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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Transport of Dangerous Goods

Sixty-second session
Geneva, 3-7 July 2023
Item 3 of the provisional agenda
Listing, classification and packing

Proposal to add class 8 as subsidiary hazard to UN 1040, UN 1041 and UN 3300

Transmitted by the expert from Germany *

Introduction

1. According to the UN Model Regulations, UN 1040 *ETHYLENE OXIDE or ETHYLENE OXIDE WITH NITROGEN up to a total pressure of 1 MPa (10 bar) at 50 °C* is classified in division 2.3 (toxic gas) with the subsidiary hazard 2.1 (flammable).

2. A new harmonised classification of ethylene oxide showing corrosive properties was published within the fourteenth "Adaptation to Technical Progress (ATP)", annex VI of the European Commission (EC) Regulation No. 1272/2008 on classification, labelling and packaging (CLP) and entered into force on 9 September 2021. Classification corresponding to class 8 was proposed in informal document INF.25 at the sixtieth session of the Sub-Committee.

3. After receiving the comments from the Netherlands at the sixtieth session of the Sub-Committee, the expert from Germany submitted a working document (ST/SG/AC.10/C.3/2022/54) for the sixty-first session including UN 3300 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 87 % ethylene oxide* and a data sheet concerning the properties of ethylene oxide.

4. Taking into account the questions raised as part of the sixty-first session of the Sub-Committee the expert from Germany prepared an updated proposal providing extensive data regarding the corrosivity of ethylene oxide. It was clear, that UN 1040 and UN 3300 are not the only UN Numbers that are related to ethylene oxide. Considering the comment by the expert from Sweden, this proposal also applies to UN 1041 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 9 % but not more than 87 % ethylene oxide*.

* A/77/6 (Sect. 20), table 20.6

Background

5. Ethylene oxide, CAS No. 75-21-8, is currently listed under Index No. 603-023-00-X in Annex VI of EC Regulation No. 1272/2008 on classification, labelling and packaging and is classified as:

Flam. Gas 1, H220
Acute Tox. 3*, H331

This meets the criteria for classification as dangerous good according to the UN Model Regulations under class 2, division 2.3, with subsidiary hazard 2.1.

6. With the fourteenth ATP entering into force, the following amendments were added (*italics*), resulting in the classification of ethylene oxide as follows:

Acute Tox. 3, H331
Acute Tox. 3, H301
Skin Corr. 1, H314

7. According to the *"Opinion proposing harmonised classification and labelling at EU level of ethylene oxide"*, which was published in 2017 by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), liquid ethylene oxide can cause severe skin lesions. As there are no accepted test possibilities for corrosivity of gases, classification should rely on human data and tests on animal skin (both after contact with ethylene oxide solutions).

Human data:

- A series of aqueous solutions with ethylene oxide concentrations between 1 % and 90 % were tested on human skin (Sexton et al., 1950). The 50 % solution caused the most severe skin reactions since the more concentrated solutions evaporated quickly preventing prolonged skin contact.
- Corrosive effects such as progressive skin lesions, burns, pain, erythema, redness, damage to subcutaneous tissue, scar formation, blisters have also been noted in varying degrees after exposure to medical materials and devices in case reports (Alomar et al., 1981, Hanifin et al., 1971, Cardenas-Camarena et al., 1998, Karacalar et al., 2000). The materials and devices have been sterilized with ethylene oxide and not adequately ventilated afterwards.
- Exposure of large areas of human skin to a 1 % aqueous solution of ethylene oxide (the lowest concentration tested) for about 2 hours resulted in severe blistering after 12-14 hours (Sexton et al., 1949).

Animal test data:

- Skins of New Zealand White rabbits were exposed to 0.5 ml of undiluted ethylene oxide for 4 hours and subdermal hemorrhages and chemical burns were observed immediately, 24 hours and 72 hours after exposure (Celanese et al., 1972).
- Skins of rabbits were exposed to 10 % and 50 % aqueous solutions of ethylene oxide for less than 60 minutes (Hollingsworth et al. 1956). In animals exposed for six minutes or longer, hyperemia and oedema were observed.

8. Based on the available data, it can be stated that ethylene oxide is skin corrosive even in lower concentrations. As the data does not allow exact differentiation between the subcategories, the RAC concluded that ethylene oxide should be classified as Skin Corr. Cat. 1, H314 (without subcategorization).

9. Ethylene oxide can be released from tanks in the event of accidents or from leaking caps and can cause frostbite in contact with skin, which exhibits similar symptoms as chemical burns (as described in paragraph 7 above). Both outcomes can lead to irreversible skin damage.

10. Ethylene oxide is transported as liquefied gas. The data presented in paragraph 7 above refer to solutions. Hence, in the event of even short direct skin contact of higher

concentrations more severe reactions resulting in irreversible skin damage are to be expected meeting the criteria of 2.8.1 of the Model Regulations (class 8, Skin Corr. Cat. 1).

11. This corresponds to a division 2.3 classification in the dangerous goods list with the subsidiary risks 2.1 and 8 in the case of UN 1040 and UN 3300. The classification of UN 1041 results in division 2.1 with subsidiary risk 8.

Proposal

12. As ethylene oxide meets the criteria for class 8, and within the scope of harmonizing GHS classification with the transport regulations of dangerous goods, Germany proposes to amend UN 1040 *ETHYLENE OXIDE or ETHYLENE OXIDE WITH NITROGEN up to a total pressure of 1 MPa (10 bar) at 50 °C,* UN 1041 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 9 % but not more than 87 % ethylene oxide* and UN 3300 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 87 % ethylene oxide* as follows (new text is underlined, deleted text in ~~strikethrough~~):

UN No. Substance	Class	Subsidiary Hazard	UN packing group	Special provisions	Limited and excepted quantities		Packagings and IBCs		Portable tanks and bulk containers	
							Packing instruction	Special packing provisions	Instructions	Special provisions
UN 1040 *ETHYLENE OXIDE or ETHYLENE OXIDE WITH NITROGEN up to a total pressure of 1 MPa (10 bar) at 50 °C*	2.3	2.1, 8		342	0	E0	P200		~~T50~~	~~TP20~~
UN 1041 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 9 % but not more than 87 % ethylene oxide*	2.1	8			0	E0	P200		~~T50~~	
UN 3300 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 87 % ethylene oxide*	2.3	2.1, 8			0	E0	P200			

Action requested of the Sub-Committee

13. The Sub-Committee is invited to consider the proposal and take action as appropriate.

14. In addition, this proposal supports Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages as part of the 2030 Agenda for Sustainable Development by promoting the safe transport of UN 1040, UN 1041 and UN 3300.

Annex

Data sheet to be submitted to the United Nations for new or amended classification of substances

Submitted by Germany Date 09.02.2023

Supply all relevant information including sources of basic classification data. Data should relate to the product in the form to be transported. State test methods. Answer all questions - If necessary, state “not known” or “not applicable” - If data is not available in the form requested, provide what is available with details. Delete inappropriate words.

Section 1. SUBSTANCE IDENTITY

1.1 Chemical name: Ethylene oxide

1.2 Chemical formula: C_2H_4O

1.3 Other names/synonyms: oxirane

1.4.1 UN number: UN 1040 / UN 1041 / UN 3300

1.4.2 CAS number: 75-21-8

1.5 Proposed classification for the Recommendations:

CLASS 2.3 (2.1, 8) / CLASS 2.1(8) / CLASS 2.3 (2.1, 8)

1.5.1 proper shipping name (3.1.2[1])

ETHYLENE OXIDE or ETHYLENE OXIDE WITH NITROGEN up to a total pressure of 1 MPa (10 bar) at 50 °C

ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 9 % but not more than 87 % ethylene oxide

ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 87 % ethylene oxide

1.5.2 UN 1040: class/division 2.3 subsidiary hazard(s): 2.1, 8

UN 1041: class/division 2.1 subsidiary hazard(s): 8

UN 3300: class/division 2.3 subsidiary hazard(s): 2.1, 8

1.5.3 proposed special provisions, if any: 342 / none / none

Limited and excepted quantities: 0, E0

Special packing provisions: none

Portable tanks and bulk containers:

Instructions: none

Special provisions: none

1.5.4 proposed packing instruction(s): P200

Section 2. PHYSICAL PROPERTIES

2.1 Melting point or range -111-112 °C

2.2 Boiling point or range 10-12 °C

2.3 Relative density at:

1.5 (air=1)

2.4 Vapour pressure at:

20 °C 146 kPa

2.5 Viscosity at 20 °C[2] ___ m^2/s

2.6 Solubility in water at 20 °C: miscible

2.7 Physical state at 20 °C (2.2.1.1[1]) solid/liquid/gas[2]

2.8 Appearance at normal transport temperatures, including colour and odour: ether-like odor, colorless

2.9 Other relevant physical properties: soluble in benzene, acetone, ethanol, ether

Section 3. FLAMMABILITY

3.1 Flammable vapour

3.1.1 Flash point (2.3.3[1]) -18 °C oc/cc

Flash point (2.3.3[1]) -29 °C oc/cc

3.1.2 Is combustion sustained? (2.3.1.3[1]) yes/no

3.2 Autoignition temperature 429 °C

3.3 Flammability range (LEL/UEL) ___ %

3.4 Is the substance a flammable solid? (2.4.2[1]) yes/no

3.4.1 If yes, give details ___

Section 4. CHEMICAL PROPERTIES

4.1 Does the substance require inhibition/stabilization or other treatment such as nitrogen blanket to prevent hazardous reactivity? yes/no

If yes, state:

4.1.1 Inhibitor/stabilizer used ___

4.1.2 Alternative method ___

4.1.3 Time effective at 55 °C ___

4.1.4 Conditions rendering it ineffective ___

4.2 Is the substance an explosive according to paragraph 2.1.1.1? (2.1[1]) yes/no

4.2.1 If yes, give details ___

4.3 Is the substance a desensitized explosive? (2.4.2.4[1]) yes/no

4.3.1 If yes, give details ___

4.4 Is the substance a self-reactive substance? (2.4.1[1]) yes/no

If yes, state:

4.4.1 exit box of flow chart ___

What is the self-accelerating decomposition temperature (SADT) for a 50 kg package? °C

Is the temperature control required? (2.4.2.3.4[1]) yes/no

4.4.2 proposed control temperature for a 50 kg package ___ °C

4.4.3 proposed emergency temperature for a 50 kg package ___ °C

4.5 Is the substance pyrophoric? (2.4.3[1]) yes/no

4.5.1 If yes, give details ___

4.6 Is the substance liable to self-heating? (2.4.3[1]) yes/no

4.6.1 If yes, give details ___

4.7 Is the substance an organic peroxide (2.5.1[1]) yes/no

If yes state:

4.7.1 exit box of flow chart ___

What is the self-accelerating decomposition temperature (SADT) for a 50 kg package? ___ °C

Is temperature control required? (2.5.3.4.1[1]) yes/no

4.7.2 proposed control temperature for a 50 kg package ___ °C

4.7.3 proposed emergency temperature for a 50 kg package ___ °C

4.8 Does the substance in contact with water emit flammable gases? (2.4.4[1]) yes/no

4.8.1 If yes, give details ___

4.9 Does the substance have oxidizing properties (2.5.1[1]) yes/no

4.9.1 If yes, give details ___

4.10 Corrosivity (2.8[1]) to:

4.10.1 mild steel ___ mm/year at ___ °C

4.10.2 aluminium ___ mm/year at ___ °C

4.10.3 other packaging materials (specify)

___ mm/year at ___ °C

___ mm/year at ___ °C

4.11 Other relevant chemical properties ___

Section 5. HARMFUL BIOLOGICAL EFFECTS

5.1 LD50, oral (2.6.2.1.1[1]) 330 mg/kg bw for rats

280-365 mg/kg bw for mice

270 mg/kg bw for guinea pigs

5.2 LD50, dermal (2.6.2.1.2[1]) no data available

5.3 LC50, inhalation (2.6.2.1.3[1]) 660 ppm, 4 h, female mice

1972 ppm, 4 h, male rats

5.4 Saturated vapour concentration at 20 °C (2.6.2.2.4.3[1]) ___ ml/m3

5.5 Skin exposure (2.8[1]) 0.5 ml undiluted ethylene oxide, 4 h exposure, rabbits > subdermal haemorrhages and chemical burns; 10 % and 50 % solutions, under 1 h, rabbits > hyperaemia and oedema

5.6 Other data ___

5.7 Human experience ___

Section 6. SUPPLEMENTARY INFORMATION

6.1 Recommended emergency action

6.1.1 Fire (include suitable and unsuitable extinguishing agents) ___

6.1.2 Spillage ___

6.2 Is it proposed to transport the substance in:

6.2.1 Bulk Containers (6.8[1]) yes/no

6.2.2 Intermediate Bulk Containers (6.5[1])? yes/no

6.2.3 Portable tanks (6.7[1])? yes/no

If yes, give details in Sections 7, 8 and/or 9.

Section 7. BULK CONTAINERS (only complete if yes in 6.2.1)

7.1 Proposed type(s)

Section 8. INTERMEDIATE BULK CONTAINERS (IBCs) (only complete if yes in 6.2.2)

8.1 Proposed type(s)

Section 9. MULTIMODAL TANK TRANSPORT (only complete if yes in 6.2.3)

9.1 Description of proposed tank (including IMO tank type if known)

9.2 Minimum test pressure ___

9.3 Minimum shell thickness ___

9.4 Details of bottom openings, if any ___

9.5 Pressure relief arrangements ___

9.6 Degree of filling ___

9.7 Unsuitable construction materials ___