

Committee for Risk Assessment
RAC

Annex 1

Background document

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

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to public consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted
9 December 2016

CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2

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
Index Number: 607-414-00-6

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CONTENTS

Part A.

1	PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING	4
1.1	SUBSTANCE.....	4
1.2	HARMONISED CLASSIFICATION AND LABELLING PROPOSAL	4
1.3	PROPOSED HARMONISED CLASSIFICATION AND LABELLING BASED ON CLP.....	5
2	BACKGROUND TO THE CLH PROPOSAL	6
2.1	HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING	6
2.2	SHORT SUMMARY OF THE SCIENTIFIC JUSTIFICATION FOR THE CLH PROPOSAL	6
2.3	CURRENT HARMONISED CLASSIFICATION AND LABELLING.....	7
2.3.1	<i>Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation</i>	<i>7</i>
2.4	CURRENT SELF-CLASSIFICATION AND LABELLING	7
2.4.1	<i>Current self-classification and labelling based on the CLP Regulation criteria</i>	<i>7</i>
3	JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL	7

Part B.

	SCIENTIFIC EVALUATION OF THE DATA	8
1	IDENTITY OF THE SUBSTANCE	8
1.1	NAME AND OTHER IDENTIFIERS OF THE SUBSTANCE.....	8
1.2	COMPOSITION OF THE SUBSTANCE	9
1.2.1	<i>Composition of test material</i>	<i>9</i>
1.3	PHYSICO-CHEMICAL PROPERTIES	10
2	MANUFACTURE AND USES	10
3	CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES	11
4	HUMAN HEALTH HAZARD ASSESSMENT	11
5	ENVIRONMENTAL HAZARD ASSESSMENT	11
5.1	DEGRADATION	11
5.1.1	<i>Stability</i>	<i>11</i>
5.1.2	<i>Biodegradation</i>	<i>11</i>
5.1.2.1	<i>Screening tests</i>	<i>11</i>
5.1.2.2	<i>Simulation tests</i>	<i>11</i>
5.1.3	<i>Summary and discussion of degradation</i>	<i>11</i>
5.2	ENVIRONMENTAL DISTRIBUTION	12
5.2.1	<i>Adsorption/Desorption.....</i>	<i>12</i>
5.2.2	<i>Volatilisation.....</i>	<i>12</i>
5.2.3	<i>Distribution modelling.....</i>	<i>12</i>
5.3	AQUATIC BIOACCUMULATION	12
5.3.1	<i>Aquatic bioaccumulation</i>	<i>12</i>
5.3.1.1	<i>Bioaccumulation estimation.....</i>	<i>12</i>
5.3.1.2	<i>Measured bioaccumulation data.....</i>	<i>12</i>
5.3.2	<i>Summary and discussion of aquatic bioaccumulation</i>	<i>13</i>
5.4	AQUATIC TOXICITY	14
5.4.1	<i>Fish</i>	<i>14</i>
5.4.1.1	<i>Short-term toxicity to fish</i>	<i>14</i>
5.4.1.2	<i>Long-term toxicity to fish</i>	<i>15</i>
5.4.2	<i>Aquatic invertebrates</i>	<i>16</i>
5.4.2.1	<i>Short-term toxicity to aquatic invertebrates</i>	<i>16</i>
5.4.2.2	<i>Long-term toxicity to aquatic invertebrates</i>	<i>16</i>
5.4.3	<i>Algae and aquatic plants</i>	<i>17</i>

ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON TRIS(2-ETHYLHEXYL)
4,4',4''-(1,3,5-TRIAZINE-2,4,6-TRIYLTRIIMINO) TRIBENZOATE

5.4.4	<i>Other aquatic organisms (including sediment)</i>	17
5.5	COMPARISON WITH CRITERIA FOR ENVIRONMENTAL HAZARDS (SECTIONS 5.1 – 5.4).....	17
5.6	CONCLUSIONS ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS (SECTIONS 5.1 – 5.4).....	17
6	OTHER INFORMATION	22
7	REFERENCES	22
8	ANNEXES	23

Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate
Trade name:	Uvinul [®] T 150
EC number:	402-070-1
CAS number:	88122-99-0
Annex VI Index number:	607-414-00-6
Degree of purity:	Ca. 99.0 %
Impurities:	Water

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	CLP Regulation
Current entry in Annex VI, CLP Regulation	Aquatic Chronic 4, H413
Current proposal for consideration by RAC	Removal: Aquatic Chronic 4, H413
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	No classification

1.3 Proposed harmonised classification and labelling based on CLP

Table 3: Proposed classification according to the CLP Regulation

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification ¹⁾	Reason for no classification ²⁾
2.1.	Explosives	none		none	
2.2.	Flammable gases	-		-	
2.3.	Flammable aerosols	-		-	
2.4.	Oxidising gases	-		-	
2.5.	Gases under pressure	-		-	
2.6.	Flammable liquids	-		-	
2.7.	Flammable solids	none		none	
2.8.	Self-reactive substances and mixtures	none		none	
2.9.	Pyrophoric liquids	-		-	
2.10.	Pyrophoric solids	none		none	
2.11.	Self-heating substances and mixtures	none		none	
2.12.	Substances and mixtures which in contact with water emit flammable gases	none		none	
2.13.	Oxidising liquids	-		-	
2.14.	Oxidising solids	none		none	
2.15.	Organic peroxides	-		-	
2.16.	Substance and mixtures corrosive to metals	none		none	
3.1.	Acute toxicity - oral	none		none	
	Acute toxicity - dermal	none		none	
	Acute toxicity - inhalation	none		none	
3.2.	Skin corrosion / irritation	none		none	
3.3.	Serious eye damage / eye irritation	none		none	
3.4.	Respiratory sensitisation	none		none	
3.4.	Skin sensitisation	none		none	
3.5.	Germ cell mutagenicity	none		none	
3.6.	Carcinogenicity	none		none	
3.7.	Reproductive toxicity	none		none	
3.8.	Specific target organ toxicity – single exposure	none		none	
3.9.	Specific target organ toxicity – repeated exposure	none		none	
3.10.	Aspiration hazard	none		none	
4.1.	Hazardous to the aquatic environment	none		Aquatic Chronic 4	Conclusive but not sufficient for classification
5.1.	Hazardous to the ozone layer				

¹⁾ Including specific concentration limits (SCLs) and M-factors

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Signal word: no signal word
 Hazard statements: no hazard-statements
 Precautionary statements: no precautionary statements

Proposed notes assigned to an entry: none

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

The substance was classified and labelled with R53 and added to Annex I of Directive 67/548/EEC by the 29th ATP. According to EC/1272/2008 Annex VI, the substance may cause long lasting harmful effects to aquatic life and thus, meets the criteria for classification with Aquatic Chronic 4. This classification was based on the high logPow value (> 3) and the resulting bioaccumulation potential of the substance and the absence of chronic aquatic toxicity data on all three trophic levels (algae, daphnia, fish).

2.2 Short summary of the scientific justification for the CLH proposal

New experimental data show that bioaccumulation of the substance is not expected due to a low BCF value of 77 and that there is no apparent chronic toxicity to aquatic organisms up to the limit of water solubility and therefore, classification of the substance with Aquatic Chronic 4 is no longer justified.

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 $BCF \geq 500$ (or, if absent, a $\log Kow \geq 4$)

With respect to the findings of the BCF study mentioned above, criterion (3) is clearly not fulfilled. Therefore, it appears appropriate to declassify the substance for environmental hazards.

For the purpose of this CLH report all registration dossier available in August 2015 have been taken into account by the dossier submitter.

2.3 Current harmonised classification and labelling

2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

Table 4: Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation (Index- No: 607-414-00-6)

Classification		Labelling			Specific Conc. Limits, M-factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Pictogram, Signal Word Code(s)		
Aquatic Chronic 4	H413	H413				

2.4 Current self-classification and labelling

2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

The following industry self-classification(s) and labelling are publically available in the ECHA C&L Inventory.

Table 5: Current industry self-classification and labelling in the ECHA C&L Inventory (January 2016)

Classification		Labelling		Specific Concentration limits, M-Factors	Notes	Number of Notifiers
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Pictograms, Signal Word Code(s)			
Aquatic Chronic 4	H413	H413				50 (joint entry)
Aquatic Chronic 4	H413	H413				69
Aquatic Chronic 4	H413	H413				1
Aquatic Chronic 4	H413	H413		M=1 M(chronic) =1		2
				M=1 M(chronic) =1		1

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

According to new data, modification of the existing entry is appropriate. The classification and labelling as Aquatic Chronic 4 is not justified.

Part B.

SCIENTIFIC EVALUATION OF THE DATA

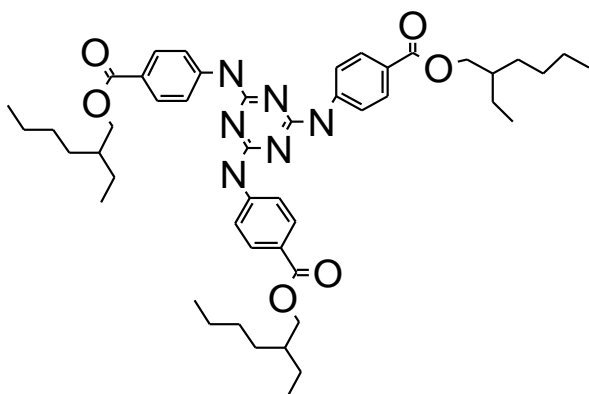
1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 6: Substance identity

EC number:	402-070-1
EC name:	tris(2-ethylhexyl)-4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate
CAS number:	88122-99-0
CAS name:	Benzoic acid, 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tris-, tris(2-ethylhexyl) ester
IUPAC name:	Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate
CLP Annex VI Index number:	607-414-00-6
Molecular formula:	C ₄₈ H ₆₆ N ₆ O ₆
Molecular weight range:	823.10 g/mol

Structural formula:



1.2 Composition of the substance

Table 7: Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks
tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	99 % (w/w)	> 98.0 – < 100.0 % (w/w)	Based on absorption method

Current Annex VI entry: Aquatic Chronic 4; H413 (table 3.1)

Table 8: Impurities (non-confidential information)

Impurity	Typical concentration	Concentration range	Remarks
Water	ca. 0.15 % (w/w)	> 0.0 – < 1.0 % (w/w)	Karl-Fischer Titration

Current Annex VI entry: none

Table 9: Additives (non-confidential information)

Additive	Function	Typical concentration	Concentration range	Remarks
None				

Current Annex VI entry: none

Further information regarding the composition is given in the technical dossier.

1.2.1 Composition of test material

The test material is a mono-constituent substance.

1.3 Physico-chemical properties

Table 10: Summary of physico-chemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
State of the substance at 20°C and 101,3 kPa	White powder	BASF AG, 2008a	
Melting/freezing point	124 – 129.8 °C	BASF AG, 1986b	
Boiling point	Not applicable	Expert judgement	Substance decomposes
Relative density	1.1 g/cm ³	BASF AG, 1986a	
Vapour pressure	<= 0.00000006 hPa at 20 °C	BASF AG, 1987a	
Surface tension	71 in mN/m at 20 °C	BASF AG, 1986h	
Water solubility	< 1 µg/L	BASF SE, 2008b	
Partition coefficient n-octanol/water	>7 at 20 °C	BASF AG, 1986j	As the water solubility of the test substance had been determined to be below 7E-6 g/L, the solubility of the substance in 1-octanol was measured by UV-spectrometry in saturated 1-octanol solutions. Based on the resulting values for solubility in water and 1-octanol, the lower limit of the partition coefficient was estimated.
Flash point	Not relevant; substance is a solid	Expert judgement	Substance is a solid
Flammability	Not highly flammable	BASF AG, 1986f	
Explosive properties	Non explosive	BASF AG, 1986g	
Self-ignition temperature	> 400 °C	BASF AG, 1986i	
Oxidising properties	No	BASF AG, 1986c	
Granulometry	D10: 14.20 µm D50: 73.13 µm D90: 163.28 µm	BASF SE, 2011	
Stability in organic solvents and identity of relevant degradation products	Stability of substance not considered as critical	Expert judgement	
Dissociation constant	Not applicable	Expert judgement	Substance not soluble in water and does not contain any ionic structure
Viscosity	Not applicable	Expert judgement	Substance is a solid at 20 °C

2 MANUFACTURE AND USES

Not relevant for this dossier.

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Not classified for physico-chemical properties.

4 HUMAN HEALTH HAZARD ASSESSMENT

Not classified for human health hazards.

5 ENVIRONMENTAL HAZARD ASSESSMENT

5.1 Degradation

Table 11: Summary of relevant information on degradation

Method	Results	Remarks	Reference
Test type: ready biodegradability activated sludge, domestic (adaptation not specified) EEC Directive 79-831, Annex V, Part C, 5.2	under test conditions no biodegradation observed % Degradation of test substance: 0 after 28 d (O ₂ consumption)	2 (reliable with restrictions) key study experimental result Test material (EC name): tris(2-ethylhexyl)-4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	BASF AG (1987b)

5.1.1 Stability

Not relevant for this dossier.

5.1.2 Biodegradation

5.1.2.1 Screening tests

One guideline study investigating the ready biodegradability of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate is available (Table 11). The biodegradation of the substance was tested in a Manometric Respirometry Test according to OECD guideline 301F using domestic activated sludge as inoculum [BASF AG, 1987b]. At test termination after 28 days the test substance was degraded by 0 %. Thus, tris(2-ethylhexyl)-4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino) tribenzoate is not readily biodegradable according to OECD criteria.

5.1.2.2 Simulation tests

No data available.

5.1.3 Summary and discussion of degradation

The substance is not rapidly degradable.

5.2 Environmental distribution

5.2.1 Adsorption/Desorption

Based upon a log K_{oc} of > 5.63 (according to OECD Guideline 121), the substance has a high potential to adsorb on soil and sewage sludge (Registration dossier).

5.2.2 Volatilisation

Not relevant for this dossier.

5.2.3 Distribution modelling

Not relevant for this dossier.

5.3 Aquatic Bioaccumulation

Table 12: Summary of relevant information on aquatic bioaccumulation

Method	Results	Remarks	Reference
Danio rerio aqueous (freshwater) flow-through Total uptake duration: 28 d Total depuration duration: 16 d OECD Guideline 305 (Bioconcentration: Flow-through Fish Test)	BCF: 99 (whole body w.w.) (Time of plateau: 1 d)(kinetic) BCF: 93 (whole body w.w.) (Time of plateau: 1 d)(steady state) BCF: 54 (whole body w.w.) (Time of plateau: 4 d)(kinetic) BCF: 58 (whole body w.w.) (Time of plateau: 4 d)(steady state) BCF: 77 (whole body w.w.) (mean bioconcentration factor) Elimination: yes; DT90: 3.6 d	1 (reliable without restriction) key study experimental result Test material (EC name): tris(2- ethylhexyl)-4,4',4''- (1,3,5-triazine-2,4,6- triylyltriimino)tribenz oate	BASF AG (2007a)

5.3.1 Aquatic bioaccumulation

5.3.1.1 Bioaccumulation estimation

Not relevant for this dossier.

5.3.1.2 Measured bioaccumulation data

In a guideline study investigating the bioaccumulation of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triylyltriimino)tribenzoate in *Danio rerio* a BCF of 77 was determined [BASF AG, 2007a] (Table 12).

5.3.2 Summary and discussion of aquatic bioaccumulation

A bioconcentration test according to OECD guideline 305 was conducted with ¹⁴C-radiolabelled tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate in *Danio rerio* [BASF AG, 2007a]. The fish were exposed to the test concentrations 0.02 and 0.10 µg/L in a flow-through-system. As the solubility of the test substance in water is very low (< 0.2 µg/L under test conditions) and as in preliminary tests it was not possible to achieve a constant test concentration without the use of a solvent, the two test concentrations were prepared by adding dimethylformamide (DMF; 0.02 mL/L) to the test substance.

The prepared stock solutions were stored in glass tanks and were pumped continuously from the stock solution tanks by dilution pumps to mixing vessels, where they were mixed with aerated and tempered dilution water. The test solutions were dosed into the test aquaria via an overflow. Water parameters such as dissolved oxygen, pH and temperature were measured regularly during the test period and remained constant. The total organic carbon was determined in water samples taken directly from the test vessels. During the uptake period TOC values determined in the control and in the test groups were in the range 1.5 – 14.4 mg/L. During the depuration period the TOC was in the range of 0.8 – 1.1 mg/L (normal value for the dilution water).

In order to check the stability of the test concentration over the study course, the radioactivity in the water samples was measured by disintegration counting in a liquid scintillation counter. The calculation of the mean measured concentration in water was based on the filtrated samples to exclude that undissolved test substance contributes to the concentration values in water used for the BCF calculation. The mean measured concentrations were 0.021 µg/L (105 % of the nominal concentration) for the low and 0.103 µg/L (103 % of the nominal concentration) for the high concentration and, thus, were kept constant within the range of +/- 20 % of the nominal concentration.

The concentration of the test substance in fish was determined by combustion of fish tissues with subsequent measurement of the radioactivity with a liquid scintillator. The measured activity from one of the control fish was then subtracted from the values of the fish from the two concentration groups. A lipid determination was conducted at each fish sampling. The lipid content in fish which relates to the whole body weight has been found to be in a normal range between 3.9 and 6.5 % over the whole uptake and elimination period.

The uptake period of the test substance in fish lasted 28 days. No increase of the concentration in fish was observed after study day 7 in the low and the high concentration, respectively. The beginning of steady state was therefore considered to be reached within 7 days. The depuration period in uncontaminated dilution water lasted 16 days. The elimination of test substance was rapid with a half-life time (t₅₀) of 0.52 days for the low and 1.6 days for the high concentration group which indicates very fast depuration of the test substance from the organism. The mean time for the depuration of 90 % (t₉₀) was 3.6 days (1.7 days for the low and 5.4 days for the high concentration group).

Based on the concentration of the test substance in fish during steady state the BCF_{ss} in the lower concentration group (0.02 µg/L) was 93 and 58 in the higher concentration group (0.10 µg/L). The mean value was 76. Based on kinetic rate constants the bioconcentration factor was found to be in the same range as during steady state: BCF_k of 99 in the lower concentration group and BCF_k of 54 in the higher concentration group. The mean value was 77.

The lipid content of the test fish was not used for further calculations of the BCF based on lipid content. 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.

In conclusion, the bioconcentration factor in whole fish derived from this study based on the mean of BCF_{ss} and BCF_k is considered to be 77. Thus, a significant bioaccumulation of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate in organisms is not to be expected.

5.4 Aquatic toxicity

Table 13: Summary of relevant information on aquatic toxicity

Method	Results	Remarks	Reference
Short-term toxicity to fish (OECD 203) static <i>Brachydanio rerio</i>	LC50 (96h) >1000 mg/L (nominal)	2 (reliable with restriction)	BASF AG (1987c)
Long-term toxicity to fish (OECD 210) flow-through <i>Danio rerio</i>	NOEC (35d) ≥ 1.01 µg/L (meas. (initial))	1 (reliable without restriction)	BASF AG (2007c)
Short-term toxicity to aquatic invertebrates (OECD 202) static <i>Daphnia magna</i>	EC50 (48h) > 500 mg/L (nominal)	2 (reliable with restriction)	BASF AG (1986d)
Short-term toxicity to aquatic invertebrates (OECD 202) static <i>Daphnia magna</i>	EC50 (48h) > 500 mg/L (nominal)	2 (reliable with restriction)	BASF AG (1986e)
Long-term toxicity to aquatic invertebrates (OECD 211) flow-through <i>Daphnia magna</i>	NOEC (21d) ≥ 1 µg/L (nominal)	1 (reliable without restriction)	BASF AG (2007b)
Toxicity to aquatic algae (EEC Directive 79/831/EEC, Annex V, Part C) static <i>Scenedesmus subspicatus</i>	ErC50 (72h) > 80 mg/L (nominal) NOErC (72h) ≥ 80 mg/L (nominal)	2 (reliable with restriction)	BASF AG (1995)

5.4.1 Fish

5.4.1.1 Short-term toxicity to fish

The toxicity of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate to *Brachydanio rerio* was tested in a study performed according to OECD guideline 203 (non GLP guideline study). The test fish were exposed to tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate for 96 hours. At test termination an LC50 >1000 mg/L was determined

[BASF AG, 1987c]. In conclusion, no effects were observed up to the limit of water solubility (< 1 µg/L) (see Table 13).

5.4.1.2 Long-term toxicity to fish

A fish early life-stage test has been conducted in order to assess the chronic effects of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate using the most critical and sensitive life-stages of zebra fish according to OECD guideline 210 (GLP guideline study) [BASF AG, 2007c]. The test organisms were exposed in a flow-through system to the nominal test concentrations of 1.0, 3.0 and 10 µg/L. Measured biological parameters were the mortality of the embryos until hatch, the number of surviving larvae at termination of swim-up (day 7) and the survival of young fathead minnow until the termination of exposure (day 35), the time to hatch and swim-up, signs of toxicity (symptoms), and the weight (wet weight) and the total length of surviving fish at the end of exposure.

As the solubility of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate is even below the analytical detection limit of the test substance under test conditions (< 7 µg/L), radiolabeled test substance was used and admixed to the test substance in a proportion that enables a detection of the test substance in the test solutions. Additionally, the solubilizer dimethylformamide (DMF; 0.1 mL/L) was added for the preparation of the stock solution.

The test substance is considered to be stable in water. Therefore it can be assumed that assured radioactivity in the test solutions reflects the actual concentration of the test substance in the test solution. For each sampling time a filtered and an unfiltered sample was analyzed to determine the proportion of the test substance which was undissolved or bound to particles. The samples were measured directly in a liquid scintillation counter.

The mean recovery of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate was in the range of 91 – 101 %. The variations between the concentration measurements of each day were very high. These deviations were most likely caused by adsorption processes. Depending on the organic material in the test solutions the amount of test substance in the aqueous phase increased or decreased. The comparison of the values found in filtrated and non-filtrated samples demonstrates that in all test concentrations the test substance was not completely dissolved and that the test concentrations were still above the limit of solubility under test conditions. Thus, the effects observed in this study cannot be related to the dissolved test substance alone, but may be caused by the undissolved fraction.

The survival and hatch rate in the solvent control and in the three concentration groups did not deviate significantly from the survival in the water control. The survival and hatch rate in all test groups was in the normal range. The time to hatch and swim-up was similar in all test groups. Neither abnormalities nor vertebral deformations were seen in any of the concentration groups or in the control groups. The body length and weight in both control groups was not significantly different. A clear substance related effect on growth was observed at the concentrations > 3.0 µg/L (nominal concentration; relates to > 2.72 µg/L based on mean analytically determined concentrations).

The overall NOEC was therefore considered to be 1.01 µg/L (mean analytically determined concentrations) and the LOEC was 2.72 µg/L (mean analytically determined concentration). The

analytical results indicated that the tested concentrations were still above the limit of solubility of the test substance in water (< 1 µg/L at 20 °C, BASF AG 2008b).

Thus, there were no effects of the test substance towards the test organisms up to the limit of water solubility (see Table 13).

5.4.2 Aquatic invertebrates

5.4.2.1 Short-term toxicity to aquatic invertebrates

Two guideline studies on the toxicity of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate to *Daphnia magna* is available. In a static test system according to OECD guideline 202 (non GLP guideline study), an EC50 > 500 mg/L was determined after 48 hours in both studies [BASF AG, 1986d,e]. In conclusion, no effects were observed up to the limit of water solubility (< 1 µg/L) (see Table 13).

5.4.2.2 Long-term toxicity to aquatic invertebrates

A 21 d long-term toxicity study according to OECD guideline 211 (GLP guideline study) has been conducted to determine effects of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate towards *Daphnia magna* reproduction [BASF SE 2007b]. The daphnids were exposed to the single test concentration of 1 µg/L in a flow-through system (limit test in the range of the water solubility).

As the solubility of the test substance in water is very low (< 1 µg/L; actual water solubility limit determined in preliminary experiment), radiolabeled test substance has been used which was additionally mixed with the solubilizer dimethylformamide (DMF) in order to prepare the stock solution. The stock solution was mixed in a mixing tank from where the test vessels were supplied.

The test substance is considered to be stable in water. Therefore, it can be assumed that assured radioactivity in the test solutions reflects the actual concentration of the test substance in the test solution. For each sampling time a filtered and an unfiltered sample was analyzed to determine the proportion of the test substance which was undissolved or bound to particles. The samples were measured directly in a liquid scintillation counter. The recovery after filtration was 33 – 54% of the radioactivity measured in the unfiltered samples. The test concentration was very likely above the limit of solubility in water. Furthermore, test substance may have been adsorbed to the feeding algae which were present in the test vessels over the whole exposure time or to other organic material. This explains the lower values obtained in the filtered samples and confirms that the tested concentration was above the limit of solubility in water.

Additionally, a second long-term toxicity study is available which has been conducted according to EEC guideline XI/681/86 [BASF AG 1999]. This study however has to be regarded as invalid because of major deficiencies during the preparation of the test solution (undissolved test material in the test media) which was very likely the reason for the decrease in reproductive success at the limit test concentration.

In conclusion, the 21d NOEC value for tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate in *Daphnia magna* was > 1.0 µg/L based on the nominal concentration of

the test substance derived from the key study. The mean analytically determined concentration in the test solutions was $1.08 + 0.04 \mu\text{g/L}$. No effect was observed up to the solubility limit of the test substance in water.

5.4.3 Algae and aquatic plants

The acute toxicity of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate has been assessed in a GLP guideline study according to EEC Directive 79/831/EEC, Annex V, Part C with the test organism *Scenedesmus subspicatus* [BASF AG, 1995]. The algae were exposed over a 72-hour study period to nine test concentrations in the range of 0.31 – 80 mg/L (nominal).

The test was performed with an aqueous extraction of the test substance. A defined amount of the substance was weighed out and suspended by stirring it for 17 h in deionized water. Afterwards the resulting suspension was passed through a membrane filter with a pore diameter of $0.45 \mu\text{m}$. The uninoculated replicates were analytically analyzed via HPLC at the beginning and at the end of the test which resulted in recovery rates smaller than the limit of detection ($\text{LoD} = 0.1 \text{ mg/L}$).

At test termination an $\text{ErC}_{50} > 80 \text{ mg/L}$ (nominal) and a $\text{NOEC} \geq 80 \text{ mg/L}$ (nominal) was determined (see Table 13). Thus, no effects were observed up to the limit of water solubility ($< 1 \mu\text{g/L}$; BASF AG 2008b).

5.4.4 Other aquatic organisms (including sediment)

No data available.

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)

Environmental hazard criteria according to Regulation (EC) No 1272/2008 – Environmental category Chronic 4 is applied in case when acute or chronic toxicity data do not allow classification but there is still some reason for concern. This category shall be applied in case of poorly water soluble substances (normally $< 1 \text{ mg/l}$) which do not reveal acute toxicity at levels up to the water solubility and if a substance has the potential to bioaccumulate ($\text{BCF} \geq 500$ or, if absent, $\log\text{Pow} \geq 4$) and is also not rapidly biodegradable.

Comparison of results with criteria for environmental hazards – tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate has been shown to be poorly water soluble ($< 1 \mu\text{g/L}$) and being not rapidly degradable. However, a bioaccumulation study (TG OECD 305: $\text{BCF} = 77$) revealed that tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate does not fulfil the criterion for bioaccumulation. Moreover, short- and long-term toxicity guideline studies have shown that tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate does neither reveal acute nor chronic toxicity effects to aquatic organisms (algae, daphnia and fish) at concentrations up to the water solubility limit (see Table 13). These results indicate no adverse effects of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate to the environment.

5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

Conclusion of environmental classification according to Regulation (EC) No 1272/2008

According to Part IV of Regulation (EC) No 1272/2008, a substance does not meet the criteria for classification Chronic 4 in case it has no chronic toxicity to aquatic invertebrates or fish up to the limit of water solubility and the substance is not bioaccumulative. Therefore, tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate should no longer be classified as Aquatic Chronic 4 according to the environmental hazard classification criteria of EC/1272/2008.

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier Submitter's proposal

According to the Annex VI of the CLP Regulation (EC) No 1272/2008 Annex VI, the substance may cause long-lasting harmful effects to aquatic life and, thus, meets the criteria for classification with Aquatic Chronic 4. According to the CLP report, the dossier submitter (DS) justified the presence of this based on "*the high log K_{ow} value (>3) and the resulting bioaccumulation potential of the substance, in the absence of chronic aquatic toxicity data on all three trophic levels (algae, daphnia, fish)*".

The DS indicated that new experimental data show that there is low potential for bioaccumulation due to a BCF value of 77 and that there is no apparent chronic toxicity to aquatic organisms up to the limit of water solubility. Therefore, classification of the substance with Aquatic Chronic 4 is no longer justified, as established by one of the classification criteria for Aquatic Chronic 4 ("have an experimentally determined BCF \geq 500 (or, if absent, a log K_{ow} \geq 4)").

Degradation

One guideline study investigating the ready biodegradability of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate is available. The biodegradation of the substance was tested according to OECD Guideline 301F (Manometric Respirometry Test), using domestic activated sludge as inoculum. After 28 days the test substance was degraded by 0%. Thus, tris(2-ethylhexyl)-4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate is not readily biodegradable according to OECD criteria.

Bioaccumulation

A bioconcentration test according to OECD Guideline 305 (Bioconcentration: Flow-through Fish Test) was conducted with ¹⁴C-radiolabelled tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate in *Danio rerio*. The fish were exposed to the test concentrations 0.02 and 0.10 µg/L in a flow-through-system. As the solubility of the test substance in water is very low (< 0.2 µg/L under test conditions) and as in preliminary tests it was not possible to achieve a constant test concentration without the use of a solvent, the two test concentrations were prepared by adding dimethylformamide (DMF; 0.02 mL/L) to the test substance.

In order to check the stability of the test concentration over the course of the study, the radioactivity in the water samples was measured by disintegration counting in a liquid scintillation counter. The calculation of the mean measured concentration in water was

based on the filtrated samples to exclude that undissolved test substance contributes to the concentration values in water used for the BCF calculation. The mean measured concentrations were kept constant within the range of +/- 20% of the nominal concentration. A lipid determination was conducted at each fish sampling. The lipid content in fish which relates to the whole body weight has been found to be in a normal range between 3.9 and 6.5% over the whole uptake and elimination period.

The uptake period of the test substance in fish lasted 28 days. No increase of the concentration in fish was observed after study day 7 in either the low or the high concentration. The beginning of steady state was therefore considered to be reached within 7 days. The depuration period in uncontaminated dilution water lasted 16 days. The elimination of the test substance was rapid with a half-life time of 0.52 days for the low and 1.6 days for the high concentration group, which indicates very fast depuration of the test substance from the organism.

Based on the concentration of the test substance in fish during steady state the BCF_{ss} was 93 in the lower concentration group (0.02 µg/L) and 58 in the higher concentration group (0.10 µg/L). The mean value was 76. Based on kinetic rate constants the bioconcentration factor was found to be in the same range as during steady state: BCF_k of 99 in the lower concentration group and BCF_k of 54 in the higher concentration group. The mean value was 77.

The lipid content of the test fish was not used for further calculations of the BCF based on lipid content. Since the variability in the lipid content is high and 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.

In conclusion, the bioconcentration factor in whole fish derived from this study based on the mean of BCF_{ss} and BCF_k is considered to be 77. Thus, a significant bioaccumulation of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate in organisms is not to be expected.

Aquatic Toxicity

The ecotoxicological tests results from available acute and chronic studies of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate for all trophic levels are summarised in the following table.

ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON TRIS(2-ETHYLHEXYL) 4,4',4''-(1,3,5-TRIAZINE-2,4,6-TRIYLTRIIMINO) TRIBENZOATE

Test organism / guideline, test method	Short-term result (endpoint)	Long-term result (endpoint)	Reference
Toxicity to fish			
Zebrafish (<i>Brachydanio rerio</i>) / OECD TG 203, GLP, static	LC50 (96h) >1000 mg/L (nominal)	-	BASF AG (1987c)
Zebrafish (<i>Danio rerio</i>)/ OECD TG 210, GLP, flow-through	-	NOEC (35d) ≥ 1.01 µg/L (meas. (initial))	BASF AG (2007c)
Toxicity to aquatic invertebrates			
<i>Daphnia magna</i> / OECD TG 202, GLP, static	EC50 (48h) > 500 mg/L (nominal)	-	BASF AG (1986d)
<i>Daphnia magna</i> / OECD TG 202, GLP, static	EC50 (48h) > 500 mg/L (nominal)	-	BASF AG (1986e)
<i>Daphnia magna</i> / OECD TG 211, GLP, flow-through	-	NOEC (21d) ≥ 1 µg/L (nominal) ≥ 1.08 µg/L (meas.) no effects observed	BASF AG (2007b)
Toxicity to algae			
<i>Scenedesmus subspicatus</i> / EEC Directive 79/831/EEC, Annex V, Part C, GLP, static	E _r C50 (72h) > 80 mg/L (nominal)	NOE _r C (72h) ≥ 80 mg/L (nominal) no effects observed	BASF AG (1995)

As shown in the table above, short- and long-term toxicity guideline studies indicate that tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate does not reveal acute nor chronic toxicity effects to aquatic organisms (algae, daphnia and fish) at concentrations up to the water solubility limit (the substance has been shown to be poorly water soluble, <1 µg/L).

In the long-term fish toxicity study a toxic effect was seen at the mean measured concentration of 2.72 µg/L (LOEC), when undissolved test substance was still present. The test concentration was above the limit of solubility of the test substance in water. Therefore, the effect observed cannot be related to the dissolved test substance alone but may be caused by the undissolved fraction.

In the long-term invertebrate toxicity test, daphnia was exposed to the single test concentration of 1 µg/L and no effect was observed.

In the algae toxicity test, the algae were exposed to a range of concentrations and no effect was observed at the highest concentration tested.

In conclusion, these results indicate no adverse effects of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate in the environment.

Comments received during public consultation

Three Member State Competent Authorities (MSCAs) submitted comments on the DS's proposal. Two of them supported the proposed removal of Aquatic Chronic 4 and the substance subsequently having no classification.

However, one MSCA asked to clarify some minor issues about the bioaccumulation study:

- if a correction factor which takes into account the growth of the fish was applied;
- the way the lipid determination was conducted.

The DS replied to both questions stating that the growth of the fish was negligible, consequently a correction for growth dilution will have no influence on the results. Moreover, the DS presented a table with lipid content during the uptake and depuration phases for each sampling time, showing only slight further changes of the mean lipid content of the control fish were observed over time.

Another commentator did not support the proposed removal, noting that a valid long-term fish study with *Danio rerio* (BASF AG, 2007c) was presented in the dossier where an overall NOEC of 1.01 µg/l was determined. This result was very close to water solubility limit which, they argued, gives some grounds for concern and therefore classification as Aquatic Chronic 4 is still warranted. The DS replied that, as the limit of water solubility was stated as < 1 µg/L, the no observed effect concentration in the *Danio rerio* study (BASF AG, 2007c) of greater or equal 1.01 µg/L (initial measured) was in good correlation with this limit value. As there was no observed effect up to the limit of water solubility, there was no grounds for concern as regards the ecotoxicity of the substance. Therefore, the Aquatic Chronic 4 classification is not appropriate.

Assessment and comparison with the classification criteria

Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate has been shown to be poorly water soluble (<1 µg/L) and not rapidly degradable. A bioaccumulation study (TG OECD 305: BCF = 77) revealed that tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate has a low potential for bioaccumulation. Moreover, short- and long-term toxicity guideline studies have shown that tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate does not reveal acute or chronic toxicity effects to aquatic organisms (algae, daphnia and fish) at concentrations up to the water solubility limit. These results indicate no adverse effects of tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate in the environment.

RAC agrees with the conclusion that the substance possesses a low potential for bioaccumulation to aquatic organisms.

According to Table 4.1.0 of Regulation (EC) No 1272/2008, a substance should be classified as Category Chronic 4 when it exhibits no chronic toxicity up to the limit of water solubility **and** it is not rapidly degradable **and** has an experimentally determined BCF ≥ 500 (or, if absent, a Log K_{ow} ≥ 4). As the latter is clearly not the case, tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate should no longer be classified as Aquatic Chronic 4. RAC agrees with **no classification for chronic aquatic toxicity**.

6 OTHER INFORMATION

None

7 REFERENCES

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8 ANNEXES

none