EUROPEAN CHEMICALS AGENCY

Helsinki, 10 -12- 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 the classification of a change in relation to the following authorised products:

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
- [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)

Member States concerned:

- France
- Netherlands
- Belgium
- Luxemburg

The request was submitted on 1 October 2019. The assessment of the classification of a change was initiated on 5 November 2019, once the fee was paid.

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

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 to be a major change**.

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

2. Description of the product

The product is a ready-to-use aerosol to be used by professionals to be sprayed into cracks and crevices and on surfaces against bedbugs.

3. Description of the proposed change

The aim of this change is to add non-professional users in the use against bedbugs. The applicant claims that it could be demonstrated that this change does not adversely affect the exposure, and that the risk assessments already done "cover" this use by non-professionals.

4. ECHA conclusions of the assessment

ECHA considers that the change proposed would require an assessment by the competent authority of its impact. Therefore, it cannot be considered as an administrative change.

According to Article 3(1)(ab) of the BPR, a minor change means "an amendment of an 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 the present case, the assessment would not be limited to a re-assessment of the properties or efficacy of the biocidal product. This is because a change in user category may have an impact on the human health and environmental risk assessments, as well as the instructions for use. It could also have an impact on any risk mitigation measures applied. Therefore, the change cannot be considered as a minor change.

A change in user category results in different exposure both for human health and the environment. Such a change in exposure may affect the conclusions with regard to the fulfilment of the conditions listed in Article 19 or Article 25 of the BPR. Accordingly, the competent authority would need to review several sections of the PAR including the risk assessment, in order to ensure that the change proposed does not affect the conclusions with regard to the fulfilment of the conditions listed in Article 19 or Article 25 of the BPR. For these reasons ECHA has concluded that the change has to be regarded as a 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.