European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product: **EuLA oxi-lime 23**

Opinion N° UAD-C-1724389-20-00/F

5 April 2024

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of EuLA oxi-lime 23

In accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013 of the European Commission 18 May 2013 on changes of biocidal products authorised in accordance with Biocidal Product Regulation (EU) No 528/2012 (BPR), the European Chemicals Agency (ECHA) has prepared this opinion on the administrative changes to the Union authorisation of:

Name of the biocidal product: EuLA oxi-lime 23

Authorisation holder: European Lime Association aisbl

Target asset number: EU-0028963-0000

Active substance common name: Calcium oxide/lime/burnt lime/quicklime

Product types: 2, 3

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 28 February 2024, and recorded in R4BP 3 under case number BC-PP093305-18.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 15 March 2024.

The evaluation included a check that the proposed changes of an existing authorisation are of a purely administrative nature involving no change to the properties or efficacy of the biocidal product in accordance with Article 3(1)aa of the BPR.

The scope of the assessment itself was based on and limited to the information provided by the authorisation holder in the supporting document for the notification for an administrative change of a Union or simplified authorisation under Regulation (EU) No 354/2013 supplied via R4BP 3.

ECHA prepared this opinion containing the conclusions of its assessment.

2. Detailed opinion and background

2.1. ECHA opinion

During the evaluation, ECHA has assessed whether the changes made in the SPC document provided by the applicant are administrative in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following changes to the biocidal product sought by the authorisation holder are changes falling under Article 3(1)(aa) of the BPR, and, after the implementation of the changes, the conditions of Article 19 of the BPR will still be met:

- Title 1, section **1** of the Annex to the Regulation (EU) No 354/2013 -

Manufacturer(s) of the active substance(s) - change N° 5: *Addition of a manufacturer of the active substance or change in the manufacturer's identity or in manufacturing location or process, where the technical equivalence between the substances from the two manufacturers, manufacturing locations and processes has been established by the Agency in accordance with Article 54 of Regulation (EU) No 528/2012, and the manufacturer or importer is listed in accordance with Article 95(2) of Regulation (EU) No 528/2012.*

- Title 1, section **2** of the Annex to the Regulation (EU) No 354/2013 - *Formulator(s) of the biocidal product* - change N° 4: *Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.*

Accordingly, it is proposed that the Commission amends the existing authorisation with the below listed administrative changes to the biocidal product sought by the authorisation holder.

2.2. ECHA assessment

2.2.1. Description of the changes as proposed by the authorisation holder

Changes as described by the authorisation holder in their supporting document supplied via R4BP 3.

<table>
<tr><th><u>Identification</u></th><th><u>Description</u></th></tr>
<tr><td>1.</td><td>Inclusion of a new product manufacturer in the dossier.

<table><tr><td>Company name</td><td>Hans G. Hauri KG Mineralstoffwerke</td></tr><tr><td>Address</td><td>Bergstraße 114, 79241 Bötzingen, Deutschland</td></tr><tr><td>Address manufacturing site Product</td><td>Paul-Mathis-Straße 1, 79291 Merdingen, Deutschland</td></tr></table></td></tr>
<tr><td>2.</td><td>Inclusion of a new active substance manufacturer in the dossier.

<table><tr><td>Company name</td><td>Hans G. Hauri KG Mineralstoffwerke</td></tr><tr><td>Address</td><td>Bergstraße 114, 79241 Bötzingen, Deutschland</td></tr><tr><td>Address manufacturing site Active substance</td><td>Paul-Mathis-Straße 1, 79291 Merdingen, Deutschland</td></tr></table>
The active substance source is a reference source.</td></tr>
</table>

2.2.2. Assessment of the changes as proposed by the authorisation holder

The assessment of the changes sought by the authorisation holder is presented in the following table:

Identification	Corresponding reference in the Annex to Regulation (EU) No 354/2013	Evaluation	Result of the evaluation	Comments
1.	Title 1, section 1, change n° 5	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
2.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	

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Annex

Draft Summary of Product Characteristics