EUROPEAN CHEMICALS AGENCY

Helsinki, 18-11-2019

[redacted]

Sent via R4BP 3

ECHA OPINION ON THE CLASSIFICATION OF A CHANGE UNDER ARTICLE 2 OF COMMISSION IMPLEMENTING REGULATION (EU) NO 354/2013

Opinion number:
Case number: [redacted]

Dear Sir or Madam,

The European Chemicals Agency (ECHA), in accordance with Article 2 of Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, has assessed your request for an opinion on classification of changes in relation to:

List of all the authorisations affected by the proposed change(s):

- [redacted] / Product Type 18 - Insecticides, acaricides and products to control other arthropods
- Product Asset numbers:
  - [redacted] (National authorisation)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)

Member States concerned:

- United Kingdom
- Germany
- Ireland
- France
- Spain
- Poland

The request was submitted on 19 September 2019. The assessment of classification of a change was initiated on 5 October 2019 once the fee was paid.

The scope of the assessment was based on the information provided by the applicant and following the principles set out in the Commission Implementing Regulation (EU) No 354/2013 and Regulation (EU) No 528/2012.

In accordance with Article 2 of Commission Implementing Regulation (EU) No 354/2013, ECHA has come to the opinion set out herein. ECHA will publish the opinion after deletion of all information of commercial confidential nature, in accordance with Article 2 of Commission Implementing Regulation (EU) No 354/2013.

Detailed opinion and background

1. Opinion

The outcome of this assessment is that the change proposed by the applicant is **considered a minor change**.

The result of the assessment is limited to the product(s) listed above and only to the change(s) specified in the application.

This change is not explicitly listed in Title 2 of the Annex to Regulation (EU) 354/2013. However according to Article 3(1)(ab) of the BPR, a minor change means "an amendment of existing authorisation that is not of a purely administrative nature and requires only a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family". In this case the assessment would be limited to the impact of the secondary packaging of the product while the dose rate, instructions for use, user category and risk mitigations measures as approved in the Summary of Product Characteristics (SPC) would not be changed. This conclusion is valid as long as a reassessment of the risk for human health and environment is not necessary. Otherwise the reassessment of the product family would not be limited to the properties or efficacy of the biocidal product and the change would be regarded as "major change".

2. Description of the product

The product is an insecticide for non-professional indoor use. It is supplied as impregnated paper strips for use against [redacted] moths and mosquitoes and as a paper sheet installed in a clothes hanger [redacted], for use against moths in contained areas.

3. Description of the proposed change

The applicant would like to include the option of secondary packaging.

[redacted]

The change requested is to include the option of an additional heat sealed sachet as secondary packaging containing between 1 and 10 individual sachets of booklets. These sachets will then be further packed in shipping cartons acting as tertiary packaging.

The applicant claims that, due to the outer sachets containing individual sachets of booklets, the primary packaging which provides the barrier function that ensures product integrity and product shelf life is unaltered. According to the applicant, the chemistry, efficacy and product characteristics remain unchanged from the original authorised.

4. ECHA conclusions of the assessment

The applicant claims that the change of packaging will not have any effect on the efficacy or product characteristics.

ECHA considers that the change proposed would require an assessment by the competent authority of the impact of the proposed change of the biocidal product and therefore, it cannot be considered as an administrative change.

Assuming that the assessment would be limited to the impact of the change of the packaging of the product while the dose rate, instructions for use, user category and risk mitigations measures as authorised in the SPC would not be changed, ECHA concludes that the requested change to the product authorisation should be considered as minor.

If the reassessment of the product family would not be limited to the properties or efficacy of the biocidal product the change would be regarded as "major change".

5. Consequences of this opinion

The applicant is advised to attach this opinion with its application for a change to an authorised biocidal product, in accordance with Article 5(5) of Commission Implementing Regulation (EU) No 354/2013.

ECHA's opinion on the classification of a change contained herein is not legally binding.

Yours faithfully,