



Bayer A/S
Arne Jacobsens Allé 13
2300 København S
Danmark
Att: Anne Mc Nair

Oslo, 18.12.2015

Your ref.:
[Your ref.]

Our ref. :
2014/14640

Contact person:
Suzanne Collett Gordon

Change to biocidal product authorisation - Racumin Foam - NO-2014-0089

We refer to the application for a change to the biocidal product authorisation for Racumin Foam - NO-2014-0089 (Case no. BC-HU016002-41).

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 treated in Regulation (EU) No 354/2013.

The change to Racumin Foam concerns extension of the shelf-life of the product to 4 years, and is classified as a minor change, in accordance with the criteria laid down in Title 2 of the Annex to Regulation (EU) No. 354/2013.

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 Racumin Foam.

No other changes than the above mentioned is accepted with this letter. Apart from the change outlined above, the authorisation conditions as stated in the authorisation letter dated 19th December 2014 are valid.

The revised SPC is enclosed, and the Word file is uploaded as an enclosure to the decision in R4BP. Please note that the SPC uploaded in R4BP is only an empty "dummy" SPC needed to finalise the application in R4BP. For the next application for a change to the product, you are requested to upload in R4BP the actual Norwegian SPC through the SPC editor.

If the product label will be updated due to this change, we kindly request that the revised label (mock-ups of final artwork) is submitted to biocides@miljodir.no within three months.

Appeal

This decision can be appealed to the Ministry of Climate and Environment, in accordance with § 7 of the Norwegian Biocide Regulation. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with § 28 of the Norwegian Public Administration Act.

Yours sincerely,
Norwegian Environment Agency



Eli Vike
Head of Section



Suzanne Gordon
Senior Adviser

Enclosure: Updated SPC