



Protim Limited
c/o Grant Thornton,
13-18 City Quay,
D02 ED70 Dublin 2,
Ireland

Oslo, 30.08.2019

Your ref.:
[Your ref.]

Our ref. :
2014/2029

Contact person:
Marianne Stave Sekkenes

Acceptance of notification of administrative change - Protim P-Vac 11 - 2014-0043

We refer to your notification for an administrative change to the biocidal product authorisation for Protim P-Vac 11 - 2014-0043, R4BP3 Case number BC-UY053129-97.

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 accepted/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.

We hereby confirm that we accept the notification for an administrative change to Protim P-Vac 11. The notification concerns change in the details of the product manufacture and manufacture sites as referred to in Section 2 of Title 1 to the Annex to Regulation (EU) No 354/2013. No other changes than the above mentioned is accepted with this letter.

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

In cases where the changes concerned 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 (final artwork) with the Norwegian authorisation number NO-2014-0043 to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Marianne Stave Sekkenes
Senior Adviser