European Chemicals Agency

Opinion on the Application for Union Authorisation of the Same Biocidal Product under Article 6 of Commission Implementing Regulation (EU) No. 414/2013

Opinion number: UBP-C-1258619-16-00/F

Date: 29 November 2022

Name of the Product family	Sanoserv H2O2
Authorisation holder	Sanoserv International franchising Ltd
Active substance(s) common name	Hydrogen peroxide
Product type(s)	PT 2
Name of the related reference product family	Oxy'Pharm H2O2
BPC Opinion number of the related reference product	ECHA/BPC/358/2022

The European Chemicals Agency ("ECHA"), in accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013[1], has evaluated the application for Union authorisation of Sanoserv H2O2.

The application for Union authorisation was submitted to ECHA on 31 January 2017 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 and recorded in R4BP3 under case number BC-CQ029788-15.

Following its acceptance by ECHA, the validation of the application was initiated on 13 February 2017.

The application was subsequently validated on 06 June 2017 following ECHA's conclusion that the information indicated in Article 2 of Commission Implementing Regulation (EU) No 414/2013 had been submitted.

The validation included a check that the proposed differences between Sanoserv H2O2 and the Oxy'Pharm H2O2 are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013[2].

Following the adoption of the BPC opinion of the related reference product and the subsequent submission of a revised version of the draft SPC of Sanoserv H2O2, ECHA confirmed again that all differences between Sanoserv H2O2 and the related reference product are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

[1] Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council
[2] Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

The evaluation was based on the information provided by the applicant in relation to the related reference product.

In accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013, ECHA's opinion is set out below.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of ECHA's opinion is that Sanoserv H2O2 is eligible for Union authorisation, and all reported differences between Sanoserv H2O2 and the related reference product are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

The biocidal product family Sanoserv H2O2, as defined in Article 3(1)(s) of Regulation (EU) No 528/2012, meets the conditions laid down in Article 19(1) of that Regulation and, therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the Product Assessment Report ("PAR") of the related reference product.

The details of any terms and conditions which should be imposed on the making available on the market and use of Sanoserv H2O2 are listed below:
The following RMMs are proposed:

During the diffusion, keep the room closed and do not enter in. Treatment should be conducted with no human or animals present. All gaps present in the room (e.g. window frame) from where fog may leak should be sealed beforehand. Ensure that access to the fog-treated area is denied during the whole procedure with a warning sign.

Treated areas may not be entered until the concentration of hydrogen peroxide is ≤0.9 ppm (1.25 mg/m3).

The professional user may enter the room only in emergency situations when the hydrogen peroxide level has dropped below 36ppm (50 mg/m3) wearing mandatory the following PPE: RPE with APF 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves, eye protection, coverall). A measuring device should be used to ensure that the concentration of hydrogen peroxide has decreased below 0.9 ppm. Unprotected person/animals may re-enter the treated room only after the hydrogen peroxide concentration in air decreases lower than 1.25 mg/m3 (0.9 ppm)

A draft summary of product characteristics ("SPC") of Sanoserv H2O2, as referred to in Article 22(2) of Regulation (EU) No 528/2012, is attached as an annex.

2. ECHA opinion

2.1. Conclusions of the evaluation

The conclusions of the risk assessment for Sanoserv H2O2 are based on the evaluation of the related reference product and described in BPC opinion ECHA/BPC/358/2022 of 28 September 2022.

2.2. Changes compared to the related reference biocidal product family

The following changes of the biocidal product family Sanoserv H2O2 compared to the related reference biocidal product family were proposed by the applicant and deemed to be acceptable.

A/ Changes in the structure of the biocidal family Sanoserv H2O2 compared to the related reference product family

Reduced family:

Product numbers of meta SPC and product names

Reference product: meta SPC	**Reference product: product name**	**Same biocidal product: meta SPC**	**Same biocidal product: product name**
Oxy'Pharm H2O2 6%	Neutral range: Nocolyse Menthe range Nocodor range	Sanoserv H2O2 6% - -	Sanochem S06 - -
Oxy'Pharm H2O2 12%	Neutral range: Nocolyse One Shot Menthe range Nocodor range	Sanoserv H2O2 12%	Sanochem S12
Oxy'Pharm H2O2 7.9 %	-	-	-

B/ Administrative changes referred to in **Section 1 of Title 1** of the Annex to Regulation (EU) No 354/2013 (changes requiring prior notification)

Change number*	**Detailed description of the change**	**Justification that the change is of administrative nature**
1	Change of name of the same biocidal product family dossier from "Oxypharm H2O2" to "Sanoserv H2O2".	Change of name is an administrative change.
2	Changes of the name of the biocidal product where there is no risk of confusion with the names of other biocidal products Two same biocidal products (biocidal product family) identical to the reference products of Oxy'Pharm H2O BPF (case BC-HC029658-43). - **Sanochem S06** and **Sanochem S06 6%** (identical to the reference product: Nocolyse of Oxy'Pharm company) - **Sanochem S12** and **Sanochem S12 12%** (identical to the reference product: Nocolyse One Shot of Oxy'Pharm company)	Change of name is an administrative change.
4	Change of the authorisation holder to a new holder (Sanoserv International franchising Ltd) established in the European Economic Area (EEA). The new registration holder is the company Sanoserv International	Change of the name of the authorisation holder is an administrative change.

	franchising Ltd (UUID: ECHA-1b2b7315-52c6-406d-be43-6377ebbda6fc)	

*according to the left column of the table in **Section 1 of Title 1** of the Annex to Regulation (EU) No 354/2013

C/ Administrative changes referred to in **Section 2 of Title 1** of the Annex to Regulation (EU) No 354/2013

Change number*	Detailed description of the change	Justification that the change is of administrative nature
2	Change of the biocidal product formulator by (but similar location of manufacturing) : - Name : Sanoserv Int Franchising Ltd - Address : SANONDAF HQ, Tereza Court, Triq Id Dghejf, NXR 1015 Naxxar, Malta	Change of the biocidal product formulator is an administrative change.
8	Only the two first Meta SPC are supported in this same dossier. Therefore, the Meta SPC 3 (Oxy'Pharm H2O2 7.9%) is not supported within this same dossier. Based on this removal, the use #3.1 (Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)) is not supported in this dossier as well.	The removal of a specific use is an administrative change.

*according to the left column of the table in **Section 2 of Title 1** of the Annex to Regulation (EU) No 354/2013

2.3. Presentation of the product family including classification and labelling

The description of Sanoserv H2O2 and the hazard and precautionary statements according to Regulation (EC) 1272/2008 are available in the SPC, see annex to this opinion.

2.4. Description of uses proposed to be authorised

The assessment supporting the intended uses in the application is described in the PAR of the related reference product.

The description of the intended uses proposed to be authorised is available in the SPC, see annex to this opinion.

2.5. Overall conclusion of the evaluation of the uses proposed to be authorised

For the uses proposed to be authorised, according to Article 19(1)(b) of Regulation (EU) No 528/2012, it has been concluded that Sanoserv H2O2:

1. is sufficiently effective;
2. has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. 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. has no unacceptable effects itself, or because of its residues, on the environment, having 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.

Therefore, it is proposed that Sanoserv H2O2 shall be authorised[3] for the uses described under section 2.3 of this opinion, subject to compliance with the proposed SPC.

Annex I: draft Summary of Product Characteristics

[3] 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 Regulation (EU) No 528/2012.