Commission Implementing Regulation (EU) 2020/1187 of 7 August 2020 granting a Union authorisation for the biocidal product family 'Iodine based products – CID LINES NV' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1187

of 7 August 2020

granting a Union authorisation for the biocidal product family 'Iodine based products – CID LINES NV'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

(1) On 13 August 2015, CID LINES NV submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Iodine based products – CID LINES NV' of product-types 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-BY019142-30 in the Register for Biocidal Products.

(2) 'Iodine based products – CID LINES NV' contains iodine including polyvinylpyrrolidone iodine, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, and the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100[(2)], the Commission is carrying out a review of the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will consider whether the Union authorisations for products containing the active substance have to be cancelled or amended in accordance with Article 48 of Regulation (EU) No 528/2012.

(3) On 28 May 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 17 January 2020, the Agency submitted to the Commission an opinion[(3)], including the draft summary of the biocidal product characteristics ('SPC') of 'Iodine based

products – CID LINES NV' and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'Iodine based products – CID LINES NV' is a biocidal product family within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(6) On 4 February 2020 the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Iodine based products – CID LINES NV'.

(8) According to the opinion of the Agency, as regards the non-active substances sodium iodide and sodium iodate contained in 'Iodine based products – CID LINES NV', it was not possible to conclude whether they meet the scientific criteria for the determination of endocrine-disrupting properties set out in Delegated Regulation (EU) 2017/2100 within the period for the evaluation of the application. Further examination of sodium iodide and sodium iodate should therefore take place. If it is concluded that sodium iodide or sodium iodate or both are considered as having endocrine-disrupting properties, the Commission will consider whether to cancel or amend the Union authorisation for 'Iodine based products – CID LINES NV' in accordance with Article 48 of Regulation (EU) No 528/2012.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0022265-0000 is granted to CID LINES NV for the making available on the market and use of the biocidal product family 'Iodine based products – CID LINES NV' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 3 September 2020 until 31 August 2030.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 August 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

Iodine based products – CID LINES NV

Product type 3 – Veterinary hygiene (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0022265-0000

R4BP asset number: EU-0022265-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Iodine based products – CID LINES NV

1.2. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants) PT04 – Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	CID LINES NV
	Address	Waterpoortstraat 2, 8900, Ieper, Belgium
Authorisation number	EU-0022265-0000	
R4BP asset number	EU-0022265-0000	
Date of the authorisation	3 September 2020	
Expiry date of the authorisation	31 August 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	CID LINES NV
Address of manufacturer	Waterpoortstraat 2, 8900 Ieper Belgium
Location of manufacturing sites	Waterpoortstraat 2, 8900 Ieper Belgium

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187. (See end of Document for details)*

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares, Piso 4, 4290 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant, 00 Pedro de Valdivia Chile

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Amunategui 178, 00 Santiago Chile
Location of manufacturing sites	Cala Cala, 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin No 499, 00 Iquique Chile
Location of manufacturing sites	Lagunas mine, 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ISE Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome, 104-0031 Tokyo Japan
Location of manufacturing sites	3695 Kitaimaizumi, 299-3201 Oamishirasato city Japan

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	ISP Chemicals LLC, Afiliate of Ashland Inc
Address of manufacturer	455 N. main st (HWY 95), KY 42029 Calvert City United States
Location of manufacturing sites	455 N. main st (HWY 95), KY 42029 Calvert City United States

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Pantheon FZE (DMCC branch)
Address of manufacturer	403, Reef Tower, Jumeira Lake Tower Shaikh Zayed Road, 00 Dubai United Arab Emirates
Location of manufacturing sites	Cala Cala, 00 Pozo Almonte Chile