Biocidal Products Committee (BPC)

Opinion on the minor change to the Union authorisation of the biocidal product family:

BPF_Iodine_VET

ECHA/BPC/419/2024

Adopted

20 March 2024

Opinion of the Biocidal Products Committee

on the minor change to a Union authorisation

In accordance with Article 12(4) of Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the minor change to the Union authorisation of:

Name of the biocidal product family	**BPF_Iodine_VET**
Asset number	**EU-0020540-0000**
Authorisation holder	**Applied Biocide GmbH**

This document presents the opinion adopted by the BPC, having regard to the conclusions of the ECHA secretariat.

Procedural history

Following its submission on 19 July 2023, recorded in R4BP 3 under case number BC-VS087869-80, the application was accepted by ECHA on 5 August 2023. The ECHA secretariat requested additional information from the authorisation holder on 1 September 2023 and 8 September 2023, which the authorisation holder submitted on 5 September 2023 and 11 September 2023. The case was subsequently validated on 11 October 2023. ECHA secretariat evaluated the minor change application and requested additional information on 26 October 2023, 19 December 2023 and 12 February 2024, which the authorisation holder provided on 5 December 2023, 29 January 2024 and 20 February 2024. The ECHA secretariat presented its conclusions to the Member State Competent Authorities (MSCA). In order to review the draft revised product assessment report (PAR), the draft revised summary of product characteristics (SPC) and the conclusions of the ECHA secretariat, the Agency organised a consultation of the MSCAs. No remarks were received from the MSCAs or the authorisation holder.

Adoption of the BPC opinion

The BPC opinion on the minor change to the Union authorisation of the biocidal product family was adopted on 20 March 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 authorisation of BPF_Iodine_VET can be amended with the proposed minor change.

After the introduction of the change, the biocidal product family meets the conditions laid down in Article 19(1) of the BPR and therefore the authorisation of BPF_Iodine_VET may be amended with the proposed change as specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft revised SPC of BPF_Iodine_VET submitted with the minor change application, as referred to in Article 22(2) of the BPR.

2. BPC Opinion

2.1 BPC conclusions of the evaluation

a) Description of the change as proposed by the authorisation holder

The following change to the authorised products was proposed by the authorisation holder:

- Extension of shelf-life for products in meta SPC 2 to 24 months
- Extension of shelf-life for products in meta SPC 4 to 24 months
- Extension of shelf-life for products in meta SPC 5 to 24 months

The authorisation holder initially requested the shelf-life of products in meta SPC 3 to be extended to 24 months. However, the authorisation holder withdrew the request during the course of the evaluation of the minor change application, on 5 December 2023. The request was not evaluated further.

b) Summary of the evaluation and conclusions

The effects of the proposed change on the physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the already authorised biocidal product family have been evaluated.

i) Physico-chemical properties

The proposed change in shelf-life is supported by new endpoint studies regarding storage stability and related physico-chemical characteristics of the product family, and new efficacy data.

The new storage stability data provide enough evidence to conclude that a shelf-life of 24 months for the products in meta SPC 2 is supported.

The new storage stability studies, together with the new efficacy data and the existing argumentation regarding the risks to human health and the environment of the degradation products of iodine already assessed and accepted during the initial Union authorisation, provide enough evidence to conclude that a shelf-life of 24 months for the products in meta SPC 4 and 5 is supported.

ii) Efficacy

The proposed change in shelf-life is supported by new efficacy tests conducted with the aged products from the meta SPC 4 and 5.

iii) Human health

The proposed change does not affect the risks to human health associated with the use of the biocidal product family since the proposed change is limited to the shelf-life. The composition of the products, the dose rate, instructions for use and user category remain unchanged compared to the one evaluated in the initial assessment of the Union authorisation. Furthermore, the risk management measures do not change. It is therefore not necessary to perform a supplementary evaluation.

iv) Environment

The proposed change does not affect the risks to the environment associated with the use of the biocidal product family since the proposed change is limited to the shelf-life. The composition of the products, the dose rate and instructions for use remain unchanged compared to the one evaluated in the initial assessment of the Union authorisation. Furthermore, the risk management measures do not change. It is therefore not necessary to perform a supplementary evaluation.

v) Overall conclusion of the evaluation

The outcome of the evaluation, as reflected in the PAR, is that the proposed change does not affect the conclusions with regard to the fulfilment of the conditions of Article 19(1) of the BPR.

2.2 BPC opinion on the change to the Union authorisation

As the conditions of Article 19(1) of the BPR are met it is proposed that the authorisation of BPF_Iodine_VET shall be amended with the proposed change.

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Annex

Draft Revised Summary of Product Characteristics