Biocidal Products Committee (BPC)

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

Pesguard® Gel

ECHA/BPC/395/2023

Adopted

9 October 2023

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	**Pesguard® Gel**
Asset number	**EU-0024951-0000**
Authorisation holder	**Sumitomo Chemical Agro Europe SAS**

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 8 April 2022, recorded in R4BP 3 under case number BC-BL074962-31, the ECHA secretariat evaluated the minor change. Subsequently, the ECHA secretariat transmitted an ECHA opinion on the change to the European Commission on 23 September 2022. The European Commission considered the ECHA opinion invalid on the basis of Article 75 of the BPR. Therefore, 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 from 4 September until 13 September 2023.

Adoption of the BPC opinion

The BPC opinion on the minor change to the Union authorisation of the biocidal product was adopted on **9 October 2023**.

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 Pesguard® Gel cannot be amended with proposed change #1 as described in section 2.1 of this opinion. However, the authorisation can be amended with proposed changes #2 and #3 as described in section 2.1 of this opinion.

The proposed change #1 as described by the authorisation holder does not meet the conditions set out in Title 2 of the Commission Implementing Regulation (EU) No 354/2013 (Changes Regulation). Therefore, the authorisation of Pesguard® Gel may not be amended with proposed change #1.

After the introduction of changes #2 and #3, the biocidal product meets the conditions laid down in Article 19(1) of the BPR and therefore the authorisation of Pesguard® Gel 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 Pesguard® Gel 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 product were proposed by the authorisation holder.

Proposed change #1:

1. The authorisation holder described the proposed change as a minor change referred to as change n°1 in Title 2 of the Annex to the Changes Regulation and meeting the conditions defined therein. It was further indicated by the authorisation holder that the proposed change concerns a change in composition related to the non-active ingredients of the biocidal product.

   The exact change in composition is reported in the confidential annex to the PAR.

Proposed changes #2 and #3:

2. Addition of the new manufacturing location “Jiangsu Flag Chemical Industry Co., Ltd.” for the active substance manufacturer “Sumitomo Chemical company Ltd” for “(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (Clothianidin)”. The manufacturing location has been demonstrated technically equivalent (Asset number EU-0025466-0000).

3. Change in the administrative details of the active substance manufacturer “Sumitomo Chemical company Ltd”. The change concerns the address of manufacturer where the manufacturing location and process remain unchanged and the manufacturer remains listed in accordance with Article 95(2) of Regulation (EU) No 528/2012.

Summary of the evaluation and conclusions

Proposed change #1:

The change proposed by the authorisation holder concerns a change in the composition of the product, affecting only the non-active substances. The change includes the addition and removal of non-active substances as well as increases and reductions in the concentrations of other non-active substances.

When the proposed change concerns a change in non-active substances of the biocidal product, the change is to be considered minor when the conditions set out in the Changes Regulation[1] are met:

> *Increase or reduction, addition, deletion or replacement of a non-active substance intentionally incorporated in the product, where:*
>
> - *The added or increased non active-substance is not a substance of concern.*
> - *The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern.*
> - *The physical-chemical properties and the shelf-life of the product are expected to remain the same.*
> - *The risk and efficacy profile are expected to remain the same.*
> - *A new quantitative risk assessment is not expected to be necessary.*

Based on the information provided by the authorisation holder, the content of two substances of concern increases in the new product formulation compared to the one authorised. Consequently, the change in the composition of biocidal product does not meet the conditions set out in Title 2 of the Annex to the Changes Regulation.

It was not assessed whether the proposed change leads to the addition or increase of any other substances of concern. Since the proposed change does not meet the conditions for a minor change in accordance with the Changes Regulation, the impact of the proposed change on the physico-chemical properties, efficacy, risks for human and animal health as well as the risks for the environment were not assessed. Thus, it has not been assessed whether the proposed change affects the conclusions underlying the authorisation of the biocidal product and whether the conditions of Article 19 would still be met.

Proposed changes #2 and 3:

The evaluation of the changes proposed by the authorisation holder is presented below.

#	Evaluation	Evaluation outcome
2.	The requested change matches the description for **Change n° 5 of section 1** of Title 1 of the Annex to the Changes Regulation.	Acceptable*
3.	The requested change matches the description for **Change n° 5 of section 2** of Title 1 of the Annex to the Changes Regulation.	Acceptable

*Change requiring prior notification

[1] Change n° 1 of Title 2 of the Annex to the Changes Regulation

b) Overall conclusion of the evaluation

The outcome of the evaluation, as reflected in the PAR, is that the proposed change #1 does not meet the conditions set out in the Changes Regulation[1] and thus, it cannot be considered minor. Proposed changes #2 and #3 are changes falling under Article 3(1)(aa) of the BPR, and, after the implementation of the changes, the conditions of Article 19 of the BPR will still be met.

2.2 BPC opinion on the changes to the Union authorisation

Since proposed change #1 does not meet the conditions set out in the Changes Regulation[1] for a minor change, it is proposed that the authorisation of Pesguard® Gel shall not be amended with the proposed change #1.

As the conditions of Article 19(1) of the BPR will be met following the introduction of proposed changes #2 and #3, it is proposed that the authorisation of Pesguard® Gel shall be amended with the proposed changes #2 and #3.

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Annex

Draft Revised Summary of Product Characteristics