

Committee for Risk Assessment
RAC

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

**tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-
triyliimino)tribenzoate**

EC Number: 402-070-1
CAS Number: 88122-99-0

CLH-O-0000001412-86-129/F

Adopted
9 December 2016

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON TRIS(2-ETHYLHEXYL) 4,4',4''-(1,3,5-TRIAZINE-2,4,6-TRIYLTRIIMINO)TRIBENZOATE

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 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: tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate
EC number: 402-070-1
CAS number: 88122-99-0
Dossier submitter: Germany

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
14.04.2016	Belgium		MemberState	1
Comment received				
Based on the reported data, BE CA can support the proposed deletion of Aquatic chronic 4, H413 for the substance tris(2-ethylhexyl)4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate.				
Some comments on the aquatic bioaccumulation study, which will however have no impact on the final conclusion : - Was BCFk corrected for growth dilution? - Correction for lipid content : OECD305 : the lipid content should be determined at least at the start and end of the uptake phase and at the end of the depuration phase. If this is not feasible at least 3 independent fish should be sampled to determine the lipid content at each of the same three time-points.				
Dossier Submitter's Response				
Thank you for your support.				
The growth of the fish was negligible. A correction for growth dilution will have no influence on the results.				
The lipid determination was conducted at each sampling time with a pooled sample of four fish of the control group.				
Sample time		Lipid content [%]		
Uptake phase day 1		4.9		
Uptake phase day 2		5.0		
Uptake phase day 4		4.2		

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON TRIS(2-ETHYLHEXYL) 4,4',4''-(1,3,5-TRIAZINE-2,4,6-TRIYLTRIIMINO)TRIBENZOATE

Uptake phase day 7	4.5
Uptake phase day 14	3.9
Uptake phase day 18	4.6
Uptake phase day 21	5.1
Uptake phase day 24	5.0
Uptake phase day 28	5.3
Depuration phase day 1	4.8
Depuration phase day 2	5.4
Depuration phase day 4	6.0
Depuration phase day 8	6.4
Depuration phase day 16	6.5

Since the variability in the lipid content is high and since it was technically not possible to determine the lipid content and the concentration of the test substance in the same fish a true adjustment to the lipid content was not possible. Further only slight changes of the mean lipid content of the control fish were observed over time.

RAC's response

RAC agrees with the Dossier Submitter's Response

Date	Country	Organisation	Type of Organisation	Comment number
14.04.2016	Finland		MemberState	2

Comment received

We do not support the proposed removal of Aquatic Chronic 4 classification for Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate.

In the CLH dossier it is mentioned that no chronic effects of the test substance on the test organisms up to the limit of water solubility (< 1.0 µg/l) were found. However, the valid long-term fish study with Danio rerio (BASF AG, 2007c) is presented in the dossier where the overall NOEC of 1.01 µg/l was determined. The result is very close to water solubility which gives some grounds of concern, and, therefore, we think that Aquatic Chronic 4 classification is still warranted.

Dossier Submitter's Response

Thank you for your comment.

According to Table 4.1.0 ("Classification categories for hazardous to the aquatic environment") of Regulation (EC) No 1272/2008, classification criteria for Aquatic Chronic 4 include

- (1) poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility
- (2) and which are not rapidly degradable
- (3) and have an experimentally determined BCF ≥ 500 (or, if absent, a log Kow ≥ 4)

unless other scientific evidence exists showing classification to be unnecessary (e.g. chronic toxicity NOECs > water solubility or > 1 mg/L).

The experimentally determined BCF value of 77 is below the cut-off value of the CLP regulation (BCF ≥ 500). Hence, the substance has no potential to bioaccumulate and a classification as Aquatic Chronic 4 is not justified.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON TRIS(2-ETHYLHEXYL) 4,4',4''-(1,3,5-TRIAZINE-2,4,6-TRIYLTRIIMINO)TRIBENZOATE

Concerning the no observed effects up to the limit of water solubility: As the limit of water solubility is stated with < 1 µg/L, the no observed effect concentration in the <i>Danio rerio</i> study (BASF AG, 2007c) of greater or equal 1.01 µg/L (initial measured) is in good correlation with this limit value. As there is no observed effect up to the limit of water solubility, there is no ground of concern for ecotoxicity of the substance. Therefore the Aquatic Chronic 4 classification is not appropriate.
RAC's response
RAC agrees with the Dossier Submitter's Response

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2016	France		MemberState	3
Comment received				
FR MSCA supports the proposal to declassify the substance tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate as Aquatic Chronic 4. The new experimental data (bioaccumulation and chronic toxicity results) allow clarifying the initials concerns.				
According to the BCF value of 77, bioaccumulation is not expected to occur and no apparent chronic toxicity to aquatic organisms up to the limit of water solubility was observed. Taking into consideration classification criteria for Aquatic Chronic 4, the substance does not fulfil the criteria to be classified as Aquatic Chronic 4.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted				