European Chemicals Agency

Opinion on the application for Union authorisation of the same biocidal product family:

Divosan PAA products

Opinion N° UBS-C-1719835-03-00/F

14 March 2024

Opinion of the European Chemicals Agency

on the application for Union authorisation of the same biocidal product Divosan PAA products

In accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 ("BPR"), the European Chemicals Agency ("ECHA") has prepared this opinion on the Union authorisation of the same biocidal product:

Name of the biocidal product family	Divosan PAA products
Authorisation holder	Diversey Europe Operations B.V.
Active substance common name	Peracetic acid (CAS number 79-21-0)
Product types	2, 3, 4
Name of the related reference Union authorisation	Airedale PAA product family
Asset number of the related reference Union authorisation	EU-0028970-0000

Procedural history

The application for Union authorisation of a same biocidal product was submitted to ECHA on 21 December 2023 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 ("SBP Regulation")[1] and recorded under case number BC-CB091187-53.

Following its acceptance by ECHA, the validation of the application was initiated on 9 January 2024. ECHA requested additional information on 11 January 2024, which was provided on 15 January 2024. The application was subsequently validated on 14 February 2024 following ECHA's conclusion that the information indicated in Article 2 of the SBP Regulation had been submitted.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of ECHA is that Divosan PAA products may be granted a Union authorisation.

All reported differences between Divosan PAA products and the related reference product are limited to information that can be the subject of an administrative change in accordance with the Changes Regulation.

[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

The biocidal product family in question, as defined in Article 3(1)(s) of the BPR, 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 authorisation.

A draft summary of product characteristics ("SPC") of Divosan PAA products, as referred to in Article 22(2) of the BPR, is attached as an annex.

2. ECHA opinion

2.1. Conclusions of the evaluation

a) Risks associated with the use of the same biocidal product

The risk assessment for the related reference product family are described in the PAR of the related reference authorisation. The conclusions are described in Commission Implementing Regulation (EU) 2023/1200 of 21 June 2023. The same conclusions apply to Divosan PAA products.

b) Differences compared to the related reference Union authorisation

Divosan PAA products differs from the related reference authorisation by the following information.

Differences in the structure of Divosan PAA products compared to the related reference authorisation

The product family was reduced: the Meta SPC "Peracetic Acid 2%" was removed from the family. The product "Airocide PAAD" was also removed.

Reference Union authorisation		**Same biocidal product**	
Meta SPC	**Product name**	**Meta SPC**	**Product name**
Peracetic Acid 2%	Peracetic Acid 2% Foamy Peracetic Acid 2%	-	- -
Peracetic Acid 5%	Airocide PAAD **Peracetic Acid 5%**	Peracetic Acid 5%	- Divosan Noble VT100
Peracetic Acid 15%	**Peracetic Acid 15%**	Peracetic Acid 15%	Divosan Splendid VT99

Differences that can be classified as administrative in accordance with **Title 1** of the Annex to the Changes Regulation

Detailed description of the differences	**Justification that the differences are of administrative nature**
The name of the product family was changed from "Airedale PAA product family" to "Divosan PAA products"	Change of the name of the biocidal product family. The change matches the description of Change No 1 of Section 1 of Title 1 of the Annex to the Changes Regulation.
Airedale tradenames were removed and Diversey product names were added: **Meta SPC peracetic acid 5%** Product name: Divosan Noble VT100	Addition and deletion of tradenames. Although there is no specific entry for the deletion of tradenames in the Annex to the Changes Regulation, the change is an administrative

Meta SPC peracetic acid 15% Product name: Divosan Splendid VT99	change. The addition of tradenames matches the description of Change No 2 of Section 1 of Title 1 of the Annex to the Changes Regulation.
Addition biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged: **Name of manufacturer:** Diversey Europe Operations B.V. **Address of Manufacturer:** Maarssenbroeksedijk 2NL- 3542 DN UtrechtNetherlands **Address of manufacturing sites** • Avenida Conde Duque 5, 7 y 9, Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain • Strada Statale 235 I26010 Bagnolo Cremasco (CR) Italy • Cotes Park Industrial Estate DE55 4PA Somercotes, Alfreton, United Kingdom • Rembrandtlaan 414, NL-7545 ZW Enschede, Netherlands • Morschheimer Strasse 12, D-67292 Kirchheimbolanden Germany	Addition of a biocidal product formulator. The change matches the description of Change No 4 of Section 2 of Title 1 of the Annex to the Changes Regulation.
Deletion of meta SPC "Peracetic acid 2%"	Removal of a meta SPC is an administrative change. (Change No 8 of Section 2 of Title 1 of the Annex to the Changes Regulation)
Deletion of product **"**Airocide PAAD" from meta SPC "Peracetic acid 5%"	Removal of a product is an administrative change. (Change No 8 of Section 2 of Title 1 of the Annex to the Changes Regulation)

c) Presentation of the biocidal product family including classification and labelling

The description of Divosan PAA products and the hazard and precautionary statements according to Regulation (EC) 1272/2008 are available in the SPC attached as an annex to this opinion.

d) 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 authorisation.

The description of the intended uses proposed to be authorised is available in the SPC attached as an annex to this opinion.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

Based on the assessment of the related reference authorisation, and subject to compliance with the draft SPC, Divosan PAA products meets the conditions laid down in Article 19(1)(b) of the BPR. Therefore, it is proposed that Divosan PAA products shall be authorised[2] for the uses described in the SPC.

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[2] 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.

Annex

Draft Summary of Product Characteristics