The Commission is carrying out an early review of the approval of the active substance propiconazole for use in biocidal products of product type 7 and 9

Before a biocidal active substance can be approved by the Commission, its safety for human health, animal health and the environment as well as its effectiveness against harmful organisms are evaluated. Based on this evaluation, the Commission may approve the active substance after consultation of Member States. The approval Regulation specifies the date of approval, when the approval will expire, and specific conditions or measures for the use of the active substance in biocidal products.

Article 15(1) of the Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR) provides that the Commission may review the approval of a biocidal active substance for one or more product-types at any time where there are significant indications that the conditions set in the BPR to approve an active substance are no longer met. Article 15(1) of the BPR requires that the Commission makes public the information that it carries out such a review.

Propiconazole has been classified as toxic for reproduction, category 1B, in accordance with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of chemical substances and mixtures (CLP Regulation). Moreover, it has been identified as having endocrine disrupting properties that may cause adverse effects in humans and in the environment[1]. Article 5(1) of the BPR provides that active substances meeting the criteria to be classified as toxic for reproduction, category 1B, and/or considered as having endocrine disrupting properties that may cause adverse effects in humans shall normally not be approved, unless the conditions set out in Article 5(2) of the BPR are met.

Furthermore, unacceptable risks have been identified in the context of the mutual recognition of applications for authorisation of biocidal products containing the substance related to the use of treated articles including or incorporating propiconazole to human health and the environment.

In accordance with Article 15(1) of the BPR, the Commission considers that there are significant indications that the use of propiconazole in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles, and that the conditions laid down in Article 4(1) of this Regulation are no longer met. Consequently, a review of the approval of that substance for use in biocidal products of product type 7 and 9 has been found necessary.

Contact details of responsible service

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Reference documents:

- Information on the Biocidal Products Regulation: https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

[1] Opinion adopted by ECHA's Biocidal Product Committee in the context of the examination of the application for renewal of approval for use in biocidal product-type 8 (https://echa.europa.eu/documents/10162/2b615a3d-38d2-0087-31b6-dda6cfea6902)

- Information on active substances approved for use in biocidal products:
https://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

- Link to Commission DG SANTE website on review of approval procedure
https://ec.europa.eu/health/biocides/active_substances/review_approval_en