Helsinki, 10 September 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 [redacted]

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 (the BPR), has evaluated your request for an opinion on classification of changes in relation to:

The authorisation affected by the proposed change:
- [redacted] /PT 08 /[redacted]

Product Asset number:
- [redacted]

Authorising Member State :
- Denmark

The request was submitted on 13 July 2021. Further information was requested from the applicant by ECHA on 28 July 2021 regarding the list of all authorisations affected by the change to be classified. Such information was received on 10 August 2021 and was duly taken account of in the assessment. The assessment of classification of a change was initiated on 27 August 2021, upon receiving payment of the applicable fee.

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 evaluation is that the change proposed by the applicant is **considered to be a major change**.

The result of the evaluation is limited to the product 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 biocidalproduct or biocidal product family. Therefore, it cannot be considered as a minor change and should be considered as a major change.

2. Description of the product

The product is a solvent based wood preservative (PT 8) for professional and amateur use by brushing and rolling in use classes 2 and 3 on softwood.

3. Description of the proposed change

The applicant would like to remove one of the active substances of the biocidal product and replace it with the solvent [redacted]

The biocidal product contains [redacted] active substances: [redacted] The applicant would like to remove the active substance [redacted] from the formulation and replace it with [redacted]

According to the applicant, the change is not expected to adversely affect the exposure and risk to human health or environment. A new quantitative risk assessment is expected to result in much better values, as there is no increase of remaining active substance or substance of concern.
However the applicant does recognise that the efficacy profile of the modified product will most probably change.

4. ECHA conclusions of the evaluation

As a result of the considered change, the composition of the product would be significantly modified and the requirements of Article 19(1)(b) concerning efficacy of the product, and 19(1)(d) relating to the determination of physical and chemical properties, of Regulation (EU) No 528/2012 may not be met anymore.

A removal of one of the active substances is a significant change of the composition of the biocidal product. This change would imply that for all physical and chemical properties and efficacy, new studies relevant for the new composition of the products would need to be provided.
Consequently, a new assessment would be necessary, covering at least the efficacy and the physical and chemical properties of the biocidal products. An in depth full reassessment of the risks would also be necessary.

Overall, ECHA concludes that the assessment cannot be considered as a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family such as the one referred to in the definition of a minor change (Cf. Article 3(1)(ab) of the BPR). Therefore, ECHA concludes 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.

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.