

Committee for Risk Assessment

RAC

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

Adopted

4 December 2015

OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND LABELLING AT EU LEVEL

In accordance with Article 37 (4) of Regulation (EC) No 1272/2008, the Classification, Labelling and Packaging (CLP) Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonized classification and labelling (CLH) of:

Chemical 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: -

The proposal was submitted by **Germany** and received by RAC on **20 March 2015**.

In this opinion, all classification and labelling elements are given in accordance with the CLP Regulation; the notation of 67/548/EEC, the Dangerous Substances Directive (DSD) is no longer provided.

PROCESS FOR ADOPTION OF THE OPINION

Germany has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at <http://echa.europa.eu/harmonised-classification-and-labelling-consultation/> on **19 May 2015**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **3 July 2015**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Marian Rucki**

The opinion takes into account the comments provided by MSCAs and concerned parties in accordance with Article 37(4) of the CLP Regulation and the comments received are compiled in Annex 2. The RAC opinion on the proposed harmonized classification and labelling was adopted on **4 December, 2015** by **consensus**.

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	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)-tetra cosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-dido decyl-phenol. n = 5 or 6	401-680-5	-	Aquatic Chronic 2	H411	GHS09	H411	-	-	-
Dossier submitters proposal	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)-tetra cosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-dido decyl-phenol. n = 5 or 6	401-680-5	-	Remove Aquatic Chronic 2	Remove H411	Remove GHS09	Remove H411	-	-	-
RAC opinion	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)-tetra cosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-dido decyl-phenol. n = 5 or 6	401-680-5	-	Remove Aquatic Chronic 2 Add Aquatic chronic 4	Remove H411 Add H413	Remove GHS09	Remove H411 Add H413	-	-	-
Resulting Annex VI entry if	604-057-00-8	reaction mass of: isomers of 2-(2H-benzotriazol-2-	401-680-5	-	Aquatic chronic 4	H413	-	H413	-	-	-

agreed by COM		yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetra-cosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-dido-decyl-phenol. n = 5 or 6									
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GROUNDS FOR THE ADOPTION OF THE OPINION

RAC general comment

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**.*

ENVIRONMENTAL HAZARD EVALUATION

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier submitter's proposal

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 µg/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 ≥ 0.2 µg/L - nominal).

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

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; Safepharm 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 $\geq 0.2 \mu\text{g/L}$ and NOEC (21d) of $\geq 0.09 \mu\text{g/L}$ 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 $0.2 \mu\text{g/L}$ exceeded the water solubility of the test item. The mean measured concentration of the highest concentration group (average of all measurements) was $0.09 \mu\text{g/L}$.

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 ($0.13 \mu\text{g/L}$).

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 $\text{BCF} \geq 500$ (or, if absent, a $\log K_{ow} \geq 4$)

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- didodecylphenol. $n = 5$ or 6 as **Aquatic Chronic 4; H413** according to the CLP Regulation.

Additional references

References not contained in the Background Document.

Fraunhofer-Institut für Umweltchemie und Ökotoxikologie (1995). Determination of the Adsorption-Coefficient on soil by means of a HPLS-Screening Method. Report no.: CIB-013/7-.Owner Company BASF SE. Report date: 1995-12-2270

ANNEXES:

- Annex 1 The Background Document (BD) gives the detailed scientific grounds for the opinion. The BD is based on the CLH report prepared by the Dossier Submitter; the evaluation performed by RAC is contained in 'RAC boxes'.
- Annex 2 Comments received on the CLH report, response to comments provided by the Dossier Submitter and RAC (excluding confidential information).