

Committee for Risk Assessment

RAC

Annex 1

Background document

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

reaction mass of:

isomers of

2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecyl phenol

isomers of

2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol

isomers of

2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol.

$n = 5$ or 6

EC Number: 401-680-5

CAS Number: -

CLH-O-0000001412-86-88/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

4 December 2015

CLH report

Proposal for Harmonised Classification and Labelling

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

Substance Name:

*reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol;
isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol;
isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol.
n = 5 or 6*

EC Number: 401-680-5
CAS Number: n/a
Index Number: 604-057-00-8

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Version number: 2.0

Date: March 2015

CONTENTS

Part A.

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

Part B.

1	IDENTITY OF THE SUBSTANCE	7
1.1	NAME AND OTHER IDENTIFIERS OF THE SUBSTANCE.....	7
1.2	COMPOSITION OF THE SUBSTANCE	8
1.2.1	<i>Composition of test material</i>	<i>8</i>
1.3	PHYSICO-CHEMICAL PROPERTIES	8
2	MANUFACTURE AND USES	8
3	CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES	9
4	HUMAN HEALTH HAZARD ASSESSMENT	9
5	ENVIRONMENTAL HAZARD ASSESSMENT	10
5.1	DEGRADATION	10
5.1.1	<i>Summary and discussion of degradation</i>	<i>10</i>
5.2	ENVIRONMENTAL DISTRIBUTION	12
5.3	AQUATIC BIOACCUMULATION	12
5.3.1	<i>Aquatic bioaccumulation</i>	<i>13</i>
5.3.2	<i>Summary and discussion of aquatic bioaccumulation</i>	<i>13</i>
5.4	AQUATIC TOXICITY	13
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>14</i>
5.4.2	<i>Aquatic invertebrates.....</i>	<i>15</i>
5.4.2.1	<i>Short-term toxicity to aquatic invertebrates.....</i>	<i>15</i>
5.4.2.2	<i>Long-term aquatic invertebrates</i>	<i>17</i>
5.4.3	<i>Algae and aquatic plants</i>	<i>17</i>
5.4.4	<i>Other aquatic organisms (including sediment).....</i>	<i>19</i>
5.5	COMPARISON WITH CRITERIA FOR ENVIRONMENTAL HAZARDS (SECTIONS 5.1 – 5.4).....	19
5.6	CONCLUSIONS ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS (SECTIONS 5.1 –5.4).....	20
6	OTHER INFORMATION.....	23
7	REFERENCES.....	23

Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 SUBSTANCE

Table 1: Substance identity

Substance name:	<i>reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6</i>
EC number:	401-680-5
CAS number:	n/a
Annex VI Index number:	604-057-00-8
Degree of purity / Impurities:	<i>100% (UVCB substance) The composition of the substance is considered confidential and therefore included in the IU5-dossier only.</i>

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 2 – H411
Current proposal for consideration by RAC	Removal: Aquatic Chronic 2 – H411
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	No classification

**ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON
REACTION MASS OF: ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
DODECYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6**

1.3 PROPOSED HARMONISED CLASSIFICATION AND LABELLING BASED ON CLP REGULATION

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				
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				
2.8.	Self-reactive substances and mixtures				
2.9.	Pyrophoric liquids				
2.10.	Pyrophoric solids				
2.11.	Self-heating substances and mixtures				
2.12.	Substances and mixtures which in contact with water emit flammable gases				
2.13.	Oxidising liquids				
2.14.	Oxidising solids				
2.15.	Organic peroxides				
2.16.	Substance and mixtures corrosive to metals				
3.1.	Acute toxicity - oral				
	Acute toxicity - dermal				
	Acute toxicity - inhalation				
3.2.	Skin corrosion / irritation				
3.3.	Serious eye damage / eye irritation				
3.4.	Respiratory sensitisation	No classification		No classification	
3.4.	Skin sensitisation				
3.5.	Germ cell mutagenicity	No classification		No classification	
3.6.	Carcinogenicity	No classification		No classification	
3.7.	Reproductive toxicity	No classification		No classification	
3.8.	Specific target organ toxicity – single exposure				
3.9.	Specific target organ toxicity – repeated exposure				
3.10.	Aspiration hazard				
4.1.	Hazardous to the aquatic environment	No classification	--	Aquatic Chronic 2	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

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

Labelling:	<u>Signal word:</u>	no signal word
	<u>Hazard statements:</u>	no hazard statements
	<u>Precautionary statements:</u>	no precautionary statements

Proposed notes assigned to an entry: none

2 BACKGROUND TO THE CLH PROPOSAL

The dossier was prepared by industry according to Article 37(6) of CLP Regulation.

For the purpose of this dossier the German CA has taken all registration dossiers available in March 2015 into account.

2.1 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

The existing classification N; R 51/53 has been added to Annex I of Directive 67/548/EEC in 2001 by the 28th ATP. With implementation of the CLP Regulation the substance was classified as Aquatic Chronic 2.

2.2 SHORT SUMMARY OF THE SCIENTIFIC JUSTIFICATION FOR THE CLH PROPOSAL

An older acute toxicity test on *Daphnia magna* revealed a measured EC₅₀ (24h) value of 4.1 mg/L (Ciba-Geigy Ltd. (1986b)). Taking this result into account, a classification for environmental hazards (Aquatic Chronic 2) was considered to be appropriate. From a scientific present-day perspective the study shows various deficiencies. The study was carried out with concentrations by orders of magnitude above the water solubility and an emulsifier with concentrations up to 510 mg/l was used. Furthermore, the test duration was only 24 hours.

In the meantime, the acute toxicity study on daphnia was repeated according to test guideline 92/69/EWG, C.2 (equivalent to OECD 202) under consideration of the OECD guidance document on aquatic toxicity testing of difficult substances (2000). This study (RCC Ltd. (2002)) did not reveal any toxicity in the range of water solubility (EC₅₀ > 100 mg/L – nominal; water solubility = 0.13 µg/L). Furthermore, the available chronic toxicity study on daphnia according to OECD guideline 211 did not reveal any toxic effects in the range of water solubility either (NOEC ≥ 2 µg/L – nominal). For details please refer to Part B of this document.

With respect to the findings of the new toxicity study on daphnia, no acute toxicity of the substance in the range of its water solubility is recorded. Furthermore, due to the absence of any bioaccumulative potential, it appears appropriate to declassify the substance for environmental hazards.

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

2.3 CURRENT HARMONISED CLASSIFICATION AND LABELLING

2.3.1 CURRENT CLASSIFICATION AND LABELLING IN ANNEX VI, TABLE 3.1 IN THE CLP REGULATION

Index -No	International Chemical Identification	EC-No	CAS -No	Classification		Labelling	
				Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)
604-057-00-8	reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecylphenol. n=5 or 6	401-680-5	-	Aquatic Chronic 2	H411	GHS09	H411

2.4 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 (November 2014)

Classification		Labelling		Number of Notifiers
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Pictograms, Signal Word Code(s)	
Aquatic Chronic 2	H411	H411	GHS09	95
Aquatic Chronic 2	H411	H411	GHS09	82
Not Classified				31 (Joint entry)
		H411	GHS07 GHS09 Wng	2
Aquatic Chronic 2	H411	H411	GHS09	9
Aquatic Chronic 2	H411	H411	GHS09	1 (Joint entry)

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Considering all available information the existing harmonised classification with Aquatic Chronic 2 (according to CLP) is not appropriate (see chapter 2.2).

Part B.

SCIENTIFIC EVALUATION OF THE DATA

1 IDENTITY OF THE SUBSTANCE

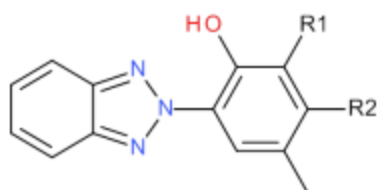
1.1 NAME AND OTHER IDENTIFIERS OF THE SUBSTANCE

Table 4: Substance identity

EC number:	401-680-5
EC name:	A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6
CAS number:	-
CAS name:	-
IUPAC name:	Reaction mass of: 2-(2H-benzotriazol-2-yl)-4-methyl-5-dodecyl (linear and branched) phenol; 2-(2H-benzotriazol-2-yl)-4-methyl-6-dodecyl (linear and branched) phenol; 2-(2H-benzotriazol-2-yl)-4-methyl-5-tetracosyl (linear and branched) phenol; 2-(2H-benzotriazol-2-yl)-4-methyl-6-tetracosyl (linear and branched) phenol; 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl (linear and branched) phenol
CLP Annex VI Index number:	604-057-00-8
Molecular formula:	C ₂₅ H ₃₅ N ₃ O and C ₃₇ H ₅₉ N ₃ O
Molecular weight range:	393.6 – 561.9

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6**

Structural formula:



R1 = isomers of
C₁₂H₂₅ and C₂₄H₄₉

R2 = H or isomers of
C₁₂H₂₅

1.2 COMPOSITION OF THE SUBSTANCE

The composition of the substance is considered confidential and therefore included in the IU5-dossier only.

1.2.1 COMPOSITION OF TEST MATERIAL

The composition of the substance is considered confidential and therefore included in the IU5-dossier only.

1.3 PHYSICO-CHEMICAL PROPERTIES

Table 5: Summary of relevant information on physico-chemical properties

Endpoint	Results	Remarks	Reference
Physical state at 20°C and 101,3 kPa	clear, viscous yellow liquid		Ciba Specialty Chemicals Inc., (2005)
Vapour pressure	0.000024 Pa at 25°C; (extrapolated)	effusion method: vapour pressure balance	CIBA-GEIGY Ltd. 1986
Surface tension	71.5 mN/m at 20°C (filtrate of a 10.0 g/L slurry)	ring method	CIBA-GEIGY Ltd. 1986 d
Water solubility	0.13 µg/L	column elution method	Huntingdon Life Sciences Ltd. (2006)
Partition coefficient n-octanol/water	logPow= 8.9	estimated by calculation	CIBA-GEIGY Ltd. 1986e

2 MANUFACTURE AND USES

Not relevant for the purpose of this dossier.

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Not classified for physico-chemical properties.

4 HUMAN HEALTH HAZARD ASSESSMENT

Not classified for human health hazards.

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 PHENOL. N=5 OR 6

5 ENVIRONMENTAL HAZARD ASSESSMENT

5.1 DEGRADATION

Table 6: Summary of relevant information on biodegradation

Method	Results	Remarks	Reference
Test type: ready biodegradability activated sludge, domestic, non-adapted OECD 301B	not readily biodegradable % Degradation of test substance: 13 after 28 d (CO ₂ evolution) (20 mg/l test substance) 19 after 28 d (CO ₂ evolution) (10 mg/l test substance)	2 (reliable with restrictions) key study experimental result Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6	Ciba-Geigy Ltd. (1986a)

5.1.1 STABILITY

Due to the high insolubility in water (0.13 µg/L), a test on hydrolysis is technically not feasible. Furthermore, the substance does not contain any functional groups that are susceptible to hydrolysis.

5.1.2 BIODEGRADATION

A guideline study performed according to OECD 301B determined the CO₂ evolution within 28 days. Non-adapted bacteria collected from activated sludge of the sewage treatment plant of CH-4153 Reinach were used as test system. The biodegradability of the test substance was determined by measurements of the carbon dioxide formation in per cent of TCO₂ calculated from the ThOC or TOC. 2 liters flasks equipped with gas inlet and magnetic stirrer were used as test vessel. During the test a temperature of 22 ± 2 °C were maintained and the aeration of the dilution water was approx. 50 mL/min free of carbon dioxide. The medium was prepared according to the method described in the guideline. 10 mg/L and 20 mg/L test substance were used as test concentrations (water solubility of test substance = 0.13 µg/L). 10 mg/L test substance is equivalent to 7.629 mg organic carbon/L.

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6**

The biodegradation was calculated on the basis of the theoretical carbon content of the test substance and the cumulative quantities of carbon dioxide determined on the days of measurements. For the calculations the formula given in the guideline was used. The test detected a degradation rate of < 20 %. The substance is poorly biodegradable.

5.1.3 SUMMARY AND DISCUSSION OF DEGRADATION

The substance is hydrolytically stable and does not readily biodegrade. Hence, the substance is not rapidly degradable.

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

5.2 ENVIRONMENTAL DISTRIBUTION

Based upon a log K_{oc} > 5.6 (OECD 121), the substance has a high potential to adsorb on soil and sewage sludge (Fraunhofer-Institut für Umweltchemie und Ökotoxikologie (1995)).

5.3 AQUATIC BIOACCUMULATION

Table 7: Summary of relevant information on aquatic bioaccumulation

Method	Results	Remarks	Reference
<p><i>Oncorhynchus mykiss</i></p> <p>aqueous (freshwater)</p> <p>flow-through</p> <p>Total uptake duration: 29 d</p> <p>Total depuration duration: 42 d</p> <p>OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish)</p>	<p>BCF: 66 — 179 dimensionless (for fish portions and whole-fish) (Time of plateau: 14 d)(steady state)</p> <p>Lipid content: 2.97.-6.84% (for fish portions and whole fish)</p> <p>BCF (lipid normalised): 111-132</p>	<p>1 (reliable without restriction)</p> <p>key study</p> <p>experimental result</p> <p>Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6</p>	<p>Huntingdon Life Sciences Ltd. (2007a)</p>
<p><i>Cyprinus carpio</i></p> <p>aqueous</p> <p>Total uptake duration: 4 wk</p> <p>Total depuration duration: 28 d</p> <p>equivalent or similar to OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish)</p>	<p>BCF: 22.5 dimensionless (Mean of 2 replication)</p> <p>BCF: 20 dimensionless (Mean of 2 replication)</p>	<p>2 (reliable with restrictions)</p> <p>supporting study</p> <p>experimental result</p> <p>Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6</p>	<p>Chemical Biotesting Center (1987)</p>

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

5.3.1 AQUATIC BIOACCUMULATION

In a GLP guideline study conducted in compliance with OECD 305C, the test fish (*Oncorhynchus mykiss*) were continuously exposed to concentrations of 0.05 µg/L ¹⁴C-labeled test material. The test substance was maintained at a nominal concentration using a continuous flow through system. A stock solution of [¹⁴C]-test substance in dimethylformamide (DMF) was prepared to provide sufficient stock solution for at least ten days. Stock solutions were stored at approx. +4 °C until required. A proportion of a stock solution of the test substance in solvent was transferred to the solvent stock vessel daily and connected to a peristaltic pump. The stock solution was delivered by the peristaltic pump at a nominal rate of 0.05-0.1 mL/min to a glass mixing vessel where it was proportionately mixed with diluent (water) to give the desired test concentrations. The flow rate in these tanks was nominally 1.0 litre/min which is equivalent to 1440 litre/day. The control tank was dosed with an equivalent volume of solvent alone. At the end of the exposure period, the fish were transferred to clean separate tanks of water also maintained under flow-through conditions with no added test substance.

Concentrations of the test substance in water and fish body were measured using a liquid scintillation counter. The total exposure / uptake duration was 29 d followed by a 42 d depuration duration. For test fish exposed to 0.05µg/L (nominal), a BCF of 66-179 (BCF (lipid normalised) = 111-132) was determined. Steady state was achieved during the exposure period. Elimination of the test item during the depuration phase was relatively slow. Kinetic analysis indicated that approximately 90% of the radioactive residues were eliminated in 36 - 44 days.

A supporting study was performed with *Cyprinus carpio* according to OECD guideline 305 C. The fish were exposed to concentrations of 1 mg/L and 0.1 mg/L for a test period of 4 weeks in a flow-through system followed by a 28 d depuration phase. BCF values of 22.5 and 20 were determined for the test concentration 1 mg/L and 0.1 mg/L, respectively. No lipid content was specified.

5.3.2 SUMMARY AND DISCUSSION OF AQUATIC BIOACCUMULATION

Experimentally determined BCF (lipid normalised) values of 111-132 demonstrate that the substance does not significantly accumulate in organisms. The BCF is below the CLP cut-off criterion of 500.

5.4 AQUATIC TOXICITY

Data on the acute toxicity are available for three trophic levels of the aquatic environment. Furthermore, data on the long-term toxicity towards *Daphnia magna* are available.

None of the tests demonstrated any acute toxic effects related to the intrinsic properties of the test substance within the range of its water solubility (0.13 µg/L).

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

5.4.1 FISH

5.4.1.1 SHORT-TERM TOXICITY TO FISH

In a guideline study (OECD 203) using *Danio rerio* a $LC_{50} > 72.3$ mg/L was detected based on analytically determined test concentrations (Ciba-Geigy Ltd. (1986c). No acute toxicity could be recorded at the highest test substance concentration.

The test was conducted as static test without renewal of the test solutions. A static test design seems to be appropriate as the test substance is hydrolytically stable under environmental conditions. It is regarded to be persistent or even very persistent in the environment. Furthermore, all test concentrations were clearly above the water solubility of the test substance due to the use of tetrahydrofuran as emulsifier. The stock solution was prepared by dissolving 5 g of the test substance in 50 mL tetrahydrofuran. Calculated amounts of stock solution to produce the desired test concentrations were given into the water and homogeneously distributed. In the concentration used for the highest test concentration the tetrahydrofuran concentration was 887 mg per 1 L water. A water and a vehicle control were run in parallel. The analytically determined value clearly exceeded the limit of water solubility of the test substance due to the use of the emulsifier.

Table 8: Overview of short-term effects on fish

Method	Results	Remarks	Reference
<i>Brachydanio rerio</i> (new name: <i>Danio rerio</i>) freshwater static OECD Guideline 203 (Fish, Acute Toxicity Test) (adopted 1984)	LC50 (96 h):> 100 mg/L test mat. (nominal) LC50 (96 h):> 72.3 mg/L test mat. (meas. (not specified))	2 (reliable with restrictions) key study experimental result Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6	Ciba-Geigy Ltd. (1986c)

5.4.1.2 Long-term toxicity to fish

No data available

ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON
REACTION MASS OF: ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
DODECYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

5.4.2 AQUATIC INVERTEBRATES

5.4.2.1 Short-term toxicity to aquatic invertebrates

In a short-term toxicity study on *Daphnia magna*, no acute toxicity could be recorded at the highest test substance concentration at test termination after 48 hours ($EC_{50} > 0.005$ mg/L, measured; RCC Ltd. (2002)). No emulsifier was used in the preparation of test solutions. The analytically determined test item concentration was below the limit of quantification of the analytical method of 0.005 mg/L. Therefore, the EC_{50} value refers to the limit of quantification. The test was conducted as static test without renewal of the test solutions. A static test design seems to be appropriate as the test substance is hydrolytically stable under environmental conditions. It is regarded to be persistent or even very persistent in the environment. Due to the low water solubility of the test item a supersaturated dispersion of the test item with a loading rate of 100 mg/L was continuously stirred at room temperature in the dark over 3 hours. Then, the dispersion was filtered (0.45 μ m membrane filter). The undiluted filtrate with the maximum concentration of dissolved test item was used as the only test medium. Additionally, a control was tested in parallel. The concentration of the test item both at test initiation and at test termination was below the detection limit of the analytical method (0.005 mg/L). The suitability of the analytical method was confirmed by measurements of spiked samples at a concentration of nominal 0.02 mg/L which had a recovery rate of 101% of the nominal value.

A second study was regarded as not reliable due to the limited exposure time of only 24 hours instead of 48 hours and the high concentration of tetrahydrofuran as emulsifier (514 mg/L in the highest test concentration). A stock solution was prepared with tetrahydrofuran and calculated amounts of this stock solution to produce the desired test concentrations were given into the water and homogeneously distributed. The test substance appeared homogeneously distributed but due to the low solubility of the test substance and the fact that the solutions were neither filtered nor centrifuged precipitates and resulting physical effect cannot be ruled out (Ciba-Geigy (1986b)).

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DODECYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

Table 9: Overview of short-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
<p><i>Daphnia magna</i></p> <p>freshwater</p> <p>static</p> <p>OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) (adopted 1984)</p> <p>EU Method C.2 (Acute Toxicity for Daphnia) (adopted 1992)</p>	<p>EC50 (48 h):> 100 mg/L test mat. (nominal) based on: mobility</p> <p>EC50 (48 h):> 0.005 mg/L test mat. (meas. (arithm. mean)) based on: mobility</p>	<p>2 (reliable with restriction)</p> <p>key study</p> <p>experimental result</p> <p>Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6</p>	RCC Ltd. (2002)
<p><i>Daphnia magna</i></p> <p>freshwater</p> <p>static</p> <p>OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) (adopted 1984)</p>	<p>EC50 (24 h): 4.1 mg/L test mat. (meas. (arithm. mean)) based on: mobility</p>	<p>3 (not reliable)</p> <p>disregarded study</p> <p>experimental result</p> <p>Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6</p>	Ciba-Geigy Ltd. (1986b)

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 REACTION MASS OF: ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
 DODECYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
 TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
 PHENOL. N=5 OR 6

5.4.2.2 Long-term aquatic invertebrates

A long term toxicity study on *Daphnia magna* according to OECD guideline 211 (*Daphnia magna* reproduction test) did not reveal any chronic toxicity up to the highest tested concentration. A NOEC of $0.09 \mu\text{g/L}$ (measured) has been derived at test termination (RCC Ltd. (2006a)). It was guaranteed, that the single concentration groups covered a range up to and exceeding the maximum water solubility of the test item. Due to the very low water solubility of the test item, a solvent (N,N-Dimethylformamide (DMF), $100 \mu\text{L DMF/L}$ test water) was used for the dosage. The highest tested concentration of nominal $0.2 \mu\text{g/L}$ exceeded the water solubility of the test item. The mean measured concentration of the highest concentration group (average over all measurements) was $0.09 \mu\text{g/L}$.

Table 10: Overview of long-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
<i>Daphnia magna</i> freshwater semi-static OECD Guideline 211 (<i>Daphnia magna</i> Reproduction Test) (adopted on September 21, 1998)	NOEC (21 d): $\geq 0.2 \mu\text{g/L}$ test mat. (nominal) based on: immobilisation NOEC (21 d): $\geq 0.09 \mu\text{g/L}$ test mat. (meas. (arithm. mean)) based on: immobilisation LOEC (21 d): $> 0.2 \mu\text{g/L}$ test mat. (nominal) based on: immobilisation LOEC (21 d): $> 0.09 \mu\text{g/L}$ test mat. (meas. (arithm. mean)) based on: immobilisation	1 (reliable without restriction) key study experimental result Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6	RCC Ltd. (2006a)

5.4.3 ALGAE AND AQUATIC PLANTS

The toxicity of the substance to *Scenedesmus subspicatus* was investigated in two tests according to or equivalent to OECD guideline 201. In the first test an ErC_{50} (72 h) $> 10 \text{ mg/L}$ (nominal) and a NOErC (72h) $\geq 10 \text{ mg/L}$ (nominal) were derived (ABC Inc. (1993)). The second test revealed an EbC_{50} (72 h) $> 3.5 \text{ mg/L}$ (measured; Safepharm Laboratories Ltd. (1995)). The test solutions of both tests were prepared using an emulsifier. The study conducted at ABC labs used 1.0, 10, and 100 mg/mL stock solutions which were prepared by weighing 0.0100, 0.1001, and 1.0000 g, respectively, of the test substance into 10-mL volumetric flask. Each was brought to volume with

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DODECYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6**

acetone. The 1.0, 10, and 100 mg/mL stock solutions were used to prepare the 0.10-, 1.0-, and 10-mg/L working standards by injecting a 0.050-mL aliquot of each primary standard into a 500-mL volumetric flask containing approximately 300 mL of algae nutrient media. Each test solution was then brought to a volume with algae nutrient media. In addition to the test substance solutions a control group (test medium only) and a vehicle control (test medium with acetone) were included in the test. The original test evaluation of the results pooled control and vehicle blank values and used this for all further statistical analyses. In this case a NOErC equal to 1 mg/L and an ErC50 greater than 10 mg/L were derived. As this evaluation did not take the effect of the solubilizer (acetone) into account, the data in the report have been re-evaluated to specifically compare the effects in the concentration groups towards the vehicle control group. The re-evaluation revealed a NOErC of greater than or equal to 10 mg/L.

The study conducted at Safepharm Labs was conducted by preparing a preliminary solution of the test substance in 1% v/v Tween 80-tetrahydrofuran. An amount of test material (500 mg) was dissolved in solvent and the volume adjusted to 10 ml to give a 500 mg/10 mL solvent stock solution. An aliquot (200 µL) of this solvent stock solution was dispersed in 2 litres of algal suspension to give the required test concentration of 5.0 mg/L.

In both studies, no effects could be recorded up to the water solubility of the test substance.

Table 11: Overview of effects on algae and aquatic plants

Method	Results	Remarks	Reference
<i>Scenedesmus subspicatus</i> (new name: <i>Desmodesmus subspicatus</i>) (algae) freshwater static equivalent or similar to OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (72 h): > 10 mg/L test mat. (nominal) based on: growth rate NOEC (72 h): ≥ 10 mg/L test mat. (nominal) based on: growth rate	2 (reliable with restrictions) key study experimental result Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6	ABC Inc. (1993)
<i>Scenedesmus subspicatus</i> (new name: <i>Desmodesmus subspicatus</i>) (algae)	EC50 (72 h): > 5 mg/L test mat. (nominal) based on:	2 (reliable with restrictions)	Safepharm Laboratories Ltd.

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DODECYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6**

Method	Results	Remarks	Reference
freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test) (adopted 1984)	biomass EC50 (72 h): > 3.5 mg/L test mat. (meas. (arithm. mean)) based on: biomass NOEC (72 h): >= 5 mg/L test mat. (nominal) based on: biomass NOEC (72 h): >= 3.5 mg/L test mat. (meas. (arithm. mean)) based on: biomass	supporting study experimental result Test material (EC name): A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6	(1995)

5.4.4 OTHER AQUATIC ORGANISMS (INCLUDING SEDIMENT)

No data available.

5.5 COMPARISON WITH CRITERIA FOR ENVIRONMENTAL HAZARDS (SECTIONS 5.1 – 5.4)

	Criteria for environmental hazards	A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6	Conclusion
Rapid Degradation	Readily biodegradable in a 28-day test for ready biodegradability	< 20% CO2 evolution in 28 days	Not rapidly degradable
Bioaccumulation	BCF \geq 500 Log Kow \geq 4	BCF _{lipid-normalised} = 111-132	Not bioaccumulative
Aquatic Toxicity	Acute toxicity data: LC50/EC50/ErC50 \leq 100 mg/L Chronic toxicity data: NOEC \leq 1mg/L	Fish: LC50 96h > 72.3 mg/L (meas.) NOEC not available Invertebrates: EC50 48h > 0.005 mg/L (meas.) NOEC 21d \geq 0.09 μ g/L (meas.) Algae: ErC50 72h > 10 mg/L (nominal)	No acute and chronic toxicity up to the water solubility

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 TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
 PHENOL. N=5 OR 6

		NOErC 72h \geq 10mg/L (nominal)	
		Water solubility = 0.13 μ g/L	

5.6 CONCLUSIONS ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS (SECTIONS 5.1 –5.4)

With respect to the findings of the acute and chronic experimental studies, no toxicity of the substance in the range of its water solubility has been recorded. Furthermore, the substance does not have a significant potential to bioaccumulate – the BCF was clearly below 500.

In conclusion, none of the criteria of Regulation (EC) No 1272/2008 have been met. Therefore, it is proposed that the substance is no longer classified for environmental hazards.

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier submitter's proposal

The proposal was prepared by industry and submitted by Germany according to Article 37(6) of the CLP Regulation (Regulation (EC) No. 1272/2008).

The substance, "reaction mass of:

isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol;

isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol;

isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6", is also known under the trade name of **Tinuvin 171/571**.

The substance has been classified as N; R 51/53 and included in Annex I to Directive 67/548/EEC in 2001 with the 28th ATP. With implementation of the CLP Regulation the substance was classified as Aquatic Chronic 2, because of the following data:

The data on biodegradation and bioconcentration considered by the DS are presented in the RAC assessment and comparison with the classification criteria further below.

An acute toxicity test on *Daphnia magna* revealed a measured EC₅₀ (24h) value of 4.1 mg/L (Ciba-Geigy Ltd., 1986b) and based on this result classification for environmental hazards (Aquatic Chronic 2; H411) was considered to be appropriate. From a scientific present-day perspective the study shows various deficiencies. The study was carried out with concentrations which are orders of magnitude above the water solubility (514 mg/L was used in the highest test concentration) and with an emulsifier (tetrahydrofuran). Furthermore, the test duration was only 24 hours.

In the meantime, the acute toxicity study on daphnia was repeated according to test method C.2 (equivalent to OECD TG 202), specified in Directive 92/69/EEC and under consideration of the OECD guidance document on aquatic toxicity testing of difficult substances (2000). This study (RCC Ltd., 2002) did not reveal any toxicity at levels up to the water solubility (EC₅₀ > 100 mg/L – nominal; water solubility = 0.13 μ g/L). Furthermore, available chronic toxicity data on daphnia according to OECD TG 211 did not show any toxic effects in the range of water solubility either (NOEC \geq 0.2 μ g/L – nominal).

With respect to the findings of the new toxicity studies on daphnia, no toxicity of the substance

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

in the range of its water solubility is recorded. Furthermore, due to the absence of any bioaccumulation potential (lipid normalised BCF = 132), the DS proposed to delete the existing classification as Aquatic Chronic 2; H411 in Annex VI to the CLP Regulation, since the substance does not meet the criteria for aquatic long-term hazard classification.

Comments received during public consultation

One MSCA proposed classification as Aquatic Chronic 4; H413 instead of the removal of Aquatic Chronic 2; H411, because chronic data are not available for all three trophic levels and the MSCA considered the bioaccumulation study was not performed according to the most appropriate methodology based on the substance low water solubility.

One company supported the no classification proposal for aquatic chronic toxicity.

Assessment and comparison with the classification criteria

Physico-chemical properties

Water solubility = 0.13 µg/L at 20°C (test method A.6 of Directive 92/69/EEC; equivalent to OECD TG 105).

Partition coefficient octanol/water log Kow= 8.9 at 20°C (estimated by calculation), log Koc > 5.6 at 40°C (OECD TG 121).

Degradation

A guideline study performed according to OECD TG 301B (Ciba-Geigy Ltd., 1986a) determined the CO₂ evolution within 28 days. The test detected a degradation rate of < 20 %, which is below the 60% threshold to be considered as rapidly degradable as per CLP criteria. Hence the substance is not rapidly degradable.

Bioaccumulation

In a GLP study conducted in compliance with OECD TG 305C, the test fish (*Oncorhynchus mykiss*) were continuously exposed to concentrations of 0.05 µg/L ¹⁴C-labeled test material. A dispersant (DMF) was used to prepare the test solutions. Concentrations of the test substance in water and fish body were measured using a liquid scintillation counter. The total exposure/uptake duration was 29 days followed by a 42 days depuration duration. For test fish exposed to 0.05 µg/L, a BCF of 66-179 was determined (Lipid content: 2.97.-6.84% for fish portions and whole fish, BCF (lipid normalised): 111-132).

A second study was performed with *Cyprinus carpio* according to OECD TG 305C. The fish were exposed to concentrations of 1 mg/L and 0.1 mg/L for a test period of 4 weeks in a flow-through system followed by a 28 days depuration phase. BCF values of 22.5 and 20 were determined for the test concentration 1 mg/L and 0.1 mg/L, respectively.

According to the equations in OECD TG 305, Annex 5, for a substance with a log Kow of 8.9 the steady state can be only be reached in more than 200 days. However, the total exposure/uptake duration for both above mentioned studies was 29 days and four weeks, respectively. This is considered to be too short to reach steady state, so the resulting BCFs are not considered reliable by RAC.

The second study with *Cyprinus carpio* involved exposure concentrations significantly above the solubility limit in pure water. In general, bioconcentration is understood to be the result of uptake of dissolved substance at the gill surface. The reported BCF values can be converted to fish wet weight (22.5 mg/kg for the 1 mg/L exposure concentration) and if divided by the water solubility value (which is presumably closer to the dissolved concentration in the test, see OECD TG 305), the obtained BCF is well above 500.

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

Aquatic toxicity

Short-term toxicity

In a guideline study (OECD TG 203) using *Danio rerio*, an LC₅₀ (96h) > 72.3 mg/L based on analytically determined test concentrations was reported (Ciba-Geigy Ltd., 1986c).

In a short-term toxicity study on *Daphnia magna*, no acute toxicity was recorded at the highest test substance concentration at test termination after 48 hours (EC₅₀ > 0.005 mg/L, measured; RCC Ltd., 2002). No emulsifier was used in the preparation of test solutions.

The toxicity of the substance to *Scenedesmus subspicatus* was investigated in two tests according to or equivalent to OECD TG 201. In the first test an E_rC₅₀ (72h) > 10 mg/L (nominal) was derived (ABC Inc., 1993). The second test revealed an E_bC₅₀ (72h) > 3.5 mg/L (measured; Safeparm Laboratories Ltd., 1995). The test solutions of both tests were prepared using an emulsifier.

Long-term toxicity

A long term toxicity study on *Daphnia magna* according to OECD TG 211 (*Daphnia magna* reproduction test) did not reveal any chronic toxicity up to the highest tested concentration. NOEC values (21d) of ≥ 0.2 µg/L and NOEC (21d) of ≥ 0.09 µg/L based on nominal and measured concentrations, respectively, have been derived at test termination (RCC Ltd., 2006a). Due to the very low water solubility of the test item, a solvent was used for the dosage. The highest tested concentration of nominal 0.2 µg/L exceeded the water solubility of the test item. The mean measured concentration of the highest concentration group (average of all measurements) was 0.09 µg/L.

Data on the acute toxicity are available for three trophic levels of the aquatic environment. Furthermore, data on the long-term toxicity towards *Daphnia magna* are available. None of the tests demonstrated any toxic effects related to the intrinsic properties of the test substance within the range of its water solubility (0.13 µg/L).

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 K_{ow} ≥ 4)

With respect to the findings of the BCF studies mentioned above, RAC considers that criterion (3) is fulfilled. Therefore, it is appropriate to classify the substance for environmental hazards as Aquatic chronic 4.

In conclusion, RAC recommends to classify the reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 as **Aquatic Chronic 4; H413** according to the CLP Regulation.

Supplemental information - In depth analyses by RAC

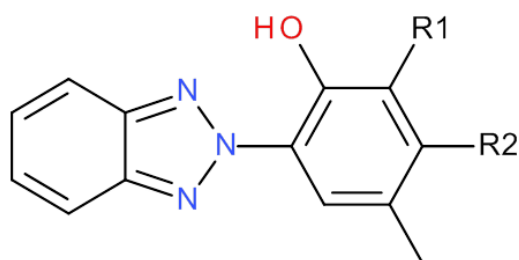
To further explore the bioaccumulation potential of the reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 QSAR calculations with EPIWIN (4.1) were performed.

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TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

SMILES used for BCF calculation:

1. Cc1cc(c(O)c(CCCCCCCCCC)c1)n2nc3cccc3n2
2. Cc1cc(c(O)c(CCCCCCCCCC)c1CCCCCCCCC)n2nc3cccc3n2
3. Cc1cc(c(O)c(CCCCCCCCCCCCCCCCCC)c1CCCCCCCCC)n2nc3cccc3n2

1. Estimated log BCF = 2.573 → BCF = 374.3
2. Estimated log BCF = 0.500 → BCF = 3.162 (log Kow= 14.9)
3. Estimated log BCF = 0.500 → BCF = 3.162 (log Kow= 20.8)



R1 = isomers of
 $C_{12}H_{25}$ and $C_{24}H_{49}$

R2 = H or isomers of
 $C_{12}H_{25}$

The maximum log Kow in the training set for EPIWIN is 11.59. However, estimated BCF values for substances with a log Kow out of the applicability domain are considered unreliable.

6 OTHER INFORMATION

Not applicable

7 REFERENCES

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ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON
REACTION MASS OF: ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
DODECYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-(N)-
TETRACOSYLPHENOL; ISOMERS OF 2-(2H-BENZOTRIAZOL-2-YL)-4-METHYL-5,6-DIDODECYL-
PHENOL. N=5 OR 6

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