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35390 Grand Fougeray,
France

Oslo, 15.06.2021

France
Your ref.:

Our ref.:
2019/14394

Contact person:
Marianne Stave Sekkenes

Amendment to the authorisation of ALPHACHLORALOSE GRAIN – NO-2019-0181

We refer to your application for minor and administrative changes to the authorisation of the biocidal product family ALPHACHLORALOSE GRAIN - NO-2019-0181, R4BP 3 Case no BC-JJ058091-44. The Norwegian Environment Agency hereby amends the authorisation.

Background

According to Article 50(2) in 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.

The amendment to the authorisation of ALPHACHLORALOSE GRAIN concerns deletion, additions and change of non-active substances in the composition, change of pack size ranges and addition of a manufacturer of the active substance, and are classified as minor changes in accordance with the criteria laid down in Title 2 and as an administrative change in accordance with the criteria laid down in Section 1 of Title 1 of the Annex to Regulation (EU) No. 354/2013.

Evaluation

The evaluation of the Norwegian Environment Agency is that the sought amendment to the authorisation of the biocidal product family ALPHACHLORALOSE GRAIN 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 proposed changes to ALPHACHLORALOSE GRAIN and amends the authorisation in conformity with the applied changes.

No other changes than the above mentioned is accepted with this letter. Apart from the changes outlined above, the terms and conditions as stated in the authorisation letter dated 18.12.2019 apply.

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

Period of grace

In accordance with Article 52 of the BPR, when an authorisation is amended, the Competent Authority shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned, with effect from the date of this letter.

Label

In cases where the change(s) accepted 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 number NO-2019-0181 to biocides@miljodir.no within three months from the date of this letter.

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

Erlend Spikkerud
Head of Section, Biocides

Marianne Stave Sekkenes
Senior Adviser

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Appendices