



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-first session

Geneva, 28 November-6 December 2022

Item 3 of the provisional agenda

Listing, classification and packing

Proposal to add class 8 as subsidiary hazard to UN 1040 ETHYLENE OXIDE or ETHYLENE OXIDE WITH NITROGEN up to a total pressure of 1 MPa (10 bar) at 50 °C

Transmitted by the expert from Germany*

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 subclass 2.3 (toxic gas) with the subsidiary hazard 2.1 (flammable).
2. Considering the new harmonised classification, which entered into force on 9 September 2021 and was published within the fourteenth adaptation to technical progress (ATP) of annex VI of the Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging (CLP), the classification corresponding to class 8 was proposed in informal document INF.25 (sixtieth session) based on the corrosive properties of ethylene oxide.
3. After considering the feedback received during that session, the expert from Germany submitted this updated working document to the sixty-first session of the Sub-Committee.

Background

4. 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 Model Regulations under class 2, subclass 2.3, with subsidiary hazard 2.1.

* A/75/6 (Sect.20), para. 20.51

5. With the fourteenth ATP entering into force, the following amendments were added (*italics*) and the existing classification was altered (*underlined*), resulting in the classification of ethylene oxide as follows:

Acute Tox. 3, H331

Acute Tox. 3, H301

Skin Corr. 1, H314

This corresponds to a subclass 2.3 classification in the dangerous goods list with the subsidiary risks 2.1 and 8.

6. 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. Skins of New Zealand White rabbits were exposed to 0.5 ml of undiluted ethylene oxide for four hours, and subdermal haemorrhages and chemical burns were observed immediately after the exposure and 24 and 72 hours after the exposure. In another study, skins of rabbits were exposed to 10 % and 50 % aqueous solutions of ethylene oxide under 60 minutes. In animals exposed for six minutes or longer, hyperaemia and oedema were observed. Based on the animal data “*Skin Corr.*” category 1B was suggested as animal tests represent a worst-case scenario. However, ethylene oxide is volatile and evaporates rapidly. As ethylene oxide is classified as skin corrosive but the data does not allow differentiation between the subcategories, the RAC Committee concluded that ethylene oxide should be classified as “*Skin Corr. Category 1, H314*” (without subcategorization).

7. As the delegation of the Netherlands pointed out at the sixtieth session of the Sub-Committee, UN 1040 is not the only UN Number that contains great amount of ethylene oxide. UN 3300 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 87 % ethylene oxide* is also classified in subclass 2.3 (toxic gas) with the subsidiary hazard 2.1 (flammable) according to the Model Regulations.

Proposal

8. As ethylene oxide meets the criteria for class 8, and within the scope of harmonizing GHS classification with the transport regulation 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* and UN 3300 *ETHYLENE OXIDE AND CARBON DIOXIDE MIXTURE with more than 87 % ethylene oxide* as follows:

In 3.2.2 Dangerous Goods List, add "8" in column (4) Subsidiary hazard after "2.1".

9. The transport conditions should remain unchanged, as indicated in principle by the Guiding Principles.

Action requested

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

Annex

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

Submitted by Germany

Date 30 August 2022

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: C₂H₄O
- 1.3 Other names/synonyms: oxirane
- 1.4.1 UN number: UN 1040 (UN 3300)
- 1.4.2 CAS number: 75-21-8
- 1.5 Proposed classification for the Recommendations:
CLASS 2.3 (2.1, 8)
 - 1.5.1 proper shipping name (3.1.2¹)
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 87% ethylene oxide)
 - 1.5.2 class/division 2.3 subsidiary hazard(s): 2.1, 8
 - 1.5.3 proposed special provisions, if any: 342 (none)
 - Limited and excepted quantities: 0, E0
 - Special packing provisions:
 - Portable tanks and bulk containers:
 - Instructions: T50 (none)
 - Special provisions: TP20 (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 °C² ___ m²/s
- 2.6 Solubility in water at 20 °C: miscible

- 2.7 Physical state at 20°C (2.2.1.1¹) solid/liquid/gas²
- 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 (2.3.3¹) -18 °C oc/cc
Flash point (2.3.3¹) -29 °C oc/cc
- 3.1.2 Is combustion sustained? (2.3.1.3¹) yes/no
- 3.2 Autoignition temperature 429 °C
- 3.3 Flammability range (LEL/UEL) ___ %
- 3.4 Is the substance a flammable solid? (2.4.2¹) 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? (2.1¹) yes/no
- 4.2.1 If yes, give details ___
- 4.3 Is the substance a desensitized explosive? (2.4.2.4¹) yes/no
- 4.3.1 If yes, give details ___
- 4.4 Is the substance a self-reactive substance? (2.4.1¹) 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? (2.4.2.3.4¹) 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? (2.4.3¹) yes/no
- 4.5.1 If yes, give details ___
- 4.6 Is the substance liable to self-heating? (2.4.3¹) yes/no
- 4.6.1 If yes, give details ___
- 4.7 Is the substance an organic peroxide (2.5.1¹) 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? (2.5.3.4.1¹) 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? (2.4.4¹) yes/no

4.8.1 If yes, give details ____

4.9 Does the substance have oxidizing properties (2.5.1¹) yes/no

4.9.1 If yes, give details ____

4.10 Corrosivity (2.8¹) 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 (2.6.2.1.1¹) 330 mg/kg bw for rats
280-365 mg/kg bw for mice
270 mg/kg bw for guinea pigs

5.2 LD₅₀, dermal (2.6.2.1.2¹) no data available

5.3 LC₅₀, inhalation (2.6.2.1.3¹) 660 ppm, 4h, female mice
1972 ppm, 4h, male rats

5.4 Saturated vapour concentration at 20 °C (2.6.2.2.4.3¹) ____ ml/m³

5.5 Skin exposure (2.8¹) 0,5 ml undiluted ethylene oxide, 4h exposure, rabbits > subdermal haemorrhages and chemical burns; 10% and 50% solutions, under 1h, 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 (6.8¹) yes/no

6.2.2 Intermediate Bulk Containers (6.5¹)? yes/no

6.2.3 Portable tanks (6.7¹)? yes for UN 1040/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) T50

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 ____
