Norwegian Environment Agency

GEA Farm Technologies GmbH
Siemensstrasse 25-27
59199, Bönen
Germany

Oslo, 20.05.2021

Your ref.:

Our ref.:
2018/13650

Contact person:
Karina Petersen

Norwegian Authorisation of the Union Authorised product family Iodine Teat Dip Products - EU-0020125-0000

We refer to your application for implementation of Union authorisation in EEA countries and Switzerland of the biocidal product (family) Iodine Teat Dip Products – EU-0020125-0000 in Norway (R4BP3 case no BC-WJ065990-16), containing the active substance iodine. The Norwegian Environment Agency hereby grants authorisation.

Background
Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocides Regulation of 18 April 2017 No. 480.

The Norwegian Environment Agency refers to Commission Implementing Regulation (EU) 2020/202 of 4 October 2019, granting a Union authorisation for the biocidal product family Iodine Teat Dip Products.

When the Commission grants a Union authorisation or decides that a Union authorisation has not been granted, the EFTA states will, according to the EEA agreement Annex II Chapter XV point 12n (e), simultaneously and within 30 days of the Commission Act take corresponding decisions.

Decision
The Norwegian Environment Agency hereby grants authorisation for the biocidal product family Iodine Teat Dip Products, issued in accordance with the Commission Implementing Regulation (EU) 2020/202 of 4 October 2019, cf. the Norwegian Biocides Regulation § 3-1.

The authorisation concerns:

Product family name:	Iodine Teat Dip Products
Active substance(s):	Iodine *(CAS no. 7553-56-2)*

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Product type: Veterinary hygiene (Disinfectants) – PT 3
Authorisation holder in Norway: GEA Farm Technologies
Family authorisation number: EU-0020125-0000
Authorisation date: 20 May 2021
Expiry date: 13 October 2029
Product family member(s):

Product name	**Authorisation number**	**Trade name(s)**
Ioklene Concentrate	*EU-0020125-0001 1-1*	Ioklene Concentrate, Coars Dual
Maxadine C	*EU-0020125-0002 1-1*	*Clinidip L Concentrate, Maxadine C, Diamond 3:1 Concentrate, Kristal 321, IO Spray 3:1 Concentrate, Coars Shield*
Dunglinson Super IO 421 Concentrate	*EU-0020125-0003 1-1*	*Clinidip Superconcentrate, Dunglinson Super IO 421 Concentrate, Ceanodine 4:1, Iodosan*
Priodine	*EU-0020125-0004 1-1*	*Priodine, Diamond Predip*
LuxSpray 30	*EU-0020125-0005 1-2*	*LuxSpray 30, Ioklene RTU, Corston Pre/Post Sprayable, Kristal Iocare Plus, PrePost, Autodine, Coars Super Pre*
LuxSpray 50	*EU-0020125-0006 1-2*	*LuxSpray 50, Silkidip, Ceanodine, IoSpray 10, Maxadine RTU, Diamond Superdip, Kristal Iocare Post, KiwiDip, Superdip Excel, Ioguard RTU, Shepherd's IoSpray 50*
LuxDip 50B	*EU-0020125-0007 1-2*	*LuxDip 50B, Postguard*
LuxDip 25	*EU-0020125-0008 1-2*	*LuxDip 25, Kote It, Corston Barracide Post Film Forming Dip, Pro-Tect, Kristal Iocare Film, Coars Iodinegel, Coars Iodogel, LuxDip 20B*
LuxSpray 15	*EU-0020125-0009 1-3*	*LuxSpray 30, Ioklene RTU, Corston Pre/Post Sprayable, Kristal Iocare Plus, PrePost, Autodine, Coars Super Pre*

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP3.

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Label
The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in accordance with the conditions provided in the attached SPC. Furthermore, Article 69(1), (2) and Article 70 of the BPR also apply.

The authorisation holder is responsible for ensuring that the information given in the above mentioned documents is accurate, and is translated to Norwegian, cf. Article 69(3) of the BPR.

For each meta-SPC an electronic copy of a representative label from one of the individual products belonging to that meta-SPC with the EU authorisation number EU-0020125-0000, shall be provided. The labels are to be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Phase-out period of existing stocks, when relevant
In line with Article 89(4), existing products that do not comply with the conditions of this authorisation, shall not be made available on the market with effect from 180 days after the date of this letter. Furthermore, the use of existing stocks of the biocidal product may continue for up to 365 days after the date of this letter. During this period, all advertising material related to products that do not comply with the new conditions, should also be removed from the market.

Annual fee
For authorised biocidal products on the Norwegian market, an annual fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. We kindly ask you to inform us using the e-mail address biocides@miljodir.no if you do not intend to place the product (family) on the Norwegian market, and therefore should not be charged with the annual fee.

Registration in the Norwegian Product Register
All biocidal products must be registered in the Norwegian Product Register. In addition, all biocidal products which are classified as hazardous must be fully declared if they are sold in amounts of 100 kg or more per year. Further information can be found at https://www.environmentagency.no/areas-of-activity/product-register/

Best regards
Norwegian Environment Agency

This document has been signed electronically

Erlend Spikkerud
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Karina Petersen
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