

HYPRED SAS
55, boulevard Jules Verger,
35803 DINARD,
France

Oslo, 27.01.2022

Your ref.:

Our ref.:
2018/11913

Contact person:
Marianne Stave Sekkenes

Amendment to the Norwegian authorisation of the Union Authorised biocidal product – HYPRED's iodine based products – EU-0018397-0000

We refer to your amendment of the implemented decision in EEA countries and Switzerland (EE-AAT) to the authorisation of the biocidal product HYPRED's iodine based products – EU-0018397-0000, R4BP 3 Case number BC-VD071759-21. The Norwegian Environment Agency hereby amends the Norwegian authorisation.
[Ingress]

Background

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

According to Article 17(6) of the BPR, the authorisation holder of a Union Authorisation shall notify the Agency and the Commission of each product within the biocidal product family at least 30 days before placing it on the market.

The Norwegian Environment Agency refers to Commission Implementing Regulation (EU) 2020/1995 of 4 December 2020 amending Implementing Regulation (EU) No 2018/1261 as regards administrative changes of the information related to the Union authorisation of the biocidal product family 'Hypred's iodine based products'.

The amendment of the implemented decision concerns a notification of new products in Meta SPC 1, 2, 3 and 5 to the biocidal product family, change of the name of the authorisation holder, addition of two manufacturers for the active substance and their respective manufacturing sites, change of administrative details of the manufacturer, addition of manufacturing location sites, and change of administrative details of manufacturing location sites. The amendments are found in Annex 1.

Evaluation

The evaluation of the Norwegian Environment Agency is that the applied for amendment to the authorisation of the biocidal product HYPRED's iodine based products is in line with the conditions for granting an authorisation laid down in Article 19 of the BPR.

Decision

The Norwegian Environment Agency hereby accepts the amendment to the Norwegian authorisation of the Union Authorised biocidal product (family) HYPRED's iodine based products.

No other changes than the above mentioned is accepted with this letter. Apart from the changes outlined in Annex I, the terms and conditions as stated in the authorisation letter dated 07.11.2018 apply.

The revised Summary of Product Characteristics (SPC) is uploaded to R4BP 3.

Label

In cases where the changes concerned in this letter have any consequences for the content on, or the design of the label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation number EU-0018397-0000 to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Marianne Stave Sekkenes
Senior Adviser

Annex 1 – Amendments of HYPRED's iodine based products (EU-0018397-0000)

Notification of new products in Meta SPC 1, 2, 3 and 5 to the biocidal product family:

Meta SPC 1:

Product name: Dip-io 2500
Trade name(s): IODOFILM
EMPRASAN UDDER SHIELD
ANGLIA FARMERS IO-FILM
BARRICADE
STANTON IODOFILM
WYNNSAN IOFILM TEAT DIP
Active substance(s): Iodine (CAS no. 7553-56-2)
Product type: PT 3 - Veterinary hygiene
Authorisation number with suffix: EU-0018397-0001 1-1

Meta SPC 2:

Product name: Liq-io 2500
Trade name(s): PRECEPT
ANGLIA FARMERS PRECLENZ
H&M PREDIP
FULLWOOD PRECLEANSE
M WILLIAMS PRECEPT
STANTON PREDIP RTU
WYNNSAN IODINE PREDIP RTU
PREMIER GOLD PRE-DIP
HODGES & MOSS PREDIP
LANODIP PREPOST
DAIRYSAN MULTICARE
EMPRASAN ADVANCE
UDDERWASH IODINE
ANGLIA FARMERS PREPOST-IO
PREMIER GOLD PRE/POST
FULLWOOD PRE/POST IODINE
HODGES & MOSS ADVANCE
WYNNSAN IODINE PREPOST
Active substance(s): Iodine (CAS no. 7553-56-2)
Product type: PT 3 - Veterinary hygiene
Authorisation number with suffix: EU-0018397-0003 1-2

Meta SPC 3:

Product name: Liq-io concentrate

Trade name(s): WYNNSAN IODINE CONCENTRATE
EMPRASAN OPTIMA
ANGLIA FARMERS CONC
PROLAC SENTINEL CONC
PREMIER GOLD CONCENTRATE
FULLWOOD IODINE CONC
H&M OPTIMA
SENTINAL CONC
HARRY TRAVIS SUPER CONC TEAT DIP
LANODIP CONC
E/SAN SOVEREIGN
PROLAC SENTINEL CONC

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

Product type: PT 3 - Veterinary hygiene

Authorisation number with suffix: EU-0018397-0005 1-3

Meta SPC 5:

Product name: Liq-io 5500

Trade name(s): GOLD GLYCODIP
EMPRASAN EXTRA CARE
H&M RTU IODINE
ANGLIA FARMERS SUPPLEDIP-IO
PROLAC RTU IODINE TEAT DIP
PREMIER GOLD POST DIP
FULLWOOD IODINE EXTRA
H&M EXTRACARE
M WILLIAMS TEAT DIP
PLATINUM
WDH GOLD DIP RTU
WYNNSAN IODINE HE RTU

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

Product type: PT 3 - Veterinary hygiene

Authorisation number with suffix: EU-0018397-0007 1-5

Change of the name of the authorisation holder:

From: HYPRED SAS

To: HYPRED SAS – KERSIA Group

Addition of manufacturers for the active substance and their respective manufacturing sites:

Manufacturer: ISE Chemicals Corporation
3-1, Kyobashi 1-Chome, Chuo-ku, Tokyo
Manufacturing site: Shirasato Plant (3695 Kitaimaizumi, Oamishirasato City, Chiba, Japan)

Manufacturer: Nihon Tennen Gas Development Co., Ltd
661 Mobara
297-8550 Mobara City, Chiba Japan
Manufacturing site: Chiba Plant, 2508 Minami Hinata, 299-4205 Shirako-Machi, Chosei-Gun,
Chiba Japan

Change of administrative details of the manufacturer:

From:

HYPRED SAS
55, Boulevard Jules Verger
BP 10180
35803 DINARD Cedex – FRANCE

To:

HYPRED SAS – KERSIA Group
55, Boulevard Jules Verger
BP 10180
35803 DINARD Cedex - FRANCE

Addition of manufacturing location sites:

- **AG France S.A.S – KERSIA Group**
Zone Industrielle Le Roineau,
72500 VAAS
FRANCE
- **KERSIA DEUTSCHLAND GmbH**
OBERBRÜHLSTRAÙE 16-18
87700 MEMMINGEN
GERMANY
- **KERSIA AUSTRIA GmbH**
PFONGAUERSTRAÙE 17
5202 NEUMARKT AM WALLERSEE
AUSTRIA
- **Kilco Holdings Ltd – KERSIA Group**
Broomhouses 2 Industrial Estate
Old Glasgow Road
LOCKERBIE - DG11 2SD
UNITED KINGDOM
- **Kilco (International) Ltd – KERSIA Group**
1A Trench Road Mallusk
Newtownabbey
CO ANTRIM BT36 4TY

IRELAND

- **Medentech Ltd – KERSIA Group**
Clonard Road
WEXFORD Y35Y7WY
IRELAND

Change of administrative details of manufacturing location sites:

From:

HYPRED SAS
55, Boulevard Jules Verger
BP 10180
35803 DINARD Cedex – FRANCE

To:

HYPRED SAS – KERSIA Group
55, Boulevard Jules Verger
BP 10180
35803 DINARD Cedex - FRANCE

From:

HYPRED POLSKA SP. Z O.O.
NIEPRUSZEWO, KASZTANOWA 4
64320 Buk Poland

To:

KERSIA POLSKA Sp.z.o.o
Niepruszewo, ul. Kasztanowa 4
64-320 BUK POLAND

From:

HYPRED IBERICA S.L
Pol. Ind. Arazuri-Orcoyen C/C n° 32
31160 Orcoyen – NAVARRA Spain

To:

KERSIA IBERICA SL
Pol. Miguel Eguía C/Zarapuz s/n
31200 ESTELLA (NAVARRA) SPAIN

From:

HYPRED GmbH
Marie-Curie-Straße 23
53332 Bornheim – Sechtem Germany

To:

KERSIA DEUTSCHLAND GmbH
Marie-Curie-Straße 23
53332 Bornheim – Sechtem Germany

From:

HYPRED Italia s.r.l
Strada Montodine-Gombito
Loc. Cà Nova
26010 Ripalta Arpina CR Italy

To:

HYPRED Italia s.r.l. – KERSIA Group
Strada Montodine-Gombito
Loc. Cà Nova
26010 Ripalta Arpina CR Italy

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
seksjonsleder

Marianne Stave Sekkenes