

CID LINES NV Waterpoortstraat 2, 8900 leper, Belgium

Oslo, 08.12.2020

Your ref.: [Your ref.]

Our ref.: 2020/14633

Contact person: Marianne Stave Sekkenes

Norwegian Authorisation of the Union Authorised product family Iodine based products - CID LINES NV- EU-0022265-0000

We refer to your application for implementation of Union authorisation in EEA countries and Switzerland of the biocidal product family Iodine based products - CID LINES NV- EU-0022265-0000 in Norway (R4BP3 case no BC-CX062671-17), containing the active substances iodine and polyvinylpyrrolidone 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) 2020/1187 of 7 August 2020, granting a Union authorisation for the biocidal product family lodine based products - CID LINES NV.

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 lodine based products - CID LINES NV, issued in accordance with the Commission Implementing Regulation (EU) 2020/1187 of 7 August 2020, cf. the Norwegian Biocides Regulation § 3-1.

The authorisation concerns:

Product family name: Iodine based products - CID LINES NV

Active substance(s): lodine (CAS no. 7553-56-2)

Polyvinylpyrrolidone iodine (CAS no. 25655-41-8)

Product type: PT 3 - Veterinary hygiene

PT 4 - Food and feed area

Authorisation holder in Norway: CID LINES NV Family authorisation number: EU-0022265-0000



Authorisation date: 08.12.2020 Expiry date: 31.08.2030

Product family members:

Product name	Authorisation number	Trade name(s)
Kenodin SD 400	EU-0022265-0000-01-01	Kenodin SD 400
		lodoSD 400
		Velvet Concentrate
		Wynnsan Iodine 3 - 1 conc
		lodin Teat Spray 400
Kenodin	EU-0022265-0000-02-01	lodoDip 3000
		Bio Tec Jodip 3000
		Recoïode
		Stalosan Io Dip
		Stalosan Super Dip
		Velvet High Visco
		Bühning Joddip 3000
		Kenodin
		Wynnsan trikill RTU
		Wynnsan Iodine RTU teat dip
		Wynnsan Iodine dip RTU
		locid
		lodip+
		Wynngold Iodine Dip
		Pezerk iv plus
		lod protect 3000 Film
		Seivit® lode 3000
		Kenostart
		GAHERYOD
		Kenodin 3000
		lodin Teat Dip 3000
		lod 3000 dip
		lodoschutz dip
		loschutz dip
		lodocoop dip
		lodotech dip
		lodactiv' dip
		lododip
		MIROX Dip Jod
		HCP lodine Dip
		Agib Jodium Dip
		Jod 3000
		lod dip
		lode 3000
		lodoschutz
		Coopjod
		Coopiode



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		Coopiode épais
		Semex jod
		lodotech
		lododip green
		lodip bio
		lododip bio
		lodactive épais
		lodactiv
		lodoactiv'
		Bayley's Premier Iodine Teat
		Dip
		Pearce Premier Iodine Teat
		Dip
		Diamond 1:3 Concentrate
		Iodine Post Dip Spray
		JODOCARE
		KENOSTART DYP
		STREPTOFIT
		Iodall Film
Vanadia Film	EU 003337E 0000 03 03	
Kenodin Film	EU-0022265-0000-02-02	Kenodin Film
		IodoFilm
		Wynnsan Iofilm teat dip
		Kenodin Film Extra
		Wynngold Film
		Wynnsan trikill film teat dip
		Kenodin Film Soft
		locid Film
		TOP Film
		Seivit® Iode Gel
		IOD protect 3000 Film
		Iodin Film Teat Dip 3000
		lodin Barrier Teat Dip 3000
		Iodin Film Teat Dip
		Iodin Barrier Teat Dip
		Iod 3000 film
		Iodoschutz film
		Ioschutz film
		Iodocoop film
		Iodotech film
		Iodactiv' film
		Iodofilm
		HCP Iodine Film
		lod 3000 film
		Coopjod film
		Coopiode film
		lodocoop film
		ioaocoop Hilli



		Common to differ
		Semex jod film
		Iodofilm
		lodofilm bio
		lofilm bio
		lodactive film
		Iodactiv film
		Iodactiv' film
		SCUDO 3000
Animal Skin Disinfectant	EU-0022265-0000-03-01	Animal Skin Disinfectant
		Dermades 3000
		lodin Skin Disinfectant
Dermades	EU-0022265-0000-03-02	Dermades
Dermades	20 0022203 0000 03 02	Animal skin disinfectant 1%
		Dermades Strong
		_
IV II. CD	FIL 002224F 0000 04 04	lodin Skin Disinfectant Strong
Kenodin SD	EU-0022265-0000-04-01	Kenodin SD
		lodoSD 3000
		Bio Tec Jodspray 3000
		Q Farm Iodine Des
		ANRO - Euterpflege Dip
		Stalosan Io Spray
		Stalosan Super Spray
		IDip+
		Bühning Jodspray 3000
		Velvet RTU
		Wynnsan trikill spray
		Wynnsan Iodine spray RTU
		Wynngold Iodine Dip and spray
		Pezerk IL
		lod protect 3000 Sprüh
		Seivit® lode Spray
		IOD protect 3000 Sprüh
		Kenodin SprayFilm
		lodo SP
		Kenostart SD
		GAHERYOD SPRAY
		lodin Teat & Skin 3000
		lod 3000 sprüh
		lodoschutz sprüh
		loschutz sprüh
		lodocoop sprüh
		lodotech sprüh
		lodactiv' sprüh
		lodosprüh
		MIROX Spray Jod
		HCP lodine SD



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		Agib Jodium Spray
		Jod 3000 spray
		lod sprüh
		Coopjod
		Coopiode spray
		lodocoop spray
		Semex jod spray
		lododip spray
		lododip spray green
		lodospray Bio
		lospray bio
		lodactive spray
		lodactiv spray
		lodactiv' spray
		Ark Iodine S+D
		Agrihealth Iodine SD
		AGRO LOGIC JODOCARE SPRAY
		IODACTIVE
lodo PVP	EU-0022265-0000-05-01	lodo PVP
10001 11	20 0022203 0000 03 01	lodin Teat Dip 3000 PVP
lodo SD PVP	EU-0022265-0000-05-02	lodo SD PVP
1000 30 1 41	20-0022203-0000-03-02	lodin Teat Spray & Dip 3000
		PVP
Dermades PVP	EU-0022265-0000-06-01	Dermades PVP
Definates PVP	E0-0022263-0000-06-01	
		Wynngold 10% Iodine Solution Iodin Skin Disinfectant PVP
Dodin 20	TH 002227E 0000 07 04	
Dodin Zu	EU-0022265-0000-07-01	Dodin 20
		lodo 20
		Bio Tec Joddesinfektion
		Dufa dine 1,8%
		Alfasan super disinfectant
		lodes
		Streptoclean
		lodin Surface Disinfectant 1,8%
		IODINE
locid 30	EU-0022265-0000-08-01	locid 30
		lodo 30
		Dufa dine
		lodin Surface Disinfectant 2,8%
Iodo CIP	EU-0022265-0000-09-01	Iodo CIP
		locip
		Bio Tec Jodreiniger
		JODOPHOS SUPER 4001
		Bühning Jodreiniger
		Wynnsan Ice bank Tank
	1	Cleaner



		Bulk Tank Sanitizer
		Iodin CIP Disinfectant
Kenodin SD 900	EU-0022265-0000-10-01	Kenodin SD 900
		lodoSD 900
		IDip+ concentrate
		Jodkonzentrat 1:9
		Bühning Jodkonzentrat 1:9
		Wynnsan Iodine Conc dip 9-1
		Kenodin 900
		Dufa Dip
		Kenostart 900
		Iodin Teat Spray 900
		HCP Iodine Concentrate
		Maxi Subliem CP
		Subliem Koncentrat Plus
Kenodin 2500	EU-0022265-0000-11-01	Kenodin 2500
		lodin Teat Dip 2500
		Jod 2500
Kenodin 5000	EU-0022265-0000-12-01	Kenodin 5000
		lodoDip 5000
		JOD 5000
		Bio Tec Jodip 5000
		Bühning Jodfilmdip-Super
		locid 5000
		lod protect 5000 Film
		IOD protect 5000 Film
		locid
		lodip+
		Protetos cua
		Iodin Teat Dip 5000
Kenodin SD 5000	EU-0022265-0000-12-02	Kenodin SD 5000
		lodoSD 5000
		IODOSPRAY 5000
		Bio Tec Jodspray 5000
		IDip+ 5000
		Bühning Jodspray 5000
		lod protect 5000 Sprüh
		Kenodin Film Spray
		IOD protect 5000 Sprüh
		lodin Spray & Dip 5000

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



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 abovementioned 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-0022265-0000, 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

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