Annex XV report

PROPOSAL FOR 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

Submitted by: Sweden

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TABLES

ABBREVIATIONS

SVHC: substance of very high concern

PROPOSAL FOR 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 proposed to be 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[1].

- The substance is proposed to be 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[1].

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

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

PART I

Justification

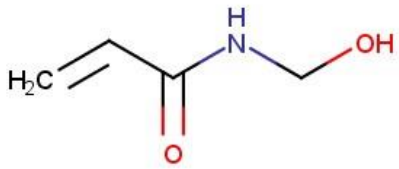
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	213-103-2
EC name:	*N*-(hydroxymethyl)acrylamide
CAS number (in the EC inventory):	-
CAS number:	924-42-5
IUPAC name:	*N*-(hydroxymethyl)acrylamide
Index number in Annex VI of the CLP Regulation	616-230-00-5
Molecular formula:	C4H7NO2
Molecular weight range:	101.1 g/mol
Synonyms:	*N*-methylolacrylamide, 2-propenamide, *N*-(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 proposed 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[2]	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	*N*-(hydroxymethyl)acrylamide	213-103-2	924-42-5	Muta. 1B Carc. 1B STOT RE 1	H340 H350 H372 (peripheral nervous system)	GHS08 Dgr	H340 H350 H372 (peripheral nervous system)			

[2] 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.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3: Registration status

From the ECHA dissemination site[3]	
Registrations	☒ Full registration(s) (Art. 10) ☐ Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 4: CLP notifications

	CLP Notifications[4]
Number of aggregated notifications	14
Total number of notifiers	525

8. Total tonnage of the substance

Table 5: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)[5]	1,000-10,000 t/pa
Tonnage information from public sources other than registration dossiers (if available)	-

[3] https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/15038 (accessed October 2021)
[4] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed February 2022)
[5] https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/15038 (accessed October 2021)

9. Information on uses of the substance

Table 6: Uses

	Uses	Registered use	Use likely to be in the scope of Authorisation
Uses as intermediate		Yes	No
Formulation or repacking		Yes	No
Uses at industrial sites	Use as monomer for polymerisation, use as fluoroalkyl acrylate copolymer, use in paints /coatings	Yes	No
Uses by professional workers		No	No
Consumer uses		No	No
Article service life		No	No

10. Information on structure of the supply chain

No information available.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

N-(Hydroxymethyl)acrylamide is structurally similar to acrylamide (EC 201-173-7) which is already included in the Candidate List, and is restricted via Annex XVII of REACH (EC, 2011). The harmonised classification and labelling of acrylamide was adopted under the previous legislation and was transferred to the CLP Regulation (index number: 616-003-00-0). Acrylamide shares similar hazardous properties with *N*-(hydroxymethyl)acrylamide and metabolism to epoxide metabolite. In addition, acrylamide has a limit value of 0,1 mg/m^3 for occupational exposure at EU level (EU, 2017).

Based on information on uses from the registration dossier and the Swedish Products Register[6], it appears that *N*-(hydroxymethyl)acrylamide might have similar uses as

[6] Products Register - Kemikalieinspektionen

acrylamide. In addition, physical chemical properties, such as water solubility and log Kow, indicate similar behaviour of these two substances. We consider it likely that *N*-(hydroxymethyl)acrylamide may be used as a substitute for acrylamide, which may lead to regrettable substitution. Inclusion of *N*-(hydroxymethyl)acrylamide in the Candidate List may help to prevent that.

N-(Hydroxymethyl)acrylamide is manufactured and/or imported in high quantities but is currently only used as a monomer in polymer production, a use not within the scope of authorisation.

11.2 Alternatives

No information on alternatives is available.

11.3 Existing EU legislation

COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (EU, 2011). *N*-(Hydroxymethyl)acrylamide is included in union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids.

REFERENCES

References for Part I

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

References for Part II

EU (2011). Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food.

EC (2011). Commission Regulation (EU) No 366/2011 of 14 April 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Acrylamide)

EU (2017). Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.