

**Committee for Risk Assessment
RAC**

Addendum to the RCOM and to the Opinion
proposing harmonised classification and labelling
at EU level of
Dimethyltin dichloride

EC Number: 212-039-2

CAS Number: 753-73-1

ECHA/RAC/CLH-O-0000001701-83-03/F

**Addendum adopted
4 October 2013**

**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: Dimethyltin dichloride

EC Number: 212-039-2

CAS Number: 753-73-1

The proposal was submitted by **France** and received by RAC on **14 February 2012**.

In this opinion, all classifications are given firstly in the form of CLP hazard classes and/or categories, the majority of which are consistent with the Globally Harmonised System (GHS) and secondly, according to the notation of 67/548/EEC, the Dangerous Substances Directive (DSD).

The proposed harmonised classification

	CLP	DSD
Current entry in Annex VI of CLP Regulation (EC) No 1272/2008	No entry	No entry
Proposal by dossier submitter for consideration by RAC	Acute Tox.3 - H301 Acute Tox.3 - H311 Acute Tox.2 - H330 Skin Corr.1B - H314 Repr. 2 - H361d STOT RE1 - H372 (nervous system)	T; R25 Xn; R21 T+; R26 C; R34 Repr. Cat. 3; R63 T; R48/25
Resulting harmonised classification (future entry in Annex VI of CLP Regulation) as proposed by dossier submitter	Acute Tox.3 - H301 Acute Tox.3 - H311 Acute Tox.2 - H330 Skin Corr.1B - H314 Repr. 2 - H361d STOT RE1 - H372 (nervous system)	T; R25 Xn; R21 T+; R26 C; R34 Repr. Cat. 3; R63 T; R48/25

PROCESS FOR ADOPTION OF THE OPINION

France 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 **14 February 2012**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **30 March 2012**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Helmut Greim**

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 **30 November 2012** and the comments received are compiled in Annex 2.

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

This addendum, amending the sections of the RCOM and RAC opinion which addressed the skin corrosion classification, was adopted on 4 October 2013 by written procedure.

AMENDED OPINION OF THE RAC

The RAC adopted the amended opinion that **Dimethyltin dichloride (DMTC)** 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
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state Code(s)	Suppl. Hazard statement Code(s)	
050-029-00-8	Dimethyltin dichloride	212-039-2	753-73-1	Repr. 2 Acute Tox.3 Acute Tox.3 Acute Tox.2 Skin Corr. 1B STOT RE1	H361d H301 H311 H330 H314 H372 (nervous system, immune system)	GHS05 GHS06 GHS08 Dgr	H361d H301 H311 H330 H314 H372 (nervous system, immune system)	EUH071	

Classification and labelling in accordance with the criteria of DSD

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits
050-029-00-8	Dimethyltin dichloride	212-039-2	753-73-1	Repr. Cat. 3; R63 T+; R26 T; R24/25-48/25 C; R34	T+; C R: 24/25-26-34-48/25-63 S: (1/2-)26-28-36/37-39-45-63	

Background

The opinion on the harmonised classification and labelling (CLH) for dimethyltin dichloride was adopted on 30 November 2012. However, classification as Skin Corr. 1 without sub-categorisation was not consistent with the CLP Regulation applicable at the time the decision to adopt this classification was made. Therefore the following amended opinion on skin irritation/corrosion has been adopted by RAC. The relevant comment in the Response to Comments (RCOM) document has also been amended as shown below.

Amended RCOM

Amended RAC response to the comment on the skin corrosion classification on p9 of the RCOM:

The RAC notes that the available information does not allow differentiation between the subcategories. However, since classification for skin corrosion without sub-categorisation is currently not possible under the CLP Regulation, RAC agreed to classify dimethyltin dichloride as **Skin Corr. 1B** (H314), (**C; R34** under DSD)

Amended RAC opinion on Irritation/Corrosion

Summary of Dossier submitter's proposal

The DS includes two studies on skin irritation/corrosion in the CLH report. One Draize test study, conducted in rabbits with DMTC alone (Affiliated Medical Enterprises, 1971c) showed moderate irritation and one OECD TG 404 compliant study in rabbits, conducted with a mixture of DMTC and MMTC (84.8%:15.2%) (Rush 1993b) reported corrosive effects on rabbit skin. The DS proposed classification as Skin Corr. 1B – H314 according to CLP and C; R34 according to DSD.

Comments received during public consultation

Comments were received from two MS during public consultation. One MS suggested that the dataset does not allow for differentiation into subcategories and supported classification as Skin Corr. 1 – H314. It also suggested the addition of hazard statement EUH071 – Corrosive to the respiratory tract. Another MS asked for further clarification on the appearance of the response. The DS agreed that classification in the subcategory 1B is not appropriate and proposed category 1C instead, along with the addition of EUH071. These changes are reflected in a revised version of the CLH report, supplied as an appendix to the RCOM. Further details are available in the RCOM.

Assessment and comparison with criteria

In the Affiliated Medical Enterprises study (1971c), very slight oedema was observed on all animals at both intact and abraded skin sites at 24 hours. No oedema was observed at 72 hours. The Primary Dermal Irritation Index is evaluated at 1.75. Moderate to severe erythema and eschar formation were observed on all animals, at both skin sites, at 24 and 72 hours. According to the evaluation criteria of the Draize test, the substance would be considered a moderate irritant to the skin.

In the Rush (1993b) study, blanching and necrosis with severe oedema were observed on all dermal sites within 1 hour after a four-hour exposure time, with irritation progressing to eschar in 3 sites by termination of the observation period (at 72 hours). Under the conditions of the test, the substance would be considered to be corrosive to rabbit dermal tissue.

In the Affiliated Medical Enterprises (1971c) study, the exposure period of 24 hours is too long for the data to be used for classification of DMTC for skin corrosion. Thus, RAC concluded that this study does not allow the classification of the substance in the skin corrosive category.

In the second study (Rush, 1993b), a positive result was obtained after a four-hour application on the rabbit dermal tissue with an observation period from about 1 hour to 72 hours, so the test substance was considered to be corrosive. As positive results were noted during the observation period of 1 hour after the four-hour exposure, classification in category 1C for skin corrosion has been proposed.

However, the RAC noted that neither study provides sufficient information on whether corrosive effects occur after a shorter exposure (i.e., ≤ 3 min for subcategory 1A, or between 3 min and 1 hr for subcategory 1B) so that no differentiation between the subcategories can be made, in contrast to the original proposal by the DS.

Since classification for skin corrosion without sub-categorisation is currently not possible under the CLP Regulation, RAC agreed to classify dimethyltin dichloride as **Skin Corr. 1B** (H314), (**C; R34** under DSD). Classification as skin corrosion sub-category 1B is consistent with the C; R34 classification under DSD and with Note 2 to table 1.1 of Annex VII of the CLP Regulation which states as follows: *"It is recommended to classify in Category 1B even if it also could be possible that 1C could be applicable for certain cases. Going back to original data, may not result in a possibility to distinguish between Category 1B or 1C, since the exposure period has normally been up to 4 hours according to Regulation (EC) No 440/2008. However, for the future, when data are derived from tests following a sequential approach as foreseen in the Regulation (EC) No 440/2008, Category 1C should be considered."*

Skin Corr. 1A would effectively be a maximum classification, and was not considered appropriate without data to justify this classification.

As DMTC is acutely toxic via inhalation and corrosive to skin, RAC additionally concluded that it is appropriate to add EUH071 (corrosive to the respiratory tract).