

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Oxivir Excel BPF

ECHA/BPC/417/2024

Adopted

29 February 2024



BPC
BIOCIDAL PRODUCTS
COMMITTEE

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product family name

Oxivir Excel 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:	Oxivir Excel BPF
Authorisation holder:	Diversey Europe Operations B.V.
Active substance(s) common name:	Hydrogen peroxide (CAS No. 7722-84-1)
Product type(s):	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 16 December 2016, recorded in R4BP3 under case number BC-DL028504-45, 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 September 2023. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-50) and its Working Groups (WG-IV-2023). 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 was reached on 29 February 2024.

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 Oxivir Excel 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

General

Oxivir Excel BPF is a biocidal product family that is used as a broad spectrum cleaner and disinfectant on hard surfaces in institutional and industrial areas and in the health care sector (PT2), as well as in areas where food or feed is processed (PT4).

The BPF contains three meta-SPCs, with one product each: a concentrate (SL) for professional use; a ready-to-use (RTU), and wipes impregnated with the RTU solution for both professional and non-professional use. All products within the family are based on hydrogen peroxide (CAS number 7722-84-1) and are effective against bacteria, yeasts and viruses.

The biocidal product family contains three biocidal products, which are attributed to the following three meta-SPCs:

Meta-SPC	Biocidal products
Meta SPC 1: Concentrate	Oxivir Excel
Meta SPC 2: RTU	Oxivir Excel Foam
Meta SPC 3: Wipes	Oxivir Excel Wipes

The biocidal product family contains two product types, PT2 and PT4, which are attributed to the following claimed uses and concerned Meta-SPCs:

PT	Concerned Meta-SPC	Claimed uses	Proposed for authorization (Yes/No)
2	Meta-SPC 1: Concentrate	Use # 1.1 – Cleaning and disinfection by mopping for healthcare areas	Yes
2	Meta-SPC 1: Concentrate	Use # 1.2– Cleaning and disinfection with a cloth or sponge for healthcare areas	Yes
2	Meta-SPC 1: Concentrate	Use # 1.3 – Cleaning and disinfection of small objects by soaking or dipping for healthcare areas	Yes
2	Meta-SPC 1: Concentrate	Use # 1.4 – Cleaning and disinfection by foaming for healthcare areas	Yes

PT	Concerned Meta-SPC	Claimed uses	Proposed for authorization (Yes/No)
2	Meta-SPC 1: Concentrate	Use # 1.5 –Cleaning and disinfection using moist wipes (incl. healthcare areas)	Yes
2	Meta-SPC 1: Concentrate	Use # 1.11 – Cleaning and disinfection of hard surfaces by mopping in non-health care areas	Yes
2	Meta-SPC 1: Concentrate	Use # 1.12 – Cleaning and disinfection of hard surfaces with a cloth or sponge in non-health care areas	Yes
2	Meta-SPC 1: Concentrate	Use # 1.13 – Cleaning and disinfection of small objects by soaking or dipping in non-health care areas	Yes
2	Meta-SPC 1: Concentrate	Use # 1.14 – Cleaning and disinfection of surfaces by foaming in non-health care areas	Yes
2	Meta-SPC 1: Concentrate	Use # 1.15 – Disinfection of pre-cleaned hard surfaces.	Yes
2	Meta-SPC 2: RTU	Use # 2.1 – Cleaning and disinfection by mopping (incl. healthcare areas)	Yes
2	Meta-SPC 2: RTU	Use # 2.2 – Cleaning and disinfection with a cloth or sponge (incl. healthcare areas)	Yes
2	Meta-SPC 2: RTU	Use # 2.3 – Cleaning and disinfection of small objects by soaking or dipping (incl. healthcare areas)	Yes
2	Meta-SPC 2: RTU	Use # 2.4 – Cleaning and disinfection by foaming (incl. healthcare areas)	Yes
2	Meta-SPC 2: RTU	Use # 2.5 – Cleaning and disinfection using moist wipes (incl. healthcare areas)	Yes
2	Meta-SPC 2: RTU	Use # 2.11 – Disinfection of pre-cleaned hard surfaces	Yes
2	Meta-SPC 3: Wipes	Use # 3.1 – Cleaning and disinfection using moist wipes on hard surfaces incl. healthcare areas	Yes
2	Meta-SPC 3: Wipes	Use # 3.3 – Wipe for disinfecting pre-cleaned hard surfaces	Yes
4	Meta-SPC 1: Concentrate	Use # 1.6 – Cleaning and disinfection of food contact surfaces using a mop	Yes
4	Meta-SPC 1: Concentrate	Use # 1.7 – Cleaning and disinfection of food contact surfaces using a cloth or sponge	Yes
4	Meta-SPC 1: Concentrate	Use #1.8 – Cleaning and disinfection of food contact small objects by soaking or dipping	Yes
4	Meta-SPC 1: Concentrate	Use # 1.9 – Cleaning and disinfection of food contact surfaces by foaming	Yes
4	Meta-SPC 1: Concentrate	Use # 1.10 –Cleaning and disinfection of food contact surfaces with moist wipes	Yes
4	Meta-SPC 2: RTU	Use # 2.6 – Cleaning and disinfection by mopping (incl. food contact surfaces)	Yes
4	Meta-SPC 2: RTU	Use # 2.7 – Cleaning and disinfection with a cloth or sponge	Yes

PT	Concerned Meta-SPC	Claimed uses	Proposed for authorization (Yes/No)
		(incl. food contact surfaces)	
4	Meta-SPC 2: RTU	Use # 2.8 – Cleaning and disinfection by soaking or dipping of small objects (incl. food contact surfaces)	Yes
4	Meta-SPC 2: RTU	Use # 2.9 – Cleaning and disinfection by foaming (incl. food contact surfaces)	Yes
4	Meta-SPC 2: RTU	Use # 2.10 – Cleaning and disinfection with moist wipes (incl. food contact surfaces)	Yes
4	Meta-SPC 3: Wipes	Use # 3.2 – Cleaning and disinfection using moist wipes on hard surfaces incl. food contact surfaces	Yes

Physico-chemical properties

The Oxivir Excel BPF consists of ready-to-use and concentrated products, which are clear, colourless to light yellow liquids with an intense and slightly pungent odour. A shelf-life of 2 years is supported for both type of formulations, any other liquid (AL, AL – RTU wipe) and soluble concentrate (SL), in high-density polyethylene (HDPE) and the impregnated polypropylene (PP) wipes in polyethylene (PE) and/or polyethylene terephthalate (PET) packaging materials. All formulations should be stored in the dark. The product in meta SPC 1 should be stored below 30°C. The products in meta SPC 2 and 3 should be stored below 50°C.

The products of the Oxivir Excel BPF are classified as corrosive to metals. No other physical hazards are applicable.

Efficacy

Disinfection uses, for PT2 and PT4, for hard surfaces are described in the 3 meta-SPCs of this BPF. Claimed target organisms include bacteria, yeasts and viruses. Application methods vary with use and include foaming, application by cloth or sponge, mopping, wiping and dipping. Efficacy is substantiated by tests with the concentrated product of meta-SPC 1, which covers the ready-to-use products of meta SPCs 2 and 3.

	Industrial and institutional areas (PT2)	Food/feed contact surfaces (PT4)	Clinical/medical area (PT2)
Meta-SPC 1	<u>Hard surfaces</u> Bactericidal: 1.5% product Yeasticidal: 3.75% product Virucidal: 2% product <u>Pre-cleaned hard surfaces</u> Bactericidal, yeasticidal and virucidal: 2.5% product 5 minutes contact time	<u>Hard surfaces</u> Bactericidal, yeasticidal, virucidal: 3.75% product <u>Hard surface with moist wipes</u> Bactericidal, yeasticidal and virucidal: 5% product 5 minutes contact time	<u>Hard surfaces</u> Bactericidal, yeasticidal, virucidal: 4.5% product <u>Hard surface with moist wipes</u> Bactericidal, yeasticidal and virucidal: 5% product 5 minutes contact time

	Industrial and institutional areas (PT2)	Food/feed contact surfaces (PT4)	Clinical/medical area (PT2)
Meta-SPC 2 & 3	100% product (RTU) 5 minutes contact time	100% product (RTU) 5 minutes contact time	100% product (RTU) 5 minutes contact time

Human health

The biocidal product family contains three substances of concern. Dodecyl benzenesulfonic acid (CAS 85536-14-7), (C9-C11) Alkyl alcohol ethoxylate (CAS 68439-46-3), and methanesulfonic acid (CAS 75-75-2) fall in Band B and trigger product classification. As their effects are covered by the assigned H and P statements, no further human health risk assessment was needed.

The concentrated product intended for professional use (meta-SPC 1) is skin and eye corrosive, therefore personal protective equipment (PPE; protective gloves, clothing and eye protection) is required to assure protection of the users during the application of the product.

No risks were identified for the professional users when applying the products as recommended, including the use of PPE. In such a situation, the exposure to the active substance and the SoCs is of no concern for human health. Moreover, no risks were identified for unprotected professional users when applying the diluted concentrate (meta-SPC 1), the RTU products (meta-SPC 2), or the impregnated wipes (meta-SPC 3). The same conclusion is valid for unprotected non-professional users applying the RTU products (meta SPC 2) and the impregnated wipes (meta SPC 3). The exposure estimation to residues in food in the worst-case scenario is low, therefore no risk for human health is expected.

Environment

No substances of concern regarding the environment were identified. Consequently, only the active substance was addressed in the environmental risk assessment.

Due to the reactive nature of the active substance, hydrogen peroxide, none of the intended uses of the products results in an unacceptable risk to the environment. Also, the combined risk of the different uses does not pose a risk to the environment.

Regarding the classification of the products in the BPF, products in meta-SPC 1 are classified as H412 - Harmful to aquatic life with long lasting effects, while products in meta-SPC 2 and 3 are not classified for the environment.

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 are 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 needed.

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 Regulation (EU) No 528/2012, 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;
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) of Regulation (EU) No 528/2012 are met it is proposed that biocidal product family shall be authorised for the uses described under section 2.1 of this opinion.