European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: **Iodine Teat dip products**

UAD-C-1704599-18-00/F

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Opinion of the European Chemicals Agency

On administrative changes of the Union authorisation of Iodine Teat Dip Products

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 family: Iodine Teat Dip Products

Authorisation holder: GEA Farm Technologies GmbH

Target asset number: EU-0020125-0000

Active substance common name: Iodine

Product type: 3

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 8 December 2023, and recorded in R4BP 3 under case number BC-YN090686-00.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 11 January 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 family 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 family 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 - *Name of the biocidal product* - change N° 2: *Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.*

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

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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.

Identification	Description
1.	Addition of the name LuxGuard C to the product Clinidip Superconcentrate
2.	Addition of the name Ioguard Superconcentrate to the product Clinidip Superconcentrate
3.	Addition of the name LuxDine C to the product Priodine
4.	Addition of the name LuxKlene C to the product Ioklene Concentrate

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° 2	The notifier reported in their supporting document the addition of a new trade name to the product "Clinidip Superconcentrate" however, "Clinidip Superconcentrate" is a tradename of "Dunglinson Super IO 421 Concentrate" rather than a product.	Acceptable	Change requiring prior notification

		Thus, the notified change corresponds to the addition of the trade name "LuxGuard C" to the product "Dunglinson Super IO 421 Concentrate". The requested change matches the description in the Regulation		
2.	Title 1, section 1, change n° 2	The notifier reported in their supporting document the addition of a new trade name to the product "Clinidip Superconcentrate" however, "Clinidip Superconcentrate" is a tradename of "Dunglinson Super IO 421 Concentrate" rather than a product. Thus, the notified change corresponds to the addition of the trade name "Ioguard Superconcentrate" to the product "Dunglinson Super IO 421 Concentrate". The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
3.	Title 1, section 1, change n° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
4.	Title 1, section 1, change n° 2	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification

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Annex

Draft Summary of Product Characteristics