

Committee for Risk Assessment
RAC

Annex 3
Records

of the targeted public consultation following submission of additional experimental information on aquatic species generated during the procedure for renewal of the approval of prothioconazole in accordance with Commission implementing regulation (EU) No 844/2012

Prothioconazole (ISO); 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione

EC Number: -
CAS Number: 178928-70-6

CLH-O-0000001412-86-269/F

Adopted
15 March 2019

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON PROTHIOCONAZOLE (ISO); 2-[2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-2-HYDROXYPROPYL]-2,4-DIHYDRO-3H-1,2,4-TRIAZOLE-3-THIONE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

During the process of the preparation of the first draft opinion, RAC became aware of additional information generated during the procedure for renewal of the approval of prothioconazole in accordance with Commission implementing regulation (EU) No 844/2012. This additional information was submitted in November 2018 and reviewed by RAC. Additional information provided in November 2018 refers to four new experimental studies performed with two degradation products of prothioconazole. Since additional information was submitted, ECHA launched the targeted public consultation (7 – 21 January 2019).

Comments provided during the targeted public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: prothioconazole (ISO); 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione

EC number: -

CAS number: 178928-70-6

Dossier submitter: United Kingdom

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
21.01.2019	United Kingdom		MemberState	1
Comment received				
<p>We welcome the opportunity to consider the new aquatic studies submitted via the pesticide review for prothioconazole in terms of their potential impact on the 2018 harmonised hazard classification proposal. The previous aquatic hazard classification proposal was based on data on both the parent substance and its main degradant (prothioconazole-desthio) since rapid primary degradation was seen in simulation tests. There was not however rapid ultimate degradation and so prothioconazole is considered 'not rapidly degradable' - however, since it is rapidly formed at a high percentage, the toxicity and classification of the main degradant, prothioconazole-desthio, was also considered. The data on prothioconazole-desthio indicated however, that it was of similar or lower acute and chronic aquatic toxicity to the parent substance and so would not affect the classification proposals for the parent substance of Category Acute 1 (Acute M-Factor: 10), Category Chronic 1 (Chronic M-Factor: 1).</p> <p>The most recent studies include data on the acute and chronic effects of more minor degradants of prothioconazole to fish, Daphnia and two species of algae. These minor degradants were not previously considered in detail in the classification dossier as they do not form a high percentage (5-10%) of applied radioactivity in degradation studies, see</p>				

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Section 11.1.4.3 in original CLH Report. Therefore, these new studies are not considered to affect the original aquatic classification proposals in the 2018 CLH Report based on prothioconazole and prothioconazole-desthio data alone

RAC's response

Noted