

Committee for Risk Assessment
RAC

Annex 2

Response to comments document (RCOM)
to the 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-TETRAMETHYL-1-OCTYLOXYPIPERIDIN-4-YL)-
DECAN-1,10-DIOYL)PIPERIDIN-1-YL)OXY]OCTANE**

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

CLH-O-0000004693-69-03/F

Adopted
06 June 2014

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 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

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in this table as submitted by the webform. Please note that some attachments received may have been copied in the table below. The attachments received have been provided in full to the dossier submitter and RAC.

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Substance name: Reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxy piperidin-4-yl)-1,10-decanedioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxy piperidin-4-yl)-decan-1,10-dioyl) piperidin-1-yl)oxy]octane

CAS number: -

EC number: 406-750-9

Dossier submitter: Germany

HAZARDOUS TO THE AQUATIC ENVIRONMENT

Date	Country	Organisation	Type of Organisation	Comment number
27/01/2014	Belgium		MemberState	1
Comment received				
<p>We support the proposed removal of aquatic chronic 4/R53 by BAuA</p> <p>The substance is a poorly soluble substance (WS < 0.046 mg/l) and no toxicity was seen up to the water solubility for all three trophic levels. A readily biodegradability study resulted in 19% degradation after 28d, by which the criterion for readily biodegradability is not met. A BCF study performed following guideline 305C determined a BCF of 32-47. The low potential to bioaccumulate is supported in a greater or lesser extent by different QSAR models as well by the fact that</p> <ul style="list-style-type: none"> - the capability of entering the membranes is hindered if the average maximum diameter is >1.7nm : min Diammax compound 1: 18.6 and compound 2 : 28.5 nm resp. - A MW higher than 1100 g/mol is indicative of a limited bioavailability : MW of the substance= 2097.26 - The aquatic BCF of a substance is probably lowered if the calculated logKow is higher than 10 : log Kow (calculated) >>10 <p>Some editorial or/and minor comments BCF study according to OECD guideline 305C : For substances with a log Kow >3, the BCF should be normalised to lipid content. Is this the case for the result given?</p>				
Dossier Submitter's Response				
<p>Thank you for your support.</p> <p>The BCF values provided in the study Ciba-Geigy Japan Ltd. (1996) are based on concentrations of the test substance in water and fish body. However, also a fat content of fish of 3.3% (2.5 - 3.8%, n=4) is reported.</p> <p>Hence, the method for lipid normalisation to 5% lipid content described in section 8 of ANNEX 5 of the OECD TG 305 adopted on October 02, 2012 can be applied retrospectively. Maximum BCF reported for the substance after 8 weeks was 47.</p>				

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According to equation A5.30, the lipid-normalised kinetic BCF_{KL} equals 0.05 divided by the mean lipid fraction, multiplied by the kinetic BCF_K :

$$BCF_{KL} = (0.05/0.033)*47 = 71.2$$

The resulting (maximum) BCF normalised to lipid content of 71 is well below the respective trigger values of 67/548/EEC and (EC) No. 1272/2008, demonstrating that the substance does not significantly accumulate in organisms.

RAC's response

Noted

Date	Country	Organisation	Type of Organisation	Comment number
24/01/2014	Sweden		MemberState	2

Comment received

The Swedish CA supports the German CA's proposal on environmental declassification of "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 406-750-9).

Page 10, Section 2.1, para 3: please rephrase the paragraph in order to clarify if the substance is already declassified.

Page 10, Section 2.2, para 1: please rephrase the paragraph to make the description of the study and the arguments clearer. A reference to the study(ies) might make it clearer, both in the background section and under Section 5, Environmental hazard assessment.

The substance was classified as R53 and added to Annex I of Directive 67/548/EEC in 2001 by the 28.ATP. This classification was based on studies showing very low water solubility (< 0.046 mg/L), no toxic effect in the range of water solubility in acute aquatic studies on fish, daphnia and algae and that the substance is not readily biodegradable (approx. 20% degradation after 28 days). Finally, the assessment of potential bioaccumulative properties of the substance was based on a calculated $\log Pow >> 10$.

A study on aquatic bioconcentration according to OECD 305C was performed (Ciba-Geigy Japan Ltd, 1996). The measured bioconcentration factor (BCF) was 32-47 within the concentration range 0.025-0.0025 mg/l. The study is supported by another study equivalent to OECD TGD 305C where the BCF ranged from 4.5-<35 at 0.1 mg/l (Kanpogyo No.5, Yakuhatu N,615, 49-Kikyoku No.392, 1974). This implies a low potential to bioaccumulate in fish, which is also supported by several QSAR estimations where a weight of evidence approach using experimentally determined BCF values of max 47 is used and molecular dimensions of the substance is taken into account.

With respect to the findings of the BCF study mentioned above, one of the classification criterias for Aquatic Chronic 4 of Regulation (EC) No 1272/2008: "an experimentally determined $BCF \geq 500$ " is not fulfilled. Therefore, it appears appropriate to declassify the substance for environmental hazards, i.e. remove Aquatic Chronic 4 of Regulation (EC) No 1272/2008 and R53 of Directive 67/548/EEC.

Dossier Submitter's Response

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Thank you for your support.

Rewording of Section 2.1, para 3: In February 2005 a study on bioconcentration according to OECD 305 C was submitted (BCF = 32 - 47). In the follow-up period to the TC C+L Meeting held in April 2006 the declassification was confirmed but not considered in the further process.

Rewording of Section 2.2, para 1: A study on aquatic bioaccumulation according to OECD Guideline 305 C was performed (Ciba-Geigy Japan Ltd (1996)). This study revealed a measured bioconcentration factor (BCF) of < 100 respectively 500 (32-46 for the upper concentration of 0.025 mg/L and 43-47 for the lower concentration of 0.0025 mg/L, respectively). For details please refer to Part B of this document.

Rewording of Section 5.3.1, para 2: In a GLP guideline study conducted in compliance with OECD 305C, the test fish (Cyprinus carpio) were continuously exposed to concentrations of 0.025 mg/l and 0.0025 mg/l, respectively, of ¹⁴C labeled test material (Ciba-Geigy Japan Ltd (1996)). ...

Rewording of Section 5.3.1, para 3: A supporting study was performed with Cyprinus carpio according to "Study Methods Concerning New Chemical Substances: The Test on the Degree of Bioconcentration in Fish and Shellfish (Kanpogyo No.5, Yakuhatu No.615, 49-Kikyoku No.392, 1974)" which is equivalent to OECD Guideline 305 C (Ciba-Geigy Japan Ltd. (1992)). ...

RAC's response

Noted