

## European Chemicals Agency

### Opinion on the Application for Union Authorisation of the Same Biocidal Product under Article 6 of Commission Implementing Regulation (EU) No. 414/2013

**Opinion number: UBP-C-1605129-22-00/F**

**Date: 08 September 2022**

Name of the Single product	BIOCALCO S
Authorisation holder	CARMEUSE EUROPE S.A.
Active substance common name	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime
Product types	PT 3,PT 2
Name of the related reference single product	EuLA hydra-lime 23 ("related reference product")
BPC Opinion number of the related reference product	ECHA/BPC/341/2022

The European Chemicals Agency ("ECHA"), in accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013<sup>1</sup>, has evaluated the application for Union authorisation of BIOCALCO S.

The application for Union authorisation was submitted to ECHA on 20 April 2018 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 and recorded in R4BP3 under case number BC-NE038810-48.

Following its acceptance by ECHA, the validation of the application was initiated on 17 May 2018.

The application was subsequently validated on 07 June 2018 following ECHA's conclusion that the information indicated in Article 2 of Commission Implementing Regulation (EU) No 414/2013 had been submitted.

The validation included a check that the proposed differences between BIOCALCO S and the product EuLA hydra-lime 23 are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013<sup>2</sup>.

Following the adoption of the BPC opinion of the related reference product and the subsequent submission of a revised version of the draft SPC of BIOCALCO S, ECHA confirmed again that all differences between BIOCALCO S and the related reference product are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

The evaluation was based on the information provided by the applicant in relation to the related

<sup>1</sup> Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

<sup>2</sup> Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

reference product.

In accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013, ECHA's opinion is set out below.

## ***Detailed opinion and background***

### **1. Overall conclusion**

The overall conclusion of ECHA's opinion is that BIOCALCO S is eligible for Union authorisation, and all reported differences between BIOCALCO S and the related reference product are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

The single biocidal product BIOCALCO S, as defined in Article 3(1)(r) of Regulation (EU) No 528/2012, meets the conditions laid down in Article 19(1) of that Regulation and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the Product Assessment Report ("PAR") of the related reference product.

A draft summary of product characteristics ("SPC") of BIOCALCO S, as referred to in Article 22(2) of Regulation (EU) No 528/2012, is attached as an annex.

### **2. ECHA opinion**

#### **2.1. Conclusions of the evaluation**

The conclusions of the risk assessment for BIOCALCO S are based on the evaluation of the related reference product and described in BPC opinion ECHA/BPC/341/2022 14 June 2022.

#### **2.2. Presentation of the Single product including classification and labelling**

The description of BIOCALCO S and the hazard and precautionary statements according to Regulation (EC) 1272/2008 are available in the SPC, see annex to this opinion.

#### **2.3. Description of uses proposed to be authorised**

The assessment supporting the intended uses in the application is described in the PAR of the related reference product.

The description of the intended uses proposed to be authorised is available in the SPC, see annex to this opinion.

#### **2.4. Overall conclusion of the evaluation of the uses proposed to be authorised**

For the uses proposed to be authorised, according to Article 19(1)(b) of Regulation (EU) No 528/2012, it has been concluded that BIOCALCO S:

1. is sufficiently effective;
2. has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. has no unacceptable effects itself, or because of its residues, on the environment, having particular regard to the following considerations:
  - the fate and distribution of the biocidal product in the environment,
  - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

- the impact of the biocidal product on non-target organisms,
- the impact of the biocidal product on biodiversity and the ecosystem.

Therefore, it is proposed that BIOCALCO S shall be authorised<sup>3</sup> for the uses described under section 2.3 of this opinion, subject to compliance with the proposed SPC.

## **Annex I: draft Summary of Product Characteristics**

---

<sup>3</sup> This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of Regulation (EU) No 528/2012.