BASF Wolman GmbH
Dr.-Wolman-Strasse 31-33
76547 Sinzheim
Germany

Oslo, 09.04.2019

Your ref.:
[Your ref.]

Our ref. :
2014/6464

Contact person:
Marianne Stave Sekkenes

Approval of a Major Change to the biocidal product authorisation – Wolsit KD-10 – NO-2014-0041

We refer to your application for a change to the biocidal product authorisation for Wolsit KD-10 – NO-2014-0041, R4BP 3 Case no BC-DF022051-74.

According to Article 50 (2) in Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, changes to the conditions laid down in a biocidal product authorisation shall be approved by the Competent Authority. Changes 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 change to the authorisation of Wolsit KD-10 concerns an amendment of the risk assessment for human health and the environment due to an update of the classification. The change qualified a co-formulant in the product as a Substance of Concern which triggered a risk assessment of this substance. The change is classified as a major change, in accordance with the criteria laid down in Title 3 of the Annex to Regulation (EU) No. 354/2013. The change has been evaluated by UK as the reference member state and has been discussed in the Coordination Group (CG) in order to reach an agreement. The decision by the reference member state has been mutually agreed by the Norwegian Environment Agency.

Decision
Subject to Articles 19 and 50 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency approves the proposed change to the authorisation of Wolsit KD-10.

No other changes than the above mentioned is accepted with this letter. Apart from the change(s) outlined above, the authorisation conditions as stated in the authorisation letter dated 31.01.1014 are valid.

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, a period of grace is granted for the making available on the market and use of existing stocks. Exceptions are made 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.

Revised labels
An electronic copy of the revised label with the Norwegian authorisation number NO-2014-0041, shall be submitted to the Norwegian Environment Agency within three months from the date of this letter, using the email address biocides@miljodir.no.

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

Marianne Stave Sekkenes
Senior Adviser