

Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

pyridaben (ISO)

EC number: 405-700-3
CAS number: 96489-71-3

CLH-O-0000002480-82-02/A2

Adopted
23 August 2013

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON PYRIDABEN (2-TERT-BUTYL-5-(4-TERT-BUTYLBENZYLTHIO)-4-CHLOROPYRIDAZIN-3(2H)-ONE)**COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION**

ECHA has compiled the comments received via the internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensively as possible. Please note that some of the comments might occur under several headings, when splitting the information provided is not reasonable.

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Substance name: Pyridaben (2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one)**EC number: 96489-71-3****CAS number: 405-700-3****GENERAL COMMENTS**

Date	Country	Organisation	Type of Organisation	Comment number
31.01.2013	France		MemberState	1
Comment received				
We agree with the classification proposal for human health and environmental hazards: Aquatic acute 1 (H400) M factor = 1000 Aquatic chronic 2 (H 410) M factor = 1000				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
30.01.2013	Germany		MemberState	2
Comment received				
The German CA supports to established a harmonised classification and labelling for pyridaben, which is an active ingredient in plant protection products.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
28.12.2012	Spain		MemberState	3
Comment received				
p. 18 Conclusions on classification and labelling for acute toxicity				
Pyridaben is listed in Annex VI of 1272/2008/EEC Regulation (CLP). The current classification for acute oral toxicity is as follows: Acute Tox. 3* H301 (minimum classification) and Acute Tox. 3* H331 (minimum classification) under the CLP Regulation and T: R23/25 under 67/548/EEC (DSD).				

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<p>After reviewing the available acute toxicity data, the Spanish CA supports the proposal to update the current classification under the CLP by removal of the minimum classification indicated by the reference (*) and to maintain unchanged the current classification under the DSD.</p> <p>Therefore, according to CLP classification criteria, pyridaben should be classified as Acute Tox. Category 3 H301, for the oral route because the lowest LD50 (161 mg/kg bw in male rat) is within the limits, $50 < ATE \leq 300$ (oral, mg/kg bw) and as Acute Tox. Category 3 H331, for the inhalation route because the LC50 (0.62 mg/L in female rat) is within the limits, $0.5 < ATE \leq 1.0$ (dusts and mists (mg/L)). The current classification according to DSD should remain unchanged as T; R23/25.</p>
Dossier Submitter's Response
Thank you for your support.
RAC's response
Noted

Date	Country	Organisation	Type of Organisation	Comment number
30.01.2013	Germany		MemberState	4
Comment received				
<p>The German CA supports to classify pyridaben for acute toxicity category 3 (H301 and H331) based on the present data. The proposed environmental classification (H400, H410) with the corresponding M-factors (acute and chronic 1000) respectively concentration limits is supported.</p>				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
01.02.2013	Sweden		MemberState	5
Comment received				
<p>SE supports the environmental classification of Pyridaben (Cas No 96489-71-3) as specified in the proposal. SE agrees with the rationale for classification into proposed hazard classes and differentiations.</p> <p>Pyridaben fulfills the criteria for classification as aquatic environmental hazard acute category 1, H400 with the M-factor 1000 and aquatic environmental hazard chronic category 1: H410 with the M factor of 1000. Acute toxicity data are available for all trophic levels. The lowest L(E)C50 value of 0.67 µg/L is obtained for aquatic invertebrates. Based on this information pyridaben fulfills criteria for classification as Aquatic Acute Cat. With an M-factor of 1000 (toxicity band: $0.0001 < L(E)50 \leq 0.001$ mg/L).</p> <p>Pyridaben is considered not rapidly degradable and has a potential to bioaccumulate. Chronic toxicity data for pyridaben are available for all trophic levels. The lowest NOEC value of 0.047 µg/L is obtained for aquatic invertebrates. Pyridaben is qualified as not rapid degradability. Based on this information pyridaben fulfills criteria for classification as Aquatic Chronic Category 1 with an M-factor of 1000 (toxicity band: $0.00001 < NOEC \leq 0.0001$ mg/L)-</p>				
Dossier Submitter's Response				

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Thank you for your support.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
31.01.2013	Belgium		MemberState	6

Comment received				
we support the environmental classification proposed by the NL MSCA. CLP : In view of the proposed classification and the toxicity band for acute toxicity between 0.0001 mg/l and 0.001 mg/l, an M-factor for acute toxicity of 1000 could be assigned, and an M-factor for chronic toxicity of 1000 (not rapidly degradable substance and 0.00001mg/l<NOEC≤0.0001 mg/l). DSD : SCL N; R50-53: $C \geq 0,025 \%$ N; R51-53: $0,0025 \% \leq C < 0,025 \%$ R52-53: $0,00025 \% \leq C < 0,0025 \%$				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
01.02.2013	Spain		MemberState	7

Comment received				
We are in agreement with the environmental acute and chronic M factors proposed by NL.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				