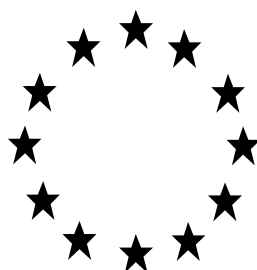


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT (FAMILY) FOR
NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)

ADDENDUM: Minor Change



Insect Spray

Product type 19

Ethyl butylacetylaminopropionate as included in the Union list of approved active substances/Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-BV080528-13

Evaluating Competent Authority: eCA Belgium

Date: 27/03/2023

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1 OVERVIEW OF APPLICATIONS

Application type	refMS	Case number in the refMS	Decision date	Product/Case owner
NA-APP	BE	BC-BL013906-42	17.05.2017	Insect Repellent Pump Spray IR3535 20%/Merck KGaA
NA-BBS	BE	BC-RC074959-20	21.06.2022	Insect Spray (Same biocidal product)/Just International AG
NA-MIC	BE	BC-BV080528-13	12.05.2023	Insect Spray (minor change: adding perfume)/Just International AG

Table 1 - Overview regarding all relevant applications

2 CONCLUSION

Evaluation of the minor change:

The minor change refers to the addition of a non-active substance (perfume) intentionally incorporated in the product (*see confidential annex for the product composition and formulation*).

Although the biocidal product contains a substance of concern we can conclude that this has no effect on the biocidal product as a consequence of the following remarks:

1. the concentration of the ingredient in the biocidal product is lower than any of the generic concentration limits specified in Annex I of the CLP Regulation (EC) No 1272/2008 and therefore the substance does not contribute to the classification and labelling of the biocidal product,
2. the concentration of the ingredient Geraniol, which is currently under evaluation as active substance for PT19 products and could thus be considered as potential synergist, is far below the concentration range in which the substance is used as active substance for PT19 products,
3. the ingredient is not included in the candidate list according to Article 59(1) of the REACH Regulation or fulfils the criteria for inclusion in the candidate list, and
4. Even if the substance is found to possess ED properties and is considered for inclusion in REACH Annex XIV according to REACH Art. 57(f), the concentration of the substance in the biocidal product is below the threshold concentration as defined in REACH Art. 56(6)a (0.1% (w/w)).

Table 2 – Remarks concerning the perfume

So in this case the requirements of Reg. (EU) No 354/2013, Annex, TITLE 2, table line 1 are deemed to be fulfilled:

1. 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*

Table 3. Regulation on Minor change

So overall this minor change is acceptable and we consider this perfume not as a substance of concern due the low concentration of it.

In conclusion the proposed change does not adversely affect the conclusion previously reached on the assessment of the biocidal product Insect Spray.

BE CA reviewed these changes and agrees that the conditions of Article 19 of the BPR are met. This will allow other Member to authorize the addition of this perfume for Insect Spray.

3 ASSESSMENT

3.1 Background

The asset owner Just International AG has applied for a minor change in accordance with Regulation (EU) No 354/2013 for the authorised biocidal product Insect Spray.

3.2 Description of changes

The following minor change is applied for:

Adding a perfume (*see table 1.2 confidential annex*).

The biocidal product contains the ingredient Geraniol (CAS 106-24-1, EC 203-377-1) as non-active ingredient with a final concentration of approx. 0.00079 % (w/w) in the biocidal product. The ingredient Geraniol is part of the perfume that the applicant intends to add to the formulation as part of the NA-MIC application submitted. The ingredient is part of the perfume formulation as carry-over substance from the contained essential oils, particularly Palmarosa oil.

The requirements of Reg. (EU) No 354/2013, Annex, TITLE 2, table line 1 are deemed to be fulfilled (see above:table 3)

3.3 Evaluation of changes

3.3.1 Identity and physico-chemical properties

the concentration of the ingredient in the biocidal product is very low so no drastic changes to the physical or chemical properties are suspected that will lead to adverse effects or changes to the CLP.

3.3.2 Authorised use and General directions of use

Not applicable because the intended uses, instructions for use, application methods, and risk-mitigation measures do not change.

3.3.3 Efficacy

The addition of the the perfume has no effect on the efficacy assessment previously reached because the intended uses, instructions for use, target organisms and application methods do not change.

3.3.4 Human Health

The conclusions as previously reached on the human and animal health assessment of the biocidal product are not adversely affected because the intended uses, instructions for use, application methods, and risk-mitigation measures do not change with adding the perfume.

3.3.5 Environment

The conclusions as previously reached on the environmental risk assessment of the biocidal product are not adversely affected because the intended uses, instructions for use, application methods, and risk-mitigation measures do not change for this minor change.

3.3.6 Endocrine-disrupting properties of a non-active substance

Although there are indications that Geraniol (CAS 106-24-1, EC 203-377-1) may have endocrine-disrupting properties we consider this for this product acceptable since this is still under review and Geraniol has a very low concentration in this biocidal product (see *also table 2 above*).

No other non-active substance of the perfume could be identified as ED on the basis of an EU decision or is subject of a relevant assessment under REACH (*the assessment was performed according to CA-march21-Doc.4.3_final_bridging_biocides_with_reach_en*). In addition, no further evidence of ED characteristics could be found for any other non-active substance of the perfume. It can be concluded that the perfume Sunrise Melody 449942-E does not contain any other non-active substances with potential ED properties besides Geraniol.