Helsinki, 19-03-2019

[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 19

- Product Asset numbers:
  - [redacted]

Member States concerned:

- Italy

The request was first submitted on 8 January 2019. ECHA requested further documents to be submitted and the case was re-submitted on the 14 January 2019. ECHA requested again further documents to be submitted and the case was re-submitted on the 16 January 2019.

The assessment of classification of a change was initiated on 13 February 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.

The change proposed is not expected to have any other consequences than a change in the classification and labelling of the product. GHS pictogram and signal word will remain the same. Reference values of the product used for the human health risk assessment will not be affected by this change.

A change in the classification is important for enforcement and will require a review by the concern member state to ensure that the change will not affect any other section of the PAR. Title 1 section 2 "Administrative changes of products which can be notified after implementation" of the annex of Regulation (EU) No 354/2013 makes reference to a change in the classification and labelling of the product that is limited to what is necessary to comply with newly applicable requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council. In the present case, the change in the classification and labelling is not the consequence of newly applicable requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council.

For these reasons we conclude that the change proposed is a "Minor change".

2. Description of the product

The product is a ready to use spray formulation [redacted]. It is spread on the uncovered skin evenly in thin layer. The product is to be used by the general public.

3. 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.

[redacted]