 6, 8:

- Acute Tox. 4; H302: Harmful if swallowed;
- Skin Irrit. 2; H315: Causes skin irritation;
- Eye Dam. 1; H318: Causes serious eye damage;
- STOT SE 3; H335: May cause respiratory irritation;

Meta SPC 3, 7, 9:

- Acute Tox. 4; H302: Harmful if swallowed;
- Skin Corr. 1; H314: Causes severe skin burns and eye damage;
- Eye Dam. 1; H318: Causes serious eye damage;
- STOT SE 3; H335: May cause respiratory irritation;

Meta SPC 4:

- Acute Tox. 4; H302: Harmful if swallowed;
- Eye Dam. 1; H318: Causes serious eye damage.

The products are intended for professional use only. Risk assessment for local effects was performed for dermal and inhalation exposure.

The risks are considered acceptable in the authorised uses with the use instructions and use-specific risk mitigation measures described in the SPC. Depending on the use the RMMs include technical measures such as automated loading, automated spraying or ventilation, and the use of PPE such as protective gloves, coverall or respiratory protective equipment. Eye protection is mandatory for all meta SPCs due to the classification.

Re-entry to disinfected premises is only allowed after safe level of hydrogen peroxide in the air has been reached. There is no risk for general public or consumers via residues in food.

Environment

The environmental risk assessment has followed the agreements made within the active substance assessment and/or previously agreed for similar uses or for rapidly reacting substances.

The products in meta SPCs 2 – 9 are classified as Aquatic Chronic 3, H412: Harmful to aquatic life with long lasting effects.

Acceptable levels of risk to all environmental compartments have been demonstrated for the proposed uses of the BPF when applying specific risk mitigation measures as follows and indicated in the SPC:

Meta SPC 4, Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP), PT 4:

Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

Meta SPC 5, Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP), PT 4:

Aerosolised or vaporised application should be used only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

Meta SPC 5, Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP), PT 4:

Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

Meta SPC 6 and meta SPC 7, Surface disinfection in food and feed processing by liquid

application, PT 4:

The waste water from breweries should not be discharged direct to surface water after simple on-site treatment. The waste water from breweries should be discharged to the sewer connected to the sewage treatment plant (STP).

Meta SPC 6 and meta SPC 7, Disinfection of distribution and storage systems for drinking water, PT 4:

The use is limited to distribution and storage systems with volume $\leq 15\ 000$ L.

Overall conclusions

Uses	Target organisms	User categories	Authorised application rates	Main conditions of use and risk mitigation measures
Use # 1 – Surface disinfection of closed spaces by aerosolised hydrogen peroxide PT2 Meta SPC 1, 2 & 3	bacteria bacterial spores fungi yeasts viruses	professional	13%, 35% or 49% hydrogen peroxide (undiluted product) applied via aerosolization in closed rooms.	Use an automated loading system. Surfaces in the treatment area must be clean and dry prior to application. Ensure all personnel have vacated the treatment enclosure prior to application. Prevent entry during disinfection process. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m ³). The duration of the ventilation period has to be established by measurement with suitable measurement equipment.
Use # 2 – Surface disinfection by liquid application in industrial and institutional areas PT2 Meta SPC 8 & 9	bacteria bacterial spores yeasts fungi viruses	professional	Use concentration 13% w/w hydrogen peroxide <ul style="list-style-type: none"> • CIP (cleaning-in-place): volume of diluted product needed to fill the disinfected system • Automated spraying: 50 -100 mL diluted product/m² • Immersion: make solution and dip items 	Use an automated loading system for CIP and automated spraying. CIP: The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems. Automated spraying: In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing. Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m ³ shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period). Immersion:

Uses	Target organisms	User categories	Authorised application rates	Main conditions of use and risk mitigation measures
				<p>Use eye protection, gloves and protective coverall. Use local exhaust ventilation (LEV) or respiratory protective equipment (RPE) in loading and immersion.</p> <p>After use, immersion baths must be emptied or covered to prevent further evaporation.</p>
<p>Use # 3 – Disinfection of surfaces associated with animal housing by spraying PT3 Meta SPC 8 & 9</p>	<p>bacteria yeasts fungi viruses</p>	<p>professional</p>	<p>Use concentration 9.5 - 13% w/w hydrogen peroxide Spraying: 50 - 100 mL diluted product/m²</p>	<p>Remove animals from spaces to be disinfected.</p> <p><u>Automated spraying systems:</u> During the operation worker must leave the area and access must be denied by appropriate barriers or locked doors.</p> <p><u>For manual spraying:</u> Use eye protection, gloves, protective coverall and respiratory protective equipment. The operator must walk backward towards the exit while spraying the surfaces so always walking away from sprayed areas. Efficient ventilation (10 ACH) must be used during spraying and access must be denied by appropriate barriers and notices. After automated and manual spraying operations efficient ventilation (10 ACH) must be used to reach a safe level. For re-entry, the undercut of AECinhalation of 1.25 mg/m³ shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).</p>
<p>Use # 4 – Disinfection of food packaging material (aseptic</p>	<p>bacterial spores</p>	<p>professional</p>	<p>Undiluted product (35 % w/w hydrogen peroxide) is used. Product consumption in vapour and aerosol</p>	<p>Use an automated loading system. During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation). During manual maintenance tasks, ensure adequate ventilation</p>

Uses	Target organisms	User categories	Authorised application rates	Main conditions of use and risk mitigation measures
packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP) PT4 Meta SPC 5			applications 0.1 – 1 mL per second per packaging line while the machine is operating.	inside the machine (LEV) before opening the doors of the aseptic area. 1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed. 2. Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed. 3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.
Use # 5 – Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP)	bacterial spores	professional	Undiluted product (35 % w/w hydrogen peroxide) is used. 100 – 800 mL product consumed per machine in one disinfection cycle.	Use an automated loading system. During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation). During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area. 1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.

Uses	Target organisms	User categories	Authorised application rates	Main conditions of use and risk mitigation measures
PT4 Meta SPC 5				<p>2. Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.</p> <p>3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required.</p> <p>Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.</p>
Use # 6 – Disinfection of distribution and storage systems for drinking water PT4 Meta SPC 6 & 7	bacteria bacterial spores yeasts fungi viruses	professional	Use concentration 13% w/w hydrogen peroxide	<p>Use an automated loading system.</p> <p>CIP and automated spraying:</p> <p>The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.</p> <p>The use is limited to distribution and storage systems with volume $\leq 15\,000$ L.</p> <p>Rinse well with potable water.</p>

Uses	Target organisms	User categories	Authorised application rates	Main conditions of use and risk mitigation measures
<p>Use # 7 – Surface disinfection in food and feed processing by liquid application PT4 Meta SPC 6 & 7</p>	<p>bacteria bacterial spores yeasts fungi viruses</p>	<p>professional</p>	<p>Use concentration 13% w/w hydrogen peroxide</p> <ul style="list-style-type: none"> • CIP (cleaning-in-place): volume of diluted product needed to fill the system to be disinfected • Automated spraying: 50 -100 mL diluted product/m² • Immersion: make solution and dip items 	<p>Use an automated loading system for CIP and automated spraying.</p> <p>CIP:</p> <p>The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.</p> <p>Automated spraying:</p> <p>In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing.</p> <p>Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries.</p> <p>Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m³ shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).</p> <p>Immersion:</p> <p>Use eye protection, gloves and protective coverall. Use local exhaust ventilation (LEV) or respiratory protective equipment (RPE) in loading and immersion.</p> <p>After use, immersion baths must be emptied or covered to prevent further evaporation.</p> <p>The waste water from breweries should not be discharged direct to surface water after simple on-site treatment. The waste water from breweries should be discharged to the sewer connected to the sewage treatment plant (STP).</p>

Uses	Target organisms	User categories	Authorised application rates	Main conditions of use and risk mitigation measures
Use # 8 – Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP) PT4 Meta SPC 4	bacterial spores	professional	Undiluted product (25 % w/w hydrogen peroxide) vaporized 400 g/h/packaging machine.	Same as in use # 5
Use # 9 – Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP) PT2 Meta SPC 2 & 3	bacteria bacterial spores fungi yeasts viruses	professional	35% or 49% hydrogen peroxide (undiluted product) applied via flash evaporation or aerosolization in filling isolators.	Same as in use # 1

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 hydrogen peroxide 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 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 use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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.