Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

Hexaflumuron (ISO); 1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea

EC number: 401-400-1

CAS number: 86479-06-3

CLH-O-*0000001412-86-77/F*

Adopted

4 December 2015

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON HEXAFLUMURON (ISO),1-(3,5-DICHLORO-4-(1,1,2,2-TETRAFLUOROETHOXY)PHENYL)-3-(2,6-DIFLUOROBENZOYL)UREA

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during 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 attachments including confidential documents received during the public consultation have been provided in full to the dossier submitter, to RAC members and to the Commission (after adoption of the RAC opinion). 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.

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

Substance name: Hexaflumuron (ISO),1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea
CAS number: 86479-06-3
EC number: 401-400-1
Dossier submitter: Portugal

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
16.07.2015	Germany		MemberState	1
Comment received				
The draft final CA-report (as circulated to MS for approval of hexaflumuron as a biocidal active substance in June 2014) proposed classification of hexaflumoron for STOT RE 2. DE-CA provided its support to approval of Hexaflumuron on basis of this report and was surprised to note that the CLH dossier no longer adheres to this proposal which was apparently also deleted from the final Assessment Report.				
Dossier Submitter's Response				
As mentioned by DE CA, in the draft final CAR, hexaflumuron is proposed for classification as STOT RE 2. However after further evaluation of the grounds for this classification, considering all the parameters needed to establish the toxicological impairment towards the blood system, it was concluded that the severity of the effects was not sufficient to trigger classification as STOT RE. This outcome was stated in the Biocides final CAR and adopted in the 8 BPC meeting (3rd Dec 2014). Non-classification is our final position as submitted in the CLH report for RAC consideration.				
RAC's response				
RAC concurs with the response provided by the DS.				

Date	Country	Organisation	Type of Organisation	Comment number
15.07.2015	France		MemberState	2
Comment received				
We support the proposal for non-classification for toxicology.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
16.07.2015	Germany		MemberState	3
Comment received				
STOT RE 2 was concluded by RMS and MS during peer review of the biocidal active substance. According to chapter 3.9.2.5.2 of the Guidance on the Application of the CLP Criteria, " consistent and significant adverse effect in clinical biochemistry, haematology or urinalysis parameters; " and/or " evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration." including "haemosiderosis" are sufficient for classification. Such effects were consistent between the studies described in the dossier. While in some cases, effects were observed at dosages above the threshold for classification, this may be attributed to species-dependent differences in susceptibility and selection of doses (dose spacing). Notably, the NOAEL of 0.5 mg/kg bw/day based on an increase in methemoglobin and an increase in hepatic hemosiderin deposits from the 52-week dog study was considered as the relevant starting point for derivation of reference values in the assessment as biocidal active substance. Also refer to additional text from the Draft Final CAR (June 2014) provided in the attachment. *ECHA comment: The following confidential attachment was provided with the comment above "Hexaflumuron_Information from Draft AR June2014.docx"*				
Dossier Submitter's Response				
As mentioned above, PT CA concluded that there were no grounds for STOT RE classification when considering all the parameters in quantitative terms; though there is consistency of effects, in our view the severity is not sufficient to trigger hazard classification. This is not contradictory with using the 52-w dog study NOAEL (hepatic hemosiderin deposits) as dose reference and starting point for risk assessment because this is a risk-based decision and doesn't take into consideration the CLP criteria. Non-classification for human health hazards is our final position as included in the Biocides final CAR and adopted in the 8 BPC meeting (3rd Dec 2014). This CLH proposal is now submitted in the CLH report for RAC consideration.				
RAC's response				
RAC concurs with the response provided by the DS.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
15.07.2015	France		MemberState	4
Comment received				
We support the proposed classification: - Acute M-factor = 1,000 - Chronic M-factor = 10,000				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
15.07.2015	France		MemberState	5
Comment received				
The concentration (nominal and minimum) of the substance Hexaflumuron reported in the point 1.2 (P13) is not coherent regarding batch analysis of Hexaflumuron technical of the biocidal dossier. However, hazards properties were performed on a test material with a purity below the minimum purity referenced in the biocidal dossier. That can explain the minimum concentration reported in the point 1.2 (P13). Nevertheless, the results obtained with the lower purity are acceptable. The substance Hexaflumuron has no physico-chemical classification.				
Dossier Submitter's Response				
The Concentration range for Hexaflumuron included in point 1.2 (P13) i.e. ≥ 96.2% w/w was set to include all available study data. Thank you for the support.				
RAC's response				
Noted.				

CONFIDENTIAL ATTACHMENT RECEIVED

1. **Hexaflumuron – Information provided on pages 8/9 of the Draft Assessment Report circulated to and agreed by DE in June 2014**, submitted by Germany on 16/07/2015 (*please refer to comment number 3*)