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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-third session

Geneva, 27 November-6 December 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\*

### I. Introduction

1. According to the *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 14<sup>th</sup> ATP<sup>1</sup>, Annex VI of the Regulation (EC) 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 an informal document (UN/SCETDG/60/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 an official document (ST/SG/AC.10/C.3/2022/54) at 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 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*.
5. While most experts at the sixty-second session of the Sub-Committee expressed their support to amend the classification of ethylene oxide by adding class 8 as subsidiary hazard, the majority of experts agreed to retain portable tank instruction T50 as there were no issues with the current requirements.

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

<sup>1</sup> ATP = Adaption to Technical Progress



## II. Background

6. Ethylene oxide, CAS No. 75-21-8, is currently listed under Index No. 603-023-00-X in Annex VI of Regulation (EC) 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 *Model Regulations* under class 2, division 2.3, with subsidiary hazard 2.1.

7. With the 14<sup>th</sup> 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*

8. 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. According to 2.2.2.1 (c) and 2.2.3 (c) of the *Model Regulations* there are gases which “are known to be so toxic or corrosive to humans as to pose a hazard to health”. Since there are no accepted test methods for the corrosivity of gases or gas mixtures, classification should rely on human data and tests on animal skin.

Human data:

- (a) 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.
- (b) 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 gas and not adequately ventilated afterwards.
- (c) 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:

- (d) Skins of New Zealand White rabbits were exposed to 0.5 ml of undiluted ethylene oxide for 4 hours and subdermal haemorrhages and chemical burns were observed immediately, 24 hours and 72 hours after exposure (Celanese et al., 1972).
  - (e) 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, hyperaemia and oedema were observed.
9. 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).

10. 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 above in paragraph 8). Both outcomes can lead to irreversible skin damage.

11. Ethylene oxide is transported as liquefied gas. The data presented in paragraph 8 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).

12. 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.

13. The discussion at the last session of the Sub-Committee did show a majority for maintaining the assignment of portable tank instruction T50 to UN 1040 and UN 1041 since there are no issues relating to the transport and not enough data that would justify a deletion. In this case, Germany believes that the *Guiding Principles* would benefit from a minor amendment – included below in proposal 2 – in order to reflect the transport of ethylene oxide in portable tanks under portable tank instruction T50.

14. In addition, this working document supports Sustainable Development Goal 3: Good Health and Well-Being as part of the 2030 Agenda for Sustainable Development by promoting the safe transport of UN 1040, UN 1041 and UN 3300.

### III. Proposal 1

15. 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):

UN No.	Name and description	Class or division	Subsidiary hazard	UN packing group	Special provisions	Limited and excepted quantities		Packagings and IBCs		Portable tanks and bulk containers	
						(7a)	(7b)	Packing instruction	Special packing provisions	Instructions	Special provisions
(1)	(2)	(3)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9)	(10)	(11)
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, <u>8</u>		342	0	E0	P200		T50	TP20
1041	ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 9 % but not more than 87 % ethylene oxide	2.1	<u>8</u>			0	E0	P200		T50	
3300	ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 87 % ethylene oxide	2.3	2.1, <u>8</u>			0	E0	P200			

### IV. Proposal 2

16. Amend table 4.3 of the *Guiding Principles* as follows (new text is underlined, deleted text is ~~stricken through~~):

Class / Division	PG	Subsidiary hazard	Tank instruction	Notes
2.1			T50/T75	T50 applies to non-refrigerated liquefied flammable gases <del>and flammable</del> chemicals under pressure (UN 3501, 3504, <del>and</del> 3505 and 1041). T75 applies to refrigerated liquefied gases. These are evaluated on a case by case basis.

## 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<sub>2</sub>H<sub>4</sub>O
- 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<sup>1</sup>)  
*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<sup>2</sup> \_\_\_ m<sup>2</sup>/s
- 2.6 Solubility in water at 20 °C: miscible
- 2.7 Physical state at 20°C (2.2.1.1<sup>1</sup>) solid/liquid/gas<sup>2</sup>
- 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<sup>1</sup>) -18 °C oc/cc  
Flash point (2.3.3<sup>1</sup>) -29 °C oc/cc
  - 3.1.2 Is combustion sustained? (2.3.1.3<sup>1</sup>) 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<sup>1</sup>)     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<sup>1</sup>)   yes/no  
 4.2.1 If yes, give details \_\_\_  
 4.3 Is the substance a desensitized explosive? (2.4.2.4<sup>1</sup>)     yes/no  
 4.3.1 If yes, give details \_\_\_  
 4.4 Is the substance a self-reactive substance? (2.4.1<sup>1</sup>)     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<sup>1</sup>)   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<sup>1</sup>)     yes/no  
 4.5.1 If yes, give details \_\_\_  
 4.6 Is the substance liable to self-heating? (2.4.3<sup>1</sup>)     yes/no  
 4.6.1 If yes, give details \_\_\_  
 4.7 Is the substance an organic peroxide (2.5.1<sup>1</sup>)     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<sup>1</sup>)     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<sup>1</sup>)     yes/no  
 4.8.1 If yes, give details \_\_\_  
 4.9 Does the substance have oxidizing properties (2.5.1<sup>1</sup>)     yes/no  
 4.9.1 If yes, give details \_\_\_  
 4.10 Corrosivity (2.8<sup>1</sup>) 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 LD<sub>50</sub>, oral (2.6.2.1.1<sup>1</sup>) 330 mg/kg bw for rats  
   280-365 mg/kg bw for mice  
   270 mg/kg bw for guinea pigs  
 5.2 LD<sub>50</sub>, dermal (2.6.2.1.2<sup>1</sup>) no data available  
 5.3 LC<sub>50</sub>, inhalation (2.6.2.1.3<sup>1</sup>) 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<sup>1</sup>) \_\_\_ ml/m<sup>3</sup>  
 5.5 Skin exposure (2.8<sup>1</sup>) 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<sup>1</sup>) yes/no

6.2.2 Intermediate Bulk Containers (6.5<sup>1</sup>)? yes/no

6.2.3 Portable tanks (6.7<sup>1</sup>)? 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 \_\_\_\_

\_\_\_\_\_