

**Substance Name: *N*-(hydroxymethyl)acrylamide**

**EC Number: 213-103-2**

**CAS Number: 924-42-5**

**SUPPORT DOCUMENT FOR IDENTIFICATION OF**

***N*-(HYDROXYMETHYL)ACRYLAMIDE**

**AS A SUBSTANCE OF VERY HIGH CONCERN  
BECAUSE OF ITS CARCINOGENIC (ARTICLE 57A)  
AND MUTAGENIC (ARTICLE 57B) PROPERTIES**

This document has been prepared according to template: TEM-0049.04

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## **ABBREVIATIONS**

SVHC: substance of very high concern

## **IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57**

**Substance name:** *N*-(hydroxymethyl)acrylamide

**EC number:** 213-103-2

**CAS number:** 924-42-5

- The substance is identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1B<sup>1</sup>.
- The substance is identified as a substance meeting the criteria of Article 57 (b) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class germ cell mutagenicity category 1B<sup>1</sup>.

### **Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation**

*N*-(Hydroxymethyl)acrylamide is covered by index number 616-230-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

*N*-(Hydroxymethyl)acrylamide is covered by index number 616-230-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class germ cell mutagenicity category 1B (hazard statement H340: "May cause genetic defects").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard classes:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH.
- Germ cell mutagenicity category 1B in accordance with Article 57 (b) of REACH.

**Registration dossiers submitted for the substance:** Yes

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<sup>1</sup> Classification in accordance with sections 3.5 and 3.6 of Annex I to Regulation (EC) No 1272/2008.

## Justification

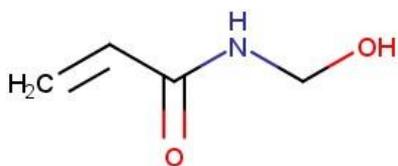
### 1. Identity of the substance and physical and chemical properties

#### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

|   |   |
|---|---|
| <b>EC number:</b>                                     | 213-103-2   |
| <b>EC name:</b>                                       | <i>N</i> -(hydroxymethyl)acrylamide                                     |
| <b>CAS number (in the EC inventory):</b>              | -   |
| <b>CAS number:</b>                                    | 924-42-5  |
| <b>IUPAC name:</b>                                    | <i>N</i> -(hydroxymethyl)acrylamide                                     |
| <b>Index number in Annex VI of the CLP Regulation</b> | 616-230-00-5  |
| <b>Molecular formula:</b>                             | C <sub>4</sub> H <sub>7</sub> NO <sub>2</sub>                           |
| <b>Molecular weight range:</b>                        | 101.1 g/mol   |
| <b>Synonyms:</b>                                      | <i>N</i> -methylolacrylamide, 2-propenamide, <i>N</i> -(hydroxymethyl)- |

#### Structural formula:



#### 1.2 Composition of the substance

**Name:** *N*-(hydroxymethyl)acrylamide

**Description:** organic

**Substance type:** mono-constituent

Note: Water is included in the compositions reported by certain registrants; the scope of the entry covers *N*-(hydroxymethyl)acrylamide independently of the presence of water.

### 1.3 Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) and (b) of the REACH Regulation.

## 2. Harmonised classification and labelling

*N*-(Hydroxymethyl)acrylamide is covered by Index number 616-230-00-5 in part 3 of Annex VI to the CLP Regulation as follows:

**Table 2: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008**

| Index No     | Chemical name                       | EC No     | CAS No   | Classification                    |  | Labelling                      |  |                                 | Spec. Conc. Limits, M-factors and ATEs <sup>2</sup> | 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) |   |       |
| 616-230-00-5 | <i>N</i> -(hydroxymethyl)acrylamide | 213-103-2 | 924-42-5 | Muta. 1B<br>Carc. 1B<br>STOT RE 1 | H340<br>H350<br>H372 (peripheral nervous system) | GHS08<br>Dgr                   | H340<br>H350<br>H372 (peripheral nervous system) |                                 |   |       |

<sup>2</sup> Acute Toxicity Estimate

### 3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) and (b) of the REACH Regulation.

### 4. Human health hazard assessment

The RAC opinion on the proposed harmonised classification and labelling of the substance *N*-(hydroxymethyl)acrylamide as Muta. 1B (H340), Carc. 1B (H350) and STOT RE 1 (H372, peripheral nervous system) was adopted on 8 June 2018 by consensus (RAC, 2018). The substance was added to Table 3, Annex VI of CLP via Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 (EU, 2020).

### 5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) and (b) of the REACH Regulation.

## 6. Conclusions on the SVHC Properties

### 6.1 CMR assessment

*N*-(Hydroxymethyl)acrylamide is covered by index number 616-230-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

*N*-(Hydroxymethyl)acrylamide is covered by index number 616-230-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class germ cell mutagenicity category 1B (hazard statement H340: "May cause genetic defects").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard classes:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH.
- Germ cell mutagenicity category 1B in accordance with Article 57 (b) of REACH.

## References

- EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.
- EU (2009). Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 as regards of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII. Official Journal of the European Union, L164: 7-31.
- EU (2020). Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Official Journal of the European Union, L 261/2, 11.8.2020.
- Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of N-(hydroxymethyl)acrylamide. 8 June 2018. Available at <https://echa.europa.eu/documents/10162/ec61c799-4adf-763d-05a7-67cabf74e9d1>