



Protim Solignum Ltd.
Fieldhouse Lane, L7 1LS Marlow
Buckinghamshire
Great Britain

Oslo, 01.11.2017

Your ref.:
[Your ref.]

Our ref. :
2014/2029

Contact person:
Merete Dæhli

Acceptance of notification of administrative change

We refer to your notification for an administrative change to the biocidal product authorisation for Protim P-Vac 11 (NO-2014-0043), Case BC-GK033658-32.

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 changes to Protim P-Vac 11. The notification concerns change of manufacture for propiconazole, as described in the Supporting document.

We have also noticed the change of authorisation holder from Osmose Sweden AB to Protim Solignum Ltd. In addition, compared with the old SPC template, there is changes to the classification and labelling to comply with the CLP regulation. According to the change regulation (EU) No 354/2013 Title 1, Section 1.3 and Title 1, Section 2.11 respectively, these two changes should also been notified via R4BP 3. However, all changes mentioned is accepted with this letter.

The content of the last uploaded SPC did still not correspond with the content of the old SPC template, thus we have made some corrections. We have uploaded the revised SPC in R4BP3.

In some cases a PDF-file of the SPC is automatically generated in R4BP3. In such cases, please refer to the uploaded SPC in XML-format, as the automatically generated PDF-file generally seems to contain some errors.

We kindly request that the revised label (final artwork) is submitted to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Merete Dæhli
Senior Adviser