



Prodhynet SA
11 avenue des châtelets
22440 PLOUFRAGAN
Frankrike

Oslo, 14.11.2018

Your ref.:
[Your ref.]

Our ref. :
2018/1942

Contact person:
Merete Dæhli

Norwegian Authorisation of the Union Authorised product family Prodhynet's iodine based products – same biocidal product family

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. Further, the Regulation (EU) No 414/2013 on the procedure for authorisation of same biocidal products applies.

The Norwegian Environment Agency refers to Commission Implementing Regulation (EU) 2018/1288 of 25 september 2018 granting a Union authorisation for the same biocidal product family **Prodhynet's iodine based products** (EU-0018497-0000), related to the reference product Hypred's iodine based products' (EU-0018397-0000).

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.

The Norwegian Environment Agency hereby grants authorisation for the biocidal product family **Prodhynet's iodine based products**, issued in accordance with the Commission Regulation Regulation (EU) 2018/1288 of 25 september 2018, cf. the Norwegian Biocides Regulation § 3-1.

The authorisation concerns:

Product family name: Prodhynet's iodine based products

EU Authorisation number: EU-0018497-0000

Active substances: Iodine

Product type: Veterinary hygiene – PT 3

Authorisation date: 14.11.2018

Expiry date: 30.09.2028

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-0018497-0000, 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.

Yearly fee

For authorised biocidal products, a yearly fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details.

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 <http://miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/>.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
Head of Section

Merete Dæhli
Senior Adviser