

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 Globally Harmonized
System of Classification and Labelling of Chemicals

1 July 2024

Forty-sixth session

Geneva, 3-5 July 2024

Item 2 (f) of the provisional agenda

Work on the Globally Harmonized System

of Classification and Labelling of Chemicals:

**Practical classification issues (proposed amendments
to the Globally Harmonized System of Classification
and Labelling of Chemicals)**

Status update on the work of the practical classification issues informal working group

**Transmitted by the expert from the United States of America on behalf
of the practical classification issues informal working group**

Purpose

1. This paper provides an update on the work undertaken by the practical classification issues informal working group (PCI IWG) since the 45th session of the Sub-Committee.

Status report

2. The PCI IWG met virtually on three occasions to further consider proposals developed by Germany on work item 4 from the PCI program of work (see INF.34, 43rd session)) on 13 December 2023, 29 February 2024 and 4 June 2024. The IWG is exploring by comparison with the relevant sections of chapter 1.3, to which extent improvements of the classification process for mixtures in chapters 3.2 to 3.4 are compatible with the rules in chapter 1.3. The work has progressed to such an extent that the PCI expects to submit an official document for the 47th session of the Sub-Committee.

3. Additionally, the PCI IWG met on 5 June 2024, to discuss a thought starter on work item 5 from the PCI program of work, which focuses on addressing simple asphyxiants in annex 11 of the GHS. The IWG was generally supportive of the proposal, however it determined that more discussion is necessary regarding the definition of simple asphyxiant. During the discussion of the thought starter, one delegation asked if an alternative location in the GHS would be better suited for information on simple asphyxiants (i.e.: aspiration hazard). This will be further discussed at the next PCI IWG meeting, but it is noted that the program of work approved by the Sub-Committee specifically states that this item be developed for annex 11. The PCI IWG plans to continue working on this item with the goal of submitting an official document for the 47th session.

4. Part I and II of this document provide a “snapshot” of the proposals for work items 4 and 5, respectively. The following convention is used in the proposals in this document:

- Black text (including deleted text which is shown in ~~striketrough~~) is existing text.
- Blue text is proposed text that is provisionally agreed upon by the PCI IWG.
- Red text indicates proposed text that is currently in discussion and thus subject to further considerations by the IWG.
- Red text in ~~striketrough~~ represents an option for which there was no support and the IWG agreed should be removed from consideration in the proposal.

5. The Sub-Committee is invited to note the progress of the PCI IWG. Any input provided by the Sub-Committee on the proposals in parts I and II in this document will be considered by the PCI IWG.

Part I: PCI work item 4

Develop and propose a scientifically sound procedure for the tiered approach for classification of mixtures in chapters 3.2 to 3.4 allowing use of the available data in the most appropriate possible way (see informal document INF.23 for proposed workstreams). A preliminary evaluation will be conducted: (i) including an analysis of the present strategies for all health hazards and aiming at identifying when and how bridging principles are best to be considered in the classification process; (ii) defining which requirements need to apply to data from similar mixtures to be useful for bridging purposes; (iii) exploring by comparison with the relevant sections of chapter 1.3, to which extent improvements of the classification process for mixtures in chapters 3.2 to 3.4 are compatible with the rules in chapter 1.3. If deemed necessary, options for improvement will be identified and proposed.

The current/ongoing discussions in the PCI IWG in relation to work item 4 are focusing on relevant sections of chapter 3.2. It is noted that potential changes in chapter 3.2 will result in the need for consequential amendments in chapters 3.3, 3.4 and 1.3 (see terms of reference in INF.2, 39th session).

NOTE: There are a number of sections within the chapter that have not been amended. To focus the readers review on what has been amended in the chapter below, only sections for which changes were discussed by the IWG members are included in this document.

3.2 Skin corrosion/irritation

3.2.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

3.2.3.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing ~~in animals~~ (in line with 1.3.2.4.6).

3.2.3.2.2 Dilution

The principle

If a tested mixture is diluted with a diluent which has an equivalent or lower classification for skin corrosivity/irritancy ~~classification~~ than the least skin corrosive/irritant original ingredient and which is not expected to affect the skin corrosivity/irritancy of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture. Alternatively, the method explained in 3.2.3.3 could be applied.

Eye irritation proposal

“If a tested mixture is diluted with a diluent which has an equivalent or lower classification for serious eye damage/eye irritation than the least seriously eye damaging/eye irritant original ingredient and which is not expected to affect the serious eye damage /eye irritancy of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture. Alternatively, the method explained in 3.3.3.3 could be applied.”

Skin sensitisation proposal

If a tested mixture is diluted with a diluent which is not a sensitizer and which is not expected to affect the sensitization of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture.

3.2.3.2.3 Batching

The principle

The skin corrosion/irritation potential of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant ~~deviation variation~~ (e.g. caused by variation in an ingredient's composition or processing conditions) such that the skin corrosion/irritation potential of the untested batch has changed. If the latter occurs, a new assessment of the classification is necessary.

3.2.3.2.4 Concentration of mixtures of the highest skin corrosion/irritation category/sub-category

The principle

If a tested mixture classified in Category 1 or the highest sub-category (Category 1A) for skin corrosion is concentrated by reducing or removing an ingredient of less severe or no classification, the more concentrated untested mixture should be classified in Category 1 or the highest corrosion sub-category (Category 1A), respectively, without additional testing.

If a tested mixture classified in Category 2 for skin irritation (~~Category 2~~) is concentrated by reducing or removing an ingredient of less severe or no classification and does not contain skin corrosive ingredients, the more concentrated untested mixture should be classified for skin irritation (Category 2) without additional testing.

If a tested mixture classified in Category 3 for mild skin irritation is concentrated by reducing or removing an ingredient of less severe or no classification and does not contain skin irritant (Category 2) and corrosive ingredients, the more concentrated untested mixture should be classified for mild skin irritation (Category 3) without additional testing.

3.2.3.2.5 Interpolation within one hazard category/sub-category

The principle

For three mixtures A, B and C (i), (ii) and (iii) with identical ingredients, where mixtures A and B (i) and (ii) have been tested and are in the same skin corrosion/irritation hazard category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but the untested mixture (iii) has concentrations of the toxicologically active ingredients intermediate to the concentrations in mixtures A and B (i) and (ii), then mixture C (iii) is assumed to be in the same skin corrosion/irritation category as A and B (i) and (ii).

The sum of the concentrations of the toxicologically active ingredients in the same hazard category in (iii) should be equal to or below (i) and (ii).

3.2.3.2.6 Substantially similar mixtures

The principle

Given the following:

- (a) Two mixtures: (i) A + B;
(ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- ~~(c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);~~
- (d) B is the ingredient driving the skin corrosion/irritation potential of the mixtures (i) and (ii) as its skin corrosive/irritant potential or classification is more severe than that of A and C; ~~or none of the ingredients in mixtures (i) and (ii) are skin corrosive/irritant;~~
- (e) Data on skin corrosion/irritation for A and C are available and substantially equivalent, i.e. they are [~~in the same hazard category~~ of less severe skin corrosive/irritant potential or classification than that of the tested mixture] and are not expected to affect the skin corrosion/irritation potential of B;

If mixture (i) or (ii) is already classified based on data, ~~test~~ then the other mixture can be assigned the same hazard category.

Ingredients A, B and C could each consist of one substance with data, one mixture with data or multiple substances and/or mixture with data for each substance or mixture.

3.2.3.2.7 Aerosols

The principle

An aerosol form of a mixture may be classified in the same hazard category as the tested non-aerosolized form of the mixture provided that the added propellant does not affect the skin corrosion/irritation properties of the mixture upon spraying.

Part II: PCI work item 5

Asphyxiation is a well-known hazard in the workplace and is not currently included in the GHS. Consider developing a global approach to addressing simple asphyxiants in Annex 11 of the GHS.

Background of issue

During its seventeenth session, the Sub-Committee approved the programme of work to be undertaken by the PCI IWG which included an item to address simple asphyxiants.

The PCI IWG considered several proposals to address simple asphyxiants in the GHS, which included covering simple asphyxiants in chapter 2.5 (Gases under pressure), chapter 3.1 (Acute toxicity) and chapter 3.8 (Specific target organ toxicity – Single exposure). The group decided it would be more appropriate to address simple asphyxiants in chapter 2.5 (Gases under pressure).

The PCI IWG developed and submitted an official document addressing simple asphyxiants in chapter 2.5 to the 20th session. Subsequent to the document being submitted it was requested that the PCI IWG hold a conference call in which there was a slight modification to the proposed definition in the official document. EIGA couldn't make the conference call and they submitted an update to the modified definition that was agreed during the PCI IWG conference call. Given the short time frame of receiving EIGA's comments, a working group meeting was held in the margins of the 20th Sub-Committee session. Consensus was not reached on the EIGA proposal during that meeting and the United States of America subsequently withdrew the official document from consideration by the Sub-Committee.

The working group put this item back on its program of work as item 5 in the current biennium.

Proposal

Annex 11

A11.3 Simple asphyxiants

This section provides information to facilitate the identification of simple asphyxiant hazards.

A11.3.1 Scope and applicability

An asphyxiant is a vapour or gas that can cause unconsciousness or death by suffocation due to lack of oxygen. Asphyxiants can be either chemical asphyxiants or simple asphyxiants. Simple asphyxiants are inert gases or vapours which are harmful to the body when they become so concentrated that they reduce oxygen in the air (normally about 21 percent) to dangerous levels (19.5 percent or less). When the concentration of a particular gas increases, the fraction of inspired oxygen decreases, causing decreased oxygen in the blood. A decrease in the fraction of inspired oxygen to less than 19.5% causes inadequate oxygen supply within minutes after exposure to a simple asphyxiant, and may result in unconsciousness or death.

Inhaling an atmosphere containing no oxygen causes loss of consciousness in a matter of seconds because such an atmosphere not only fails to provide fresh oxygen, but also removes that already present in the bloodstream. There will be little sense of breathlessness to warn the victim that something is amiss, and they will rapidly lose consciousness. The heart will continue to function for a short time, but will then arrest, causing circulatory failure.

Asphyxiation is a well-known hazard in the workplace. Simple asphyxiants frequently contribute to industrial accidents involving loss of life and are of particular concern for those who work in confined spaces.

Chemical asphyxiants cause suffocation by either preventing the uptake of oxygen in the blood or by preventing the normal oxygen transfer from the blood to the tissues or within the cell itself. The specific toxic health effects associated with chemical asphyxiants are covered by the Specific Target Organ Toxicity Single Exposure (Chapter 3.8) and Specific Target Organ Toxicity Repeated Exposure (Chapter 3.9).

A11.3.2 Definition

Version 1: Simple asphyxiant means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

Note: this definition was agreed to by the PCI WG and included in the working paper

A blend of Version 1, suggestions from the UK and alignment with the existing structure of health definitions:

“Simple asphyxiants refers to a gases or vapours which can displace oxygen to dangerous levels which can result in unconsciousness and death to those exposed without any warning of the imminent danger after exposure to a substance or mixture.”

Version 2: Simple asphyxiant means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation (before the occurrence of significant physiological effects) in those who are exposed, leading to unconsciousness or death”.

Note: this definition was agreed to by the PCI WG in October 2010

~~*Version 3: Simple asphyxiant* means a substance or mixture that displaces oxygen has no other health hazard than displacing oxygen in the ambient atmosphere, and thus can cause oxygen deprivation (before the occurrence of significant physiological effects) in those who are exposed, leading to unconsciousness or death”.~~

~~*Note: this definition was proposed by EIGA in November 2010. During a meeting in the margins of the 20th Session many participants supported the EIGA proposal. However, the U.S. and Canada did not agree with the proposal. Subsequently, the U.S. withdrew the working paper given the lack of consensus on the definition.*~~

A11.3.3 Identification of simple asphyxiant

Simple asphyxiants are of particular concern in enclosed spaces. Some examples of simple asphyxiants include: carbon dioxide, hydrogen, nitrogen, helium, neon, argon, krypton, xenon, ethane, ethylene, acetylene, methane, propane, propylene, aliphatic alkanes and the chlorofluorocarbons. These gases are well-known simple asphyxiants from experience in the workplace. Evaluation of other gases and vapours as simple asphyxiants requires expert judgment to evaluate evidence such as human experience, information from similar substances, and other pertinent data.

A11.3.4 Supplemental information for hazard communication

A11.3.4.1 As explained in 1.4.6.3, there are many communication elements which have not been standardized in the harmonized system. Some of these clearly need to be communicated to the downstream user. For substances and mixtures that are simple asphyxiants, information should be provided in section 2 of the SDS (A4.3.2) that addresses hazards that do not result in classification.

A11.3.4.2 To communicate the simple asphyxiant hazard, competent authorities may require the use of the following phrases on labels, SDSs and/or operating instructions or may leave the choice to the manufacturer or supplier.

- (a) “May displace oxygen and cause rapid suffocation.”
- (b) In addition, the phrase “Warning” may be used in conjunction with item (a).

References

ST/SG/AC.10/C.4/2010/16: <https://unece.org/DAM/trans/doc/2010/ac10c4/ST-SG-AC10-C4-2010-16e.pdf>

UN/SCEGHS/20/INF.40: <https://unece.org/DAM/trans/doc/2010/ac10c4/UN-SCEGHS-20-INF40e.pdf>
