Helsinki, 28 October 2021

[redacted]

Sent via R4BP 3

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

Decision number: [redacted]
Case number: [redacted]

Dear Sir/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] – PT 08
- Product Asset numbers
  - [redacted] (National authorisation)
  - [redacted] (National authorisation)
  - [redacted] (National authorisation)
  - [redacted] (National authorisation)
- Member States concerned:
  - The Netherlands
  - Germany
  - Switzerland
  - Austria

The request was submitted on 29 July 2021. The assessment of classification of a change was initiated on 07 September 2021 once the fee was paid.

The evaluation 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 major change:**

The result of the assessment is limited to the products listed above and only to the change specified in the application.

This change is not explicitly listed in the Annex to Commission Implementing Regulation (EU) No 354/2013. ECHA considers that the change proposed would require more than a limited re-assessment of the properties or efficacy of the biocidal product. Therefore, it cannot be considered as a minor change and should be considered as a major change.

2. Description of the product

The biocidal product is a RTU water-based wood preservative for preventive treatment of wood in Use Class 1 by industrial, (trained) professional and general public (non-professional) users.

3. Description of the proposed change

The current authorisation is limited to the following uses against house longhorn beetle [redacted] larvae and termites [redacted]

- Preventive Insecticide treatment General public (non-professional) (indoors) Brush/Roller
- Preventive Insecticide treatment professionals (indoors) Spraying/Brush/Roller/Dipping

The applicant would like to add the target organism [redacted] with a new use which is curative action [redacted] by injection. It is an indoor use by professionals and industrial users.

4. ECHA conclusions of the assessment

ECHA considers that the change proposed correspond to the addition of a new use with a new target organism and a new method of application.

To assess whether this new use may be authorised would require an assessment of its efficacy, a full exposure assessment of the new method of application for human health and the environment and an assessment of the related risks.

Therefore, ECHA concludes that the change to the product authorisation should 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.

Yours faithfully,

[redacted]