

Applied Biocide GmbH
Siemensstraße 42,
59199 Bönen,
Germany

Oslo, 04.10.2021

Your ref.:

Our ref.:
2018/10825

Contact person:
Marianne Stave Sekkenes

Amendments to the Norwegian authorisation of the Union Authorised biocidal product family – BPF_Iodine_VET - EU-0020540-0000

We refer to your amendments of the implemented decision in EEA countries and Switzerland (EE-AAT) to the authorisation of the biocidal product family BPF_Iodine_VET - EU-0020540-0000, R4BP 3 Case numbers BC-WM064604-18, BC-VN064607-11, BC-KX064610-15 and BC-FQ064613-28. The Norwegian Environment Agency hereby amends the Norwegian authorisation.

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 amendment of the implemented decision concerns a notification of a new product in Meta SPC 4 and 5, to the biocidal product family.

Meta SPC 4:

Product name:	FINK – Iodip 15
Trade name(s):	FINK – Iodip 15 Euter-Dip FINK – Euter-Dip PVP-D
Active substance(s):	Iodine (CAS no. 7553-56-2.)
Product type:	PT 3 - Veterinary hygiene
Authorisation number with suffix:	EU-0020540-0014 1-4

Meta SPC 5:

Product name: FINK – Iodine Dip 30
Trade name(s): FINK – Iodine Dip 30
Iodine Dip 30
ST – Iodine Dip
DESINTEC MH Iodine Film
Iodine Dip 3000
Iodine Dip
Active substance(s): Iodine (CAS no. 7553-56-2.)
Product type: PT 3 - Veterinary hygiene
Authorisation number with suffix: EU-0020540-0015 1-5

Product name: FINK – Iodine Dip 50
Trade name(s): FINK – Iodine Dip 50
Iodine Dip 50
Iodine Dip 5000
IODOPLUS 5000
Active substance(s): Iodine (CAS no. 7553-56-2.)
Product type: PT 3 - Veterinary hygiene
Authorisation number with suffix: EU-0020540-0013 1-5

Product name: YODIN RTU
Trade name(s): YODIN RTU
Active substance(s): Iodine (CAS no. 7553-56-2.)
Product type: PT 3 - Veterinary hygiene
Authorisation number with suffix: EU-0020540-0016 1-5

Evaluation

The evaluation of the Norwegian Environment Agency is that the applied for amendments to the authorisation of the biocidal product family BPF_Iodine_VET are 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 BPF_Iodine_VET.

No other change(s) than the above mentioned is accepted with this letter. Apart from the change(s) outlined above, the terms and conditions as stated in the authorisation letter dated 18.02.2020 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 numbers 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