

Merck KGaA  
Frankfurter strasse  
64293 Darmstadt  
Tyskland

Oslo, 04.05.2022

Your ref.:

Our ref.:  
2015/8449

Contact person:  
Lina Agneberg Dahl

## Amendment to authorisation – Insect Repellent Pump Spray IR3535 20% – NO-2018-0156

We refer to the change to the authorisation of the biocidal product Insect Repellent Pump Spray IR3535 20% – NO-2018-0156, R4BP 3 Asset number NO-0019825-0000. The Norwegian Environment Agency hereby amends the authorisation.

### Background

According to Article 50(2) of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Product Regulation, BPR), the Competent Authority shall decide whether a change of an authorised biocidal product can be accepted with regard to ensuring compliance with Article 19 or, where relevant, Article 25, and whether terms and conditions of the authorisation need to be amended. Procedures for amendments to a product authorisation are further described in Regulation (EU) No 354/2013.

Regulation (EU) No 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

As the Norwegian Environmental Agency have been made aware of several changes to the SPC done by the rMS, with reference to Article 19(5) of the BPR, CA-Nov-Doc.4.7 and Commission Implementing Decision (EU) 2018/1477 of 2 October 2018, we have updated the Norwegian SPC accordingly.

The amendment to the authorisation of Insect Repellent Pump Spray IR3535 20% concerns number of application doses per application, number of applications per day, separation into two age groups for use for children, addition of protection time and addition of some points regarding personal precautions, protective equipment, and emergency procedures.

### Evaluation

The evaluation of the Norwegian Environment Agency is that the amendment to the authorisation of the biocidal product Insect Repellent Pump Spray IR3535 20% is in line with the conditions for granting an authorisation laid down in Article 19 of the BPR.

## Decision

Subject to Articles 50 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency accepts the changes to Insect Repellent Pump Spray IR3535 20% and amends the authorisation in line with the changes.

No other changes than the above mentioned are accepted with this letter. Apart from the changes outlined above, the terms and conditions as stated in the authorisation letter dated 16.11.2018 apply.

The revised Summary of Product Characteristics (SPC) is uploaded to R4BP3.

## Label

In cases where the changes described in this letter have any consequences for the content on, or the design of the label, you are kindly requested to implement these changes for the next label print out, and submit an electronic copy of the revised label with the Norwegian authorisation number NO-2018-0156 to [biocides@miljodir.no](mailto:biocides@miljodir.no) when this is done.

## 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*

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Head of Section

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Adviser