

Committee for Risk Assessment
RAC

Opinion
proposing harmonised classification and labelling
at EU level of
1,1',1''-nitrilotripropan-2-ol (TIPA)

EC Number: 204-528-4

CAS Number: 122-20-3

ECHA/RAC/CLH-O-0000002510-87-01/F

Adopted
8 March 2012

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

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

Substance Name: 1,1',1''-nitriлотripropan-2-ol (TIPA)

EC Number: 204-528-4

CAS Number: 122-20-3

The proposal was submitted by **Germany** and received by RAC on **3 October 2011**

The proposed harmonised classification

	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC
Current entry in Annex VI of CLP Regulation (EC) No 1272/2008	Eye Irrit. 2; H319 Aquatic Chronic 3; H 412	Xi; R36 R52/53
Proposal by dossier submitter for consideration by RAC	Not classified for Aquatic Chronic 3	Not classified for R52/53
Resulting harmonised classification (future entry in Annex VI of CLP Regulation) as proposed by dossier submitter	Eye Irrit. 2; H319	Xi; R36

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/consultations/harmonised_cl/harmon_cl_prev_cons_en.asp on **03 October 2011**. Parties concerned and MSCAs were invited to submit comments and contributions by **17 November 2011**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Katalin Gruiz**
 Co-rapporteur, appointed by RAC: **Ceu Nunes**

The opinion takes into account the comments of MSCAs and parties concerned provided in accordance with Article 37 (4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling has been reached on **8 March 2012**, in accordance with Article 37 (4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex 2.

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

OPINION OF RAC

The RAC adopted the opinion that **1,1',1''-nitriлотрипропан-2-ол (TIPA)** should be classified and labelled as follows^[1]:

¹ Note that not all hazard classes have been evaluated

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)		
	1,1',1''-nitrilotripropan-2-ol; triisopropanolamine	204-528-4	122-20-3	Eye Irrit. 2 ;	H319	GHS07 Wng	H319			

Classification and labelling in accordance with the criteria of Directive 67/548/EEC

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	1,1',1''-nitrilotripropan-2-ol; triisopropanolamine	204-528-4	122-20-3	Xi; R36	Xi R36- S: (2-)26		

SCIENTIFIC GROUNDS FOR THE OPINION

The opinion relates only to the hazard class that has been reviewed in the proposal for harmonised classification and labelling, as submitted by Germany.

HUMAN HEALTH HAZARD ASSESSMENT

Not reviewed in the proposal for harmonised classification and labelling, as submitted by Germany.

ENVIRONMENTAL HAZARD ASSESSMENT

Summary of dossier submitter's proposal

The dossier submitter proposed to remove the current Annex VI classification as hazardous to the aquatic environment, categories Chronic 3 - H412, according to the Regulation (EC) 1272/2008 (CLP), and R52/53, according to Directive 67/548/EEC (DSD).

The current environmental classification resulted from two acute toxicity algae studies, providing E_bC_{50} (algae) < 100 mg/l (based on number of cells and biomass) and from biodegradation screening tests, indicating not rapid biodegradability.

The dossier submitter argues that according to the CLP Regulation the classification should be based on the algal growth rate, and hence the E_rC_{50} should be used instead of the E_bC_{50} .

Since E_rC_{50} (algae) is higher than 100 mg/l in both acute toxicity studies, the dossier submitter considers the substance as not toxic to the aquatic environment. This is consistent with the L(E) C_{50} values for the other tested trophic levels, fish (three species) and crustaceans (one species), which are all also above the trigger value of 100 mg/l.

Under environmental conditions the substance is partly present in its charged form and it is shown to be hydrolytically stable.

Screening tests show that the substance is neither readily nor inherently biodegradable. A simulation tests in a water-sediment system provides a half-life of 14.3 days but for the identified metabolite no information is available on its toxicity and degradability. Another simulation test in soil shows that the substance is mineralised by 66 to 72% in 20 days. Its metabolite is considered to be not toxic and readily biodegradable. Based on all this information, the dossier submitter concludes that the substance is not rapidly degradable.

The water solubility is high (830 g/l) and the experimentally determined BCF is < 0.57, thus indicating no potential to bioaccumulate. Considering also the absence of acute toxicity, the dossier submitter concludes that the substance does not meet the criteria for aquatic Chronic 3 (CLP) and R52/53 (DSD).

After the public consultation, the dossier submitter has resubmitted a new version of the CLH report, which implements the changes (see section "Comments received during public consultation") proposed by some commenting party. This report is provided at the end of the response to comments (RCOM) document in the Annex 2.

Comments received during public consultation

During the public consultation, comments on hazards to the aquatic environment were received from four Member States.

The comments supported the proposal for removal of the classification. Besides editorial changes, some concern was expressed by a commenting Member State about the table of physico-chemical properties (table 9) since the method used were mostly not indicated and the values for K_{oc} were not present. This comment however does not affect the proposed classification.

For the full set of comments and responses, see the response to comments (RCOM) in the Annex 2.

Outcome of RAC assessment - comparison with criteria and justification

RAC agrees with the proposal of the dossier submitter to remove the classification for aquatic hazard and supports the provided justification and comparison with criteria, summarized in the heading "*Summary of dossier submitter's proposal*".

ANNEXES:

- Annex 1 Background Document (BD)¹
- Annex 2 Comments received on the CLH report, response to comments provided by the dossier submitter and RAC (excl. confidential information). A revised version of the CLH report, submitted after PC by the dossier submitter as part of the RCOM, is included in Annex 2, section 2.

¹ The Background Document (BD) gives the detailed scientific grounds for the Opinion. The BD is based on the CLH report prepared by a dossier submitter; the evaluation performed by RAC is contained in RAC boxes.