

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in this table as submitted by the webform. Please note that the comments displayed below may have been accompanied by attachments which are not published in this table.

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Last data extracted on 13.02.2020

Substance name: transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

CAS number: 118712-89-3

EC number: 405-060-5

Dossier submitter: The Netherlands

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	1
Comment received				
Comment will be divided into several attachments				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment M-677979-01-1 Position Paper Carc classification Redacted.pdf				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment M-677979-01-1 Position Paper Carc classification.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	2
Comment received				
Comments will be divided several submissions due to file size				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Cover letter_Redacted				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Zip 2.7z				

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	3
Comment received				
Comment were divided into several attachments				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment M-540892-01-1_preparation_Redacted2.zip				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment M-540892-01-1.zip				

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	4
Comment received				
please refer to attachment				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment M-677979-01-1 Position Paper Carc classification Redacted.pdf				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment M-677979-01-1 Position Paper Carc classification.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	5
Comment received				
please refer to attachments				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Cover letter_Redacted				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Zip 2.7z				

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	6
Comment received				
As explained in the cover letter in one of my previous submission a 3rd mechanistic study is on going and the study plan M-678078-01-1 is submitted. A 1st draft report is expected on Week 13 and we propose to submit the final report to ECHA in April/May 2020.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment M-540892-01-1_preparation_Redacted2.zip				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment M-540892-01-1.zip				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
15.01.2020	Denmark		MemberState	7
Comment received				
Addition of Acute tox 4, H302 is supported.				

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
15.01.2020	Denmark		MemberState	8
Comment received				
Removal of Skin Irrit. 2, H315 is supported.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Single Exposure

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	9
Comment received				
please refer to attachments				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Cover letter_Redacted				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Zip 2.7z				

Date	Country	Organisation	Type of Organisation	Comment number
15.01.2020	Denmark		MemberState	10
Comment received				
Addition of STOT SE 1, H370 (causes damage to the nervous system) is supported.				

Date	Country	Organisation	Type of Organisation	Comment number
07.02.2020	France	Bayer	Company-Manufacturer	11
Comment received				
The study report M-540892-01-1 is too large for submission via this website and will be submitted via the webform "Submission of documents in relation to the Harmonised Classification and Labelling process"				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment M-540892-01-1_preparation_Redacted2.zip				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment M-540892-01-1.zip				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
15.01.2020	Denmark		MemberState	12
Comment received				
Addition of STOT RE 2, H373 (kidneys) is supported.				

Date	Country	Organisation	Type of Organisation	Comment number
05.02.2020	France		MemberState	13
Comment received				
Could you please detail the justification regarding the adaptive nature of the observed liver effects?				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
05.02.2020	France		MemberState	14
Comment received				

We agree with the classification proposal.

Please note that in the table 27 of the CLH report (summary of relevant information on chronic aquatic toxicity), the results for the growth inhibition test on algae is NOErC \geq 57 $\mu\text{g/L}$ instead of NOErC \geq 557 $\mu\text{g/L}$.

PUBLIC ATTACHMENTS

1. M-540892-01-1_preparation_Redacted2.zip [Please refer to comment No. 3, 6, 11]
2. M-677979-01-1 Position Paper Carc classification Redacted.pdf [Please refer to comment No. 1, 4]
3. Cover letter_Redacted [Please refer to comment No. 2, 5, 9]

CONFIDENTIAL ATTACHMENTS

1. M-540892-01-1.zip [Please refer to comment No. 3, 6, 11]
2. M-677979-01-1 Position Paper Carc classification.pdf [Please refer to comment No. 1, 4]
3. Zip 2.7z [Please refer to comment No. 2, 5, 9]