

Committee for Risk Assessment
RAC

Opinion
proposing harmonised classification and labelling
at EU level of

**TINUVIN 123; REACTION MASS OF
BIS(2,2,6,6-TETRAMETHYL-1-OCTYLOXYPIPERIDIN-4-YL)
-1,10-DECANEDIOATE AND
1,8-BIS[(2,2,6,6-TETRAMETHYL-4-((2,2,6,6-TETRAMET
HYL-1-OCTYLOXYPIPERIDIN-4-YL)-DECAN-1,10-DIOYL)PI
PERIDIN-1-YL)OXY]OCTANE**

EC number: 406-750-9
CAS number: -

CLH-O-0000004693-69-03/F

Adopted
06 June 2014

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 (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 harmonised classification and labelling (CLH) of:

Chemical name: **Tinuvin 123;**
Reaction mass of bis(2,2,6,6-tetramethyl -1-octyloxypiperidin-4-yl)-1,10-decanedioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin -4-yl)-decan-1,10-dioyl)piperidin -1-yl)oxy]octane

EC number: **406-750-9**
CAS number: **-**

The proposal was submitted by **Germany** and received by the RAC on **28 November 2013**. All classifications are given in the form of CLP hazard classes and/or categories, the majority of which are consistent with the Globally Harmonised System (GHS); the notation of 67/548/EEC, the Dangerous Substances Directive (DSD) is no longer given.

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 **13 December 2013**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **27 January 2014**.

ADOPTION OF THE OPINION OF THE RAC

Rapporteur, appointed by the 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.

The RAC opinion on the proposed harmonised classification and labelling was reached on **06 June 2014** and the comments received are compiled in Annex 2.

The RAC Opinion was adopted by **consensus**.

OPINION OF THE RAC

The RAC adopted the opinion on **Tinuvin 123** that should be classified and labelled as follows:

Classification and labelling in accordance with the CLP Regulation

	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	607-331-00-5	reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decane dioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-dec an-1,10-dioyl)piperidin-1-yl)oxy]octane	406-750-9	129757-67-1	Aquatic Chronic 4	H413		H413			
Dossier submitters proposal	607-331-00-5	reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decane dioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-dec an-1,10-dioyl)piperidin-1-yl)oxy]octane	406-750-9	129757-67-1	Remove: Aquatic Chronic 4	Remove: H413		Remove: H413			

	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)		
RAC opinion	607-331-00-5	reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decane dioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-dec an-1,10-dioyl)piperidin-1-yl)oxy]octane	406-750-9	129757-67-1	Remove: Aquatic Chronic 4	Remove: H413		Remove: H413			
Resulting Annex VI entry if agreed by COM	-	reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decane dioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-dec an-1,10-dioyl)piperidin-1-yl)oxy]octane	No resulting Annex VI entry								

SCIENTIFIC GROUNDS FOR THE OPINION

ENVIRONMENTAL HAZARD ASSESSMENT

RAC evaluation of environmental hazards

Summary of the Dossier submitter's proposal

The proposal was drafted by BASF SE and submitted by BAuA Germany according to CLP article 37(6).

The reaction mass of bis (2,2,6,6 -tetramethyl-1-octyloxypiperidin-4-yl) -1,10-decanedioate and 1,8-bis [(2,2,6,6-tetramethyl-4- ((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl) -decan-1,10-dioyl) piperidin-1-yl) oxy]octane (Tinuvin 123) was classified as R53 and added to Annex I of Directive 67/548/EEC in 2001 by the 28th ATP, based on the following data.

The substance has very low water solubility (< 0.046 mg/L) and shows no toxic effects within the water solubility range in acute aquatic studies on fish, daphnia and algae. Furthermore, the substance is not readily biodegradable (approx. 20% degradation after 28 days). The assessment of potential bioaccumulative properties of the substance was based on a calculated log Kow >> 10.

However, a new GLP study on bioconcentration (Ciba-Geigy Japan Ltd., 1996) conducted in compliance with OECD TG 305 C resulted in a BCF = 32 - 47. Based on the results of this study, in the follow-up period to the TC C&L Meeting held in April 2006 the declassification was confirmed.

In this study, the test fish (*Cyprinus carpio*) were continuously exposed to concentrations of 0.025 mg/L and 0.0025 mg/L of ¹⁴C-labeled test material (Tinuvin 123). Concentrations of the test substance in water and fish body were measured using a liquid scintillation counter. The test concentrations were measured every 2 weeks and remained in the range 0.0242 to 0.0246 mg/L and 0.00260 to 0.00269 mg/L for the high and low concentration solutions, respectively. A dispersant (HCO-30) was used to prepare the test solutions. The concentration of HCO-30 in the final test solutions at different concentrations of test material and in the control was 0.025 mg/L. The test temperature was 25 ± 2 °C and the concentration of dissolved oxygen during the exposure period was > 6.3 mg/L.

The test was terminated after 8 weeks of exposure. For test fish exposed to 0.025 mg/l, a BCF = 32 - 46 was determined, whereas at the test concentration of 0.0025 mg/L, a BCF = 43 - 47 was observed.

A supporting study (Ciba-Geigy Japan Ltd., 1992) was performed with *Cyprinus carpio* according to a method equivalent to OECD TG 305C (see the background document for more details). The fish were exposed to concentrations of 1 mg/L and 0.1 mg/L for a test period of 8 weeks in a flow-through system. A BCF < 4.6 was determined for the test concentration of 1 mg/L. At a concentration of 0.1 mg/L the BCF ranged from 4.5 to < 35.

Based on the study on bioconcentration of the substance according to OECD TG 305 C, the weight of evidence of another supporting bioconcentration study and the results of supporting QSAR estimations, the dossier submitter proposed to delete the existing classification in CLP (Regulation (EC) No. 1272/2008) of Tinuvin 123 as Aquatic Chronic 4; H413, since the substance does not meet the criteria for aquatic chronic classification .

Comments received during public consultation

Two MSCAs supported the no classification proposal for aquatic chronic toxicity. No comments opposing the proposal were received.

Assessment and comparison with the classification criteria

According to Table 4.1.0 ("Classification categories for hazardous to the aquatic environment") of the CLP Regulation, classification criteria for Aquatic Chronic 4 includes:

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

Tinuvin 123 fulfils criteria (1) and (2), but with respect to the findings of the BCF study (as described above), criterion (3) is clearly not fulfilled. Therefore, it is considered appropriate to declassify the substance for environmental hazards.

In conclusion, RAC recommends that Tinuvin 123 should not be classified as aquatic chronic according to CLP (Regulation (EC) No. 1272/2008).

ANNEXES:

- Annex 1 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 rapporteurs' comments (excl. confidential information).