



**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****Thirty-sixth session**

Geneva, 5-7 December 2018

Item 3 (e) of the provisional agenda

**Classification criteria and related hazard communication:
practical classification issues****Proposals to address issues from the programme of work for the
practical classification issues correspondence group****Transmitted by the expert from the United States of America on behalf of
the informal correspondence group on practical classification issues*****Purpose**

1. The informal correspondence working group on practical classification issues (PCI) provides in this document recommendations to clarify classification criteria in the GHS.

Background

2. During the thirty-fifth session, the PCI informal group submitted informal document INF.21 to the Sub-Committee, providing an update on its work. The PCI informal group met surrounding the Sub-Committee meeting to further discuss the proposals presented in informal document INF.21, in addition to proposals on other issues from the PCI informal group agreed program of work for this biennium (informal document INF.39 (thirty-second session)). As a

* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, paragraph 98 and ST/SG/AC.10/44, paragraph 14).

result of discussions on these issues, the PCI has developed proposed editorial changes to the GHS as provided in this document.

Proposal

3. The correspondence group invites the Sub-Committee to consider the recommended editorial amendments to the GHS text as set forth in the Annex of this document.

Annex

PCI Program of Work Item (b)

Consider developing an example(s) to illustrate how to interpret both single exposure and repeated exposure data when interpreting the statements in Chapter 3.8 Specific Target Organ Toxicity – Single Exposure (GHS paragraph 3.8.1.6) and Chapter 3.9 Specific Target Organ Toxicity – Repeated Exposure (GHS paragraph 3.9.1.6) that effects covered in other health hazard chapters are not included in Chapters 3.8 and 3.9. In addition, the PCI will consider if further editorial updates to the GHS text are appropriate.

Chapter 3.8 Specific Target Organ Toxicity - Single Exposure

3.8.1 Definitions and general considerations

Proposed recommendation: Amend paragraph 3.8.1.6 as follows (amended text is shown in bold underlined)

3.8.1.6 Specific target organ toxicity following a repeated exposure is classified in the GHS as described in Specific target organ toxicity – Repeated exposure (Chapter 3.9) and is therefore excluded from the present chapter. **Substances and mixtures should be classified for single and repeated dose toxicity independently.**

Other specific toxic effects, such as acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, and aspiration toxicity are assessed separately in the GHS and consequently are not included here.

3.8.3 Classification criteria for mixtures

Proposed recommendation: Amend paragraphs 3.8.3.1 and 3.8.3.4.1 as follows (amended text is shown in bold underlined)

3.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures **should** be classified for specific target organ toxicity **for single and repeated exposure** (Chapter 3.9) independently.

3.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture will be classified as a specific target organ toxicant (specific organ specified), **following single exposure** when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant - **single exposure** and is present at or above the appropriate cut-off value/concentration limit as mentioned in Table 3.8.2 below for Category 1 and 2 respectively.

Proposed recommendation: Delete Paragraphs 3.8.3.4.2 and 3.8.3.4.3.

Chapter 3.9 Specific Target Organ Toxicity - Repeated Exposure

3.9.1 Definitions and general considerations

Proposed recommendation: Amend second sentence of paragraph 3.9.1.1 as follows (new text is shown in bold underlined)

All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in chapters 3.1 to 3.7 and 3.10 are included **(see also 3.9.1.6).**

Proposed recommendation: Amend paragraph 3.9.1.6 as follows (new and amended text are shown in bold underlined)

3.9.1.6 Non-lethal toxic effects observed after a single-event exposure are classified in the GHS as described in *Specific target organ toxicity – Single exposure* (Chapter 3.8) and are therefore excluded from the present chapter. **Substances and mixtures should be classified for single and repeated dose toxicity independently.** Other specific toxic effects, such as acute toxicity, **skin corrosion/irritation, serious eye damage/eye irritation,** respiratory or skin sensitization, **germ cell mutagenicity, carcinogenicity,** reproductive toxicity and aspiration toxicity are assessed separately in the GHS and consequently are not included here.

3.9.3 Classification criteria for mixtures

Proposed recommendation: Amend paragraph 3.9.3.1 and 3.9.3.4.1 as follows (new and amended text are shown in bold underlined)

3.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances mixtures **should be classified for Specific Target Organ Toxicity for single (Chapter 3.8) and repeated exposure independently.**

3.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture will be classified as a specific target organ toxicant (specific organ specified), following **repeated exposure,** when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant – **repeated exposure** and is present at or above the appropriate cut-off value/concentration limit as mentioned in Table 3.9.3 below for Category 1 and 2 respectively.

PCI Program of Work Item (e)

Consider the need for clarification of the existing criteria on bridging principles via editorial changes to the text and/ or the development of additional guidance/ example(s) illustrating the application of the bridging principles. This would include inter alia the definition of an ingredient in the context of bridging principles (i.e., can an “ingredient” be composed of several substances or can it be a mixture?), the application of the “Substantially similar mixture” bridging principle to mixtures that have more than 2 ingredients, etc.”

Chapter 1.3 Classification of Hazardous Substances and Mixtures

1.3.2.3 *Classification criteria*

Proposed recommendation: Amend paragraph 1.3.2.3.1 (b) to include a second sentence as follows:

“Bridging may also be applied when test data conclusively show that no classification is warranted;”
