Lodi S.A.S.
Parc d'Activités des Quatre Routes
35390 Grand Fougeray, France

Oslo, 24.04.2020

Your ref.:	Our ref. :	Contact person:
[Your ref.]	2019/14395	Hilde Mariken Andersen

Amendment to the authorisation of ALPHACHLORALOSE PASTA – NO-2019-0182

We refer to the Norwegian authorisation of the biocidal product family ALPHACHLORALOSE PASTA – NO-2019-0182, R4BP 3 asset no NO-0021975-0000, containing the active substance alphachloralose, and to the amendment made by the Swedish Chemicals Agency on the authorisations of rodenticide products with alphachloralose as active substance, dated 17th of December 2019. The Norwegian Environment Agency hereby amends the terms and conditions of the current authorisation subject to Article 48(3) of the Biocidal Products Regulation. The amendment concerns removal of the general public as a user category, in addition to other risk mitigation measures.

Decision

According to Article 48(3), ref Biocide Regulation of 18 April 2017 No. 480 § 1, the Norwegian Environment Agency amends the authorisations of rodenticide products with alphachloralose as the active substance. The amendment concerns the following:

- Removal of the general public as a user category
- Addition of the following risk mitigation measures which must be included on the product label:
    - The product must not be used in environments where cats may be expected to be present.
    - Dead mice must be collected.

Apart from the change(s) 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.

Background

Reported cases of poisoning by alphachloralose

Over the past two years, Norwegian veterinarians have reported an increase in suspected cases of alphachloralose poisonings among pets. Upon our request, veterinary clinics in Norway have reported a high number of cats (and some dogs) being treated for suspected alphachloralose

poisoning. In an ongoing project at the Norwegian Veterinary Institute, chemical analyses have so far identified alphachloralose in samples from 26 pets where alphachloralose poisoning was suspected based on the symptoms. The Norwegian Environment Agency has received information indicating that the present use of biocidal products containing the active substance alphachloralose might cause secondary poisoning. Reports to support this suspicion include information that mice have been found in the digestive system of deceased cats which presented symptoms of alphachloralose poisoning prior to death. In addition, several owners have observed their cat ingesting mice shortly prior to developing symptoms of alphachloralose poisoning, and veterinarians have identified remnants of mice after vomiting was induced in cats with these symptoms.

The Norwegian Environment Agency considers that the reports from Norwegian veterinary clinics are reliable and trustworthy, and that the professional assessment of the case history and clinical findings done by the veterinarians meets the requirements of objectivity and scientific method.

Sweden has also experienced a dramatic increase in alphachloralose poisoning incidents. Thus, on the 17th of December 2019 the Swedish Chemicals Agency amended the authorisations of rodenticide products with alphachloralose as active substance, according to Article 48, ref. art. 19 (1)(b)(iii) of Regulation (EU) No 528/2012 (BPR).

Biocidal products containing alphachloralose were previously authorised for professional (user class 2) and non-professional (user class 3) use in Sweden. The applied change was to restrict the user class to trained professionals with a special permit. Other risk mitigation measures include the following: "The product must not be used in environments where cats may be expected to be present" and "Dead mice must be collected" which must be included on the product label.

Current authorised terms and conditions
In Norway, we have national authorisations for one single biocidal product and two biocidal product families affected by the Swedish amendment following the use of Article 48 of the BPR. This concerns the following authorisations: ALPHACHLORALOSE PASTA (NO-2019-0182), ALPHACHLORALOSE GRAIN (NO-2019-0181) and Protect home express (NO-2019-0164).

The biocidal product family amended with this decision, is ALPHACHLORALOSE PASTA which was granted an authorisation in Norway 18th December 2019 subject to Article 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation. However, one of the members in the biocidal product family, called Black Pearl Pasta (NO-2015-0092), has been authorised in Norway since 19th of March 2015.

The current authorised terms and conditions include indoor use against mice (adults and juveniles) by both the general public (non-professionals) and trained professionals. Solid bait stations are required, and the products in the biocidal product family are sold separately as refill.

Notification
On the 11th of February 2020, the Norwegian Environment Agency informed the authorisation holder LODI S.A.S, that we consider the terms of Article 19.1 b iii of the BPR not to be fulfilled, and thus intended to amend the national authorisation according to Article 48 in the cited regulation. We informed that a restriction to trained professional would be appropriate as a risk mitigation

measure for the product family in question, in order to protect cats from possible secondary poisoning. In addition, we suggested including a claim to inform the possible bystanders of the risk of secondary poisoning of cats.

The authorisation holder was offered to comment to this notification within the 24th of February 2020. This deadline was extended, and we received their comments by the 16th of March 2020.

LODI S.A.S view is that it has not been provided any scientific information linking the alphachloralose intoxications to secondary poisoning or a particular biocidal product placed on the market. Further, the authorisation holder states that the poisoning cases are best described as primary poisoning of cats, and that the risk of secondary poisoning of cats is highly unlikely due to certain toxicokinetic properties. They also claim that any risks of secondary poisoning would be effectively mitigated by restricting the biocidal products' use to pre-filled bait stations.

Evaluation
The Biocidal Products Regulation (BPR, (EU) No 528/2012) is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

According to Article 48(3), competent authorities that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly.

We consider the Norwegian conditions to be comparable to the Swedish, due to similarity both in the use of rodenticides, climatic conditions and how pets are kept. We have also experienced the same increase in alphachloralose-poisoning incidents and share the Swedish Chemicals Agency's suspicion for secondary poisoning. Thus, according to Article 48(3), ref. Biocide Regulation of 18 April 2017 No. 480 § 1, we amend the authorisations of rodenticide products containing alphachloralose in accordance with the Swedish amendment. The amendment concerns removal of the general public as a user category, in addition to other risk mitigation measurements.

Period of grace
In accordance with Article 52 of the BPR, ref. Biocide Regulation of 18 April 2017 No. 480 § 1, 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. The Norwegian Environment Agency considers that keeping these products on the market would constitute an unacceptable risk and grants a period of grace not exceeding 14 days.

Label
In cases where the change(s) accepted in this letter have any consequences for the content on or the design of the product label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation number NO-2019-0182 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

Trine-Lise Torgersen
Head of Section

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