Rütgers Organic GmbH
Oppauerstr. 43,
68305 Mannheim,
Germany

Oslo, 17.08.2020

| Your ref.: | Our ref. : | Contact person: |
|---|---|---|
| [Your ref.] | 2018/12970 | Marianne Stave Sekkenes |

# Authorisation of Impralit ACA protect family – NO-2020-0190

**We refer to your application for mutual recognition of the biocidal product family Impralit ACA protect family (R4BP case no. BC-AW043748-11), containing the active substances tebuconazole, basic copper carbonate and propiconazole. The Norwegian Environment Agency hereby grants authorisation.**

**Background**
Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480. The conditions for granting an authorisation of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. To facilitate the renewal procedure, it is agreed (CA-Sept14-Doc.5.7 –Final) that authorisations granted by the concerned Member States should have the same expiry date as the authorisation which is granted by the reference Member State.

**Evaluation**
Tebuconazole is, however, considered a candidate for substitution, since it meets two of the criteria for being PBT (very persistent and toxic, but not bioaccumulative). Under Article 23(1) of the BPR, Member States evaluating biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1), are required to perform a comparative assessment. The Norwegian Environment Agency has performed a screening comparative assessment and has concluded that the criteria of Article 23(3) of BPR are not met. The Norwegian Environment Agency finds that the conclusions made by the Reference member state are valid also in Norway. The product can therefore be authorised for a period not exceeding 5 years.

Propiconazole is considered a candidate of exclusion, since it meets the criteria for being classified as toxic for reproduction category 1B according to 13$^{th}$ ATP to CLP. Propiconazole, however, satisfies the conditions laid down in Article 5(2)(c), meaning that not authorising products containing this active substance would have disproportionate negative consequences for society in

comparison with the risk associated with the use. This imply that propiconazole satisfies the criteria given in Article 10(1)(a) and must be viewed as a substance eligible for substitution. Under Article 23(1) of the BPR, Member States evaluating biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1), are required to perform a comparative assessment. The Norwegian Environment Agency has performed a screening comparative assessment and has concluded that the criteria of Article 23(3) of BPR are not met. The product can therefore be authorised for a period not exceeding 5 years.

**Decision**
Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants an authorisation of Impralit ACA protect family until 09.06.2022.

**The authorisation concerns:**

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| Product family name: | Impralit ACA protect family |
| Active substance: | Tebuconazole (CAS no.: 107534-96-3)<br>Basic Copper Carbonate (CAS no.: 12069-69-1)<br>Propiconazole (CAS no.: 60207-90-1) |
| Product type: | PT08 (wood preservatives) |
| Authorisation holder in Norway: | Rütgers Organic GmbH |
| Family authorisation number: | NO-2020-0190 |
| Authorisation date: | 17.08.2020 |
| Expiry date: | 09.06.2022 |

Product family member(s):

| **Product name** | **Authorisation number** | **Trade name(s)** |
|---|---|---|
| *Impralit ACA protect* | *NO-2020-0190-01-01* | *Impralit ACA protect* |
| *Impralit ACA protect brown* | *NO-2020-0190-01-02* | *Impralit ACA protect brown* |

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP.

The Norwegian Environment Agency may, in accordance with article 47 of the BPR, cancel or amend the authorisation should new information on the product or the active substance come to our attention that may affect the authorisation. Should the authorisation holder be aware of such information, the Norwegian Environment Agency should be notified without delay.

According to Article 31(1) of the Biocidal Products Regulation, an application for a renewal of the authorisation must be submitted 550 days before the authorisation period expires, at the latest.

**Label**
The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in accordance with the conditions provided in the attached SPC. Furthermore, Article 69(1), (2) and Article 70 of the BPR also apply.

The authorisation holder is responsible for ensuring that the information given in the above-mentioned documents is accurate, and is translated to Norwegian, cf. Article 69(3) of the BPR.

An electronic copy of the label with the Norwegian authorisation number NO-2020-0190 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

**Phase-out period of existing stocks, when relevant**
In line with Article 89(4), existing products that do not comply with the conditions of this authorisation, shall not be made available on the market with effect from 180 days after the date of this letter. Furthermore, the use of existing stocks of the biocidal product may continue for up to 365 days after the date of this letter. During this period, all advertising material related to products that do not comply with the new conditions, should also be removed from the market.

**Changes to the authorisation**
If it is desirable to make any changes to the product authorisation, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This procedure is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

**Annual fee**
For authorised biocidal products on the Norwegian market, an annual fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. We kindly ask you to inform us using the e-mail address biocides@miljodir.no if you do not intend to place the product (family) on the Norwegian market, and therefore should not be charged with the annual fee.

**Registration in the Norwegian Product Register**
All biocidal products must be registered in the Norwegian Product Register. In addition, all biocidal products which are classified as hazardous must be fully declared if they are sold in amounts of 100 kg or more per year. Further information can be found at
https://tema.miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/

**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