Myggstopp Nordic AS
Lundehaugveien 12
5357 FJELL

Oslo, 12.03.2019

Your ref.:	Our ref. :	Contact person:
[Your ref.]	2015/11173	Kjetil Haugstad

Authorisation of same biocidal product – Insect repellent pump spray IR3535 20% – NO-2019-0163

We refer to your application for authorisation of the biocidal product Insect repellent pump spray IR3535 20%, R4BP 3 Case number BC-LK020304-51 as a same biocidal product, with reference to the related reference product Insect repellent pump spray (NO-2018-0156).

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 Biocide Regulation 18 April 2017 No. 480. The conditions for granting an approval of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply. For applications for same biocidal products, Regulation (EU) No 414/2013 on the procedure for authorisation of same biocidal products also applies.

Decision
Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation and Regulation (EU) 414/2013 on the procedures for authorisation of same biocidal products, the Norwegian Environment Agency grants an authorisation of Insect repellent pump spray.

The expiry date shall be set identical to the expiry date of the related reference product, cf. Regulation (EU) 414/2013. This means that the authorisation of Insect repellent pump spray is granted until 16.05.2027.

The authorisation concerns

Product name: Insect repellent pump spray

Trade name: -Myggstopp spray active plus.
-Myggstopp flåttspray

Active substance: Ethyl butylacetylaminopropionate (IR3535; 20%)

Product type: Repellants and attactants – PT 19

Authorisation holder in Norway: Myggstopp Nordic AS

Authorisation number: NO-2019-0163

Authorisation date: 12.03.2019

Expiry date: 16.05.2027

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

The Norwegian Environment Agency may, in accordance with article 48 of the BPR, cancel or amend the authorisation should new information on the product, the related reference product or the active substances come to our attention that may affect the authorisation. Should the authorisation holder be aware of such information, the Norwegian Environment Agency should be notified without delay.

According to Article 31(1) of the BPR, an application for a renewal of the authorisation has to be submitted 550 days before the authorisation period expires, at the latest.

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 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.

An electronic copy of the label with the Norwegian authorisation number NO-2019-0163 shall 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 not comply with the new conditions, should also be removed from the market.

Changes to the authorisation

If it is desirable to make any changes to the product authorisation, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This procedure is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

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 Product Register by using the biocide notification form. In addition, biocidal products which are classified as hazardous must be fully declared, using the declaration form, if they are sold in amounts of 100 kg or more per year. Forms and further information can be found on our website
http://miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/.

Appeal
This decision can be appealed to the Ministry of Climate and Environment, in accordance with Article 28 of the Public Administration Act. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with Article 29 of the Public Administration Act.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen	Kjetil Haugstad
Head of Section	Senior Adviser