Helsinki, 21 -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: [redacted]
Case number:

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
- [redacted] / Product Type 18 - Insecticides, acaricides and products to control other arthropods
- [redacted] / Product Type 18 - Insecticides, acaricides and products to control other arthropods
- [redacted] / Product Type 18 - Insecticides, acaricides and products to control other arthropods
- [redacted] / Product Type 18 - Insecticides, acaricides and products to control other arthropods
- [redacted] / Product Type 18 - Insecticides, acaricides and products to control other arthropods
- [redacted] / Product Type 18 - Insecticides, acaricides and products to control other arthropods

- Product Asset numbers:
  - [redacted]
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)
  - [redacted] (Mutual recognition)

Member States concerned:

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

The request was submitted on 25 September 2019. The assessment of classification of a change was initiated on 12 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 authorised 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 change requested is to change the conditions of the packaging. The applicant would like to change package sizes and packaging material. The primary packaging will be printed opaque and the secondary and tertiary package size will be increased to hold higher number of individual hangers.

The applicant claims that the proposed change would not affect the shelf life stability of the product. The applicant noted that the original stability study in the product was performed on sachets only.

4. ECHA conclusions of the assessment

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,

[redacted]