# Committee for Risk Assessment

# RAC

## Addendum to the Opinion

proposing harmonised classification and labelling
at EU level of

## Acrolein

**EC Number: 203-453-4**

**CAS Number: 107-02-8**

ECHA/RAC/CLH-O-0000001792-72-03/F

**Addendum adopted**

**4 October 2013**

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**4 October 2013**
**CLH-O-0000001792-72-03/F**

# 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 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:** **Acrolein**

**EC Number:** **203-453-4**

**CAS Number:** **107-02-8**

The proposal was submitted by **the United Kingdom** and received by RAC on **18 November 2010.**

**The proposed harmonised classification**

| | **Regulation (EC) No 1272/2008 (CLP Regulation)** | **Directive 67/548/EEC** |
|---|---|---|
| **Current entry in Annex VI to CLP Regulation** | Flam. Liq. 2 (H225)<br>Acute Tox. 2* (H330)<br>Acute Tox. 3* (H311)<br>Acute Tox. 3* (H301)<br>Skin Corr. 1B (H314)<br>Aquatic Acute 1 (H400) | F; R11<br>$T^+$; R26<br>T; R24/25<br>C; R34<br>N; R50 |
| **Proposal by dossier submitter for consideration by RAC** | Acute Tox. 1 (H330)<br>Acute Tox. 2 (H300)<br>Acute Tox. 3 (H311)<br>Skin Corr. 1B (H314),<br>SCL = 1%<br>Aquatic Chronic 1 (H410)<br>Acute M-factor = 100<br>Chronic M-factor = 1 | $T^+$; R26/28<br>T; R24<br><br>N; R50, Cn ≥ 0.25% |
| **Resulting harmonised classification (future entry in Annex VI to CLP Regulation) based on the proposal by the dossier submitter** | Flam. Liq. 2 (H225)<br>Acute Tox. 1 (H330)<br>Acute Tox. 2 (H300)<br>Acute Tox. 3 (H311)<br>Skin Corr. 1B (H314),<br>SCL=1%<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410)<br>Acute M-factor = 100<br>Chronic M-factor = 1 | F; R11<br>T+; R26/28<br>T; R24<br>N; R50, Cn ≥ 0.25% |

## PROCESS FOR ADOPTION OF THE OPINION

**The United Kingdom** 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/web/guest/harmonised-classification-and-labelling-previous-consultations*** on **29 July 2011**. Parties concerned and MSCAs were invited to submit comments and contributions by **12 September 2011.**

## ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Helmut Greim**
Co-rapporteurs, appointed by RAC: **Annick Pichard, Hans-Christian Stolzenberg**

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

The opinion of RAC on the proposed harmonised classification and labelling has been reached on **15 June 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 opinion of RAC was adopted by **consensus*.***

**This addendum, amending the sections of the 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 **Acrolein** 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) | | |
| 605-008-00-3 | Acrolein; prop-2-enal; acrylaldehyde | 203-453-4 | 107-02-8 | Flam. Liq. 2<br>Acute Tox. 1<br>Acute Tox. 2<br>Acute Tox. 3<br>Skin Corr. 1B<br>Aquatic Acute 1<br>Aquatic Chronic 1 | H225<br>H330<br>H300<br>H311<br>H314<br>H400<br><br>H410 | GHS02<br>GHS06<br>GHS05<br>GHS09<br>Dgr | H225<br>H330<br>H300<br>H311<br>H314<br>H410 | EUH071 | Skin Corr. 1B; H314: C ≥ 0.1 %<br><br><br><br>M = 100 (Acute)<br>M = 1 (Chronic) | D[1] |

### Classification and labelling in accordance with the DSD

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| 605-008-00-3 | Acrolein; prop-2-enal; acrylaldehyde | 203-453-4 | 107-02-8 | F; R11<br>T+; R26/28<br>T; R24<br>C; R34<br>N; R50 | F; T+; C; N<br>R: 11-26/28-24-34-50<br>S: 23-26-28-36/37/39-45-61 | C; R34: C ≥ 0.1%<br><br>N; R50: C ≥ 0.25% | D[1] |

[1] Note D is defined in Annex VI, 1.1.3.1 of Regulation (EC) No 1272/2008

## Background

The opinion on the harmonised classification and labelling (CLH) for acrolein was adopted on 15 June 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 corrosion has been adopted by RAC.

## Amended RAC opinion on Skin Corrosion

### Summary of the Dossier Submitter's proposal

Acrolein caused severe adverse skin reactions in a non-standard study in human volunteers, indicative of skin corrosion. Acrolein also caused severe skin reactions in a standard study in rats[2], which became progressively more severe over the 14-day observation period. Severe skin reactions were also observed in rabbits after single (see Annex 1, table 11 and section 4.2.1.3) and repeated dermal application (see Annex 1, section 4.7).

### Comments received during public consultation

Germany supports the proposed classification for acrolein as C; R34 and Skin Corr. 1B (H314), respectively. France argues that since the rabbits were exposed to acrolein for 24 hours, no conclusion on the subcategory for Skin Corr. (1A, 1B or 1C) could be made.

### RAC assessment and comparison with classification criteria

In the rabbit study acrolein did not induce corrosions. Since there is no information which concentrations have been used the study is invalid for proper evaluation. In the human study a 10% solution induced necrosis in all exposed subjects. Although these data do not formally meet the criteria for corrosion RAC agrees with the conclusion of the Dossier Submitter: "The proposal is to retain the current corrosion classification, based on a weight of evidence assessment. However, we acknowledge that it is difficult to identify the correct corrosion subcategory based on the available information." This is supported by the acute dermal toxicity study in rabbits (Muni 1981a), which showed ulceration, oedema and haemorrhage of the dermis at all dose groups (200, 240, 280 mg/kg). Although the available data do not allow differentiation between the skin corrosion subcategories 1A/1B/1C, since classification for skin corrosion without sub-categorisation is currently not possible under the CLP Regulation, RAC agreed to classify acrolein 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 additional data to justify this classification.

[2] RAC: according to the BD the species was rabbits: Muni 1982

**Specific Concentration Limit**

In the human volunteer patch tests acrolein has been applied at concentrations of 0.01, 0.1, 1 and 10% in ethanol on groups of 8, 10, 48 and 20 volunteers, respectively (Lacroix *et al*., 1976). No further information, especially on duration of application, is available. At 1%, positive skin reactions were recorded in 6 out of 48 subjects; four of the six with serious oedema and bullae and the remaining two with erythema. No adverse skin reactions were observed at 0.01 (n = 8) or 0.1% (n = 10). RAC concludes that a specific concentration limit of 1% does not protect from skin reactions, whereas 0.1% is a concentration limit which is considered sufficiently protective.