

3 July 2009

**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 (“the CLP Regulation”), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

**Substance Name:** *Diantimony trioxide*

**EC Number:** *215-17-50*

**CAS Number:** *1309-64-4*

The proposal was submitted by *Sweden*  
and received by RAC (co-) rapporteur on *28 January 2009*

**PROCESS FOR ADOPTION OF THE OPINION**

*Sweden* 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/doc/consultations/cl/clh\\_axvrep\\_sweden\\_diantimony\\_trioxide.pdf](http://echa.europa.eu/doc/consultations/cl/clh_axvrep_sweden_diantimony_trioxide.pdf) on *23 February 2009*. MSCAs and parties concerned were invited to submit comments and contributions by *9 April 2009*.

**ADOPTION OF THE OPINION OF RAC**

Rapporteur, appointed by RAC: *Andrew Smith*

Co-rapporteur, appointed by RAC: *Norbert Rupprich*

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 *3 July 2009*, in accordance with Article 37 (4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex II.

The RAC Opinion was adopted by *consensus*.

### **OPINION OF RAC**

RAC adopted the opinion that the proposal from Sweden did not justify a change to the current classification of *Diantimony trioxide* and so this substance should continue to be classified and labelled as follows:

#### **Classification & labelling in accordance with Directive 67/548/EEC**

**Classification<sup>1</sup>: Carc Cat 3; R40**

**Specific concentration limits: None**

**Notes: None**

**Labelling: Xn: R40 S(2)-22-36/37**

#### **Classification & Labelling in accordance with the Classification, Labelling and Packaging Regulation**

**Classification: Carc. 2 - H351**

**Specific concentration limits: None**

**M-factors: None**

**Notes: None**

**Labelling: Warning - GHS08 - H351**

### **Opinion on justification for need for action at Community level**

The opinion given above is reached by RAC following review only of a proposal to classify diantimony trioxide as a skin irritant. No other endpoints were assessed in this review, including carcinogenicity. Since the opinion of RAC is simply that the data relating to skin irritation do not justify classification for this endpoint, there is no basis to comment further on the need for action on harmonised classification and labelling at Community level. However, RAC recommends that due consideration be made by the relevant authorities and /or industry, as appropriate, to adequately control the risks of adverse effects in workers exposed to fumes or dusts containing diantimony trioxide in hot, sweaty conditions. Specifically, the concerns relate to fumes and dusts generated during smelting and processing of metallic antimony or antimony-containing ores.

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<sup>1</sup> This section should reflect all relevant entries for the C&L: classification, R-phrases, S-phrases, concentrations limits, nota.

## **SCIENTIFIC GROUNDS FOR THE OPINION**

The Background Document, attached as Annex I, gives the detailed scientific grounds for the Opinion.

### **ANNEXES:**

- Annex 1      Background Document (BD)<sup>2</sup>
- Annex 2      Comments submitted during the public consultation on the CLH report and responses to comments provided by the dossier submitter and RAC rapporteurs (excl. confidential information)

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<sup>2</sup> The Background Document (BD) supporting the opinion contains scientific justifications for the CLH proposal. The BD is based on the CLH report prepared by a dossier submitter. The original CLH report may need to be changed as a result of the comments and contributions received during the public consultation(s) and the comments by and discussions in the Committees.