Biocidal Products Committee (BPC)

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

DEC-AHOL® Product Family

ECHA/BPC/410/2024

Adopted

9 January 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	**DEC-AHOL® Product Family**
Asset number	**EU-0024324-0000**
Authorisation holder	**Veltek Associates Inc. Europe**

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

Procedural history

Following the submission of an application on 09 August 2023, recorded in R4BP 3 under case number BC-HJ088175-32, 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. Revisions agreed upon were presented and the draft revised PAR and the draft revised SPC were updated accordingly.

Adoption of the BPC opinion

The BPC opinion on the minor change to the Union authorisation of the biocidal product family was adopted on 9 January 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 DEC-AHOL® Product Family can be amended with the proposed minor change.

After the introduction of the changes, the biocidal product family meets the conditions laid down in Article 19(1) of the BPR and therefore the authorisation of DEC-AHOL® Product Family may be amended with the proposed changes 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 DEC-AHOL® Product Family 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 changes as proposed by the authorisation holder

The following changes to the authorised products were proposed by the authorisation holder:

1. Change in the instructions of use due to the decrease of contact time for yeast and bacteria from x to 1 minute in meta SPC 2 (use #2.1), 3 (use #3.1, #3.2) and 4 (use #4.1).

2. Increase of shelf-life from 2 years to 3 years.

3. Change in the pack size range. Wipes with the size of 23 cm x 23 cm were added to meta SPC 1.

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. Part of the studies had been already available at the time of authorisation but were not taken into account for setting the shelf-life.

The newly evaluated studies combined with the read-across approach already assessed and accepted during authorisation provide enough evidence to conclude that all meta SPC can be considered stable after 3 years of storage.

This change does not affect the conclusions reached regarding the safety for human and animal health and for the environment and the efficacy of the already authorised biocidal product family.

The proposed change regarding addition of a new pack size is supported by data and read-across argumentation to already existing packaging which have been found to be acceptable in the authorisation. The new pack size is very similar in size and material to already

existing packaging and there is enough evidence to conclude that the new packaging belongs to meta SPC 1 and has no effect on the conclusions regarding the product family.

ii) Efficacy

The proposed change affects the conclusions reached regarding the efficacy of the biocidal product family. Based on the assessment, the tested biocidal product shows sufficient efficacy to substantiate the claim with reduced contact time from 2 minutes to 1 minute for meta SPCs 2, 3, and 4. However, the currently provided tests demonstrating efficacy after 1 minute contact time against bacteria and yeast has been conducted without soiling and as a consequence the use of the products needs to be limited to cleanrooms only and the following sentence needs to be added to the instructions of use: "*Use product only in cleanrooms which are classified according to ISO 14644-1 in class 1 to 9 or according to GMP EU classification in grade A to D*."

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 efficacy claim, pack size and 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 efficacy claim, pack size and 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 changes do 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 changes to the Union authorisation

As the conditions of Article 19(1) of the BPR are met it is proposed that the authorisation of DEC-AHOL® Product Family shall be amended with the proposed changes.

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Annex

Draft Revised Summary of Product Characteristics