

Hypred SAS
55 Boulevard Jules Verger
35803 Dinard
France

Reykjavík, 16 February 2022
UST202202-158/H.I.I.
07.06.04

Amendment to the Icelandic authorisation of the Union authorised biocidal product family, HYPRED's iodine based products

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products and Commission Implementing Regulation (EU) No 354/2013 (on changes), are implemented into Icelandic legislation through the Icelandic Regulation No 878/2014 on biocidal products.

HYPRED's iodine based products is authorised in Iceland with an implementing decision in EEA countries and Switzerland (EE-APP), with reference to the Union Authorisation – EU-0018397-0000.

The Environment Agency of Iceland (Umhverfisstofnun) received your application for amendment of the implemented decision on 29 November 2021, Case No. BC-FY071758-97. The amendment concerns addition of trade names 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 and addition and change of manufacturing location site for HYPRED SAS as referred to in Sections 1 and 2 of Title 1 of the Annex to Commission Implementing Regulation (EU) No 354/2013 (on changes).

The application for administrative change of the Icelandic authorisation of the Union authorised biocidal product family is accepted with reference to Article 50(2) of Regulation (EU) No 528/2012 (BPR) and Commission Implementing Regulation (EU) No 2020/1995 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 concerns

- Addition of the following trade names:
 - o Product name: Liq-io 2500:
 - 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
- WYNNNSAN IODINE PREPOST
- Product name: Liq-io 5500:
 - 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
 - WYNNNSAN IODINE HE RTU
- Product name: Liq-io concentrate:
 - WYNNNSAN 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
- Product name: Dip-io 2500:
 - IODOFILM
 - EMPRASAN UDDER SHIELD
 - ANGLIA FARMERS IO-FILM
 - BARRICADE
 - STANTON IODOFILM
 - WYNNNSAN IOFILM TEAT DIP
- Change of the name of the authorization holder:
 - From: HYPRED SAS
 - To: HYPRED SAS – KERSIA Group.
- Addition of the following manufacturers for the active substance and their respective manufacturing sites:
 - Manufacturer: ISE Chemicals Corporation, 3-1, Kyobashi 1-Chrome, Chuo-ku, Tokyo, Japan.
Manufacturing site: Shirasato Plant, 3695, Kitaimaizumi, Oamishirasato City, Chiba, Japan.
 - Manufacturer: Nihon Tennen Gas Development Co., Ltd, 661 Mobar, 297-8550, Mobar 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:
 - o 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 the following manufacturing location sites:
 - o AG France S.A.S - KERSIA Group - Zone Industrielle Le Roineau, 72500 VAAS, France.
 - o KERSIA DEUTSCHLAND GmbH, OBERBRÜHLSTRAÙE 16-18, 87700 MEMMINGEN, Germany.
 - o KERSIA AUSTRIA GmbH, PFONGAUERSTRAÙE 17, 5202 NEUMARKT AM WALLERSEE, Austria.
 - o Kilco Holdings Ltd - KERSIA Group, Broomhouses 2 Industrial Estate, Old Glasgow Road, DG11 2SD LOCKERBIE, United Kingdom.
 - o Kilco (International) Ltd - KERSIA Group, 1A Trench Road Mallusk, Newtownabbey, BT36 4TY CO ANTRIM, Ireland.
 - o Medentech Ltd - KERSIA Group, Clonard Road, Y35Y7WY WEXFORD, Ireland.

- Change of the administrative details for the following manufacturing location sites:
 - o 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.
 - o 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.
 - o 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/Zarapus s/n, 31200 ESTELLA (NAVARRA), Spain.
 - o From: HYPRED GmbH, Marie-Curie-StraÙe 23, 53332 Bornheim – Sechtem, Germany.
To: KERSIA DEUTSCHLAND GmbH, Marie-Curie-StraÙe 23, 53332 Bornheim – Sechtem, Germany.
 - o 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.

Accordingly, the Environment Agency of Iceland has made the relevant changes to the Summary of Product Characteristics (SPC) under asset number IS-0019639-0000. The relevant criteria for the biocidal product authorisation apply as described therein.

Sincerely

Hafdís Inga Ingvarsdóttir
Advisor