

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

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Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

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Item 2 (h) of the provisional agenda

**Classification criteria and related hazard communication:
other issues**

Proposed clarification of eye irritation sub-categorization

Transmitted by the expert from Australia

Background

Note: Feedback received from other delegations in the lead up to the 38th session has highlighted two errors in the table that follows paragraph 19 of INF.4. The differences in the proposed text presented in this document (INF.4/Rev.1) as compared to that presented in informal document INF.4 are shown in red underlined text, while deleted text is shown in ~~strikethrough~~.

1. Work in progress to implement the seventh revised edition of the GHS in Australia has highlighted that the presentation of the classification criteria for Eye Irritation Category 2 in Chapter 3.3 of the GHS is causing confusion for some classifiers and is inconsistent with other health hazards
2. While this proposal is not related to or affected by the review of the Chapter being undertaken by the Working Group on use of non-animal testing methods for classification of health hazards, the review of the chapter provides an opportune time for the Sub-Committee to consider this issue.
3. Chapter 3.3 of the GHS sets out criteria for the classification of serious eye damage/eye irritation. Serious eye damage/eye irritation has the following categories.
 - (a) Category 1 – Serious eye damage (irreversible effects on the eye);
 - (b) Category 2 – Eye irritation (reversible effects on the eye).
4. Paragraph 3.3.2.1.2.1 sets out that “substances that have the potential to induce reversible eye irritation should be classified in Category 2 where further categorization into Category 2A and Category 2B is not required by the competent authority or where data are not sufficient for further categorization.”
5. Paragraph 3.3.2.1.2.2 sets out that “for authorities wanting more than one designation for reversible eye irritation, Categories 2A and 2B are provided:
 - (a) Where data are sufficient and where required by a competent authority substances may be classified in Category 2A or 2B in accordance with criteria in Table 3.2.2;
 - (b) For substances inducing eye irritant effects reversing within an observation time of normally 21 days, Category 2A applies. For substances inducing eye irritant effects reversing within an observation time of 7 days, Category 2B applies.”

Table 3.3.2: Reversible effects on the eye categories

	Criteria
	Substances that have the potential to induce reversible eye irritation
Category 2/2A	Substances that produce in at least 2 of 3 tested animals a positive response of: <ul style="list-style-type: none"> (a) corneal opacity ≥ 1; and/or (b) iritis ≥ 1; and/or (c) conjunctival redness ≥ 2; and/or (d) conjunctival oedema (chemosis) ≥ 2 calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material, and which fully reverses within an observation period of normally 21 days.
Category 2B	Within Category 2A an eye irritant is considered mildly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.

Description of the issue

6. The expert from Australia contends that there are two issues with the representation of Category 2 within the chapter which warrant consideration by the Sub-Committee.

7. Firstly, the term ‘Category’ is used when referring to eye irritation ‘2A’ and ‘2B’. This is a misuse of terminology and inconsistent with the approach taken in other parts of the GHS. See for example, paragraph 3.2.2.2.1.2 which, like 3.3.2.1.2.2, sets out the categorization schema for Skin Corrosion Category 1, in which ‘1A’, ‘1B’ and ‘1C’ are correctly referred to as Sub-Categories. Table 3.2.1 (refer below) is an example of how Sub-Categories typically operate in the GHS.

8. There is also an issue with how the criteria for eye irritation 2/2A and 2B are presented. As can be seen in Table 3.3.2 above, the time based criteria for Category 2/2A and 2B overlap. The table text for 2B states that “**Within Category 2A** an eye irritant is considered mildly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.”

9. The effect of this is that any chemical classified into 2B eye irritation also meets the criteria for Category 2/2A eye irritation, because Category 2/2A captures effects reversing in 21 days or less (including effects reversing in 7 days). This can be visually represented as follows:

Days	0 to 7	8 to 21
	Category 2/2A	
	Category 2B	

10. This approach is different to other hazard classes in the GHS, where sub-categories are mutually exclusive. For example, the categorization and sub-categorization for Skin Corrosion Category 1 as presented in Table 3.2.1.

Table 3.2.1: Skin corrosion category and sub-categories

	Criteria
Category 1	Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure \leq 4 h
Sub-Category 1A	Corrosive responses in at least one animal following exposure \leq 3 min during an observation period \leq 1 h
Sub-Category 1B	Corrosive responses in at least one animal following exposure $>$ 3 min and \leq 1 h and observations \leq 14 days
Sub-Category 1C	Corrosive responses in at least one animal after exposures $>$ 1 h and \leq 4 h and observations \leq 14 days

11. Australia's implementation of the third revised edition of the GHS (2012 to present) captures all eye irritants under Category 2A (and in later revisions Category 2/2A). However, experience has shown that classifiers are confused by the sub-categorization employed in the serious eye damage/irritation chapter, and how it interacts with local legislation.

12. For example, if the competent authority adopts the single Category 2/2A for eye irritation, many classifiers are unsure if and how they are meant to classify Sub-Category 2B eye irritants. Australia considers this confusion results from both the use of the 2/2A terminology, and the classification criteria which encompasses Sub-Category 2B within Category 2/2A

13. Confusion about sub-categorization has led to some Sub-Category 2B eye irritants not being classified or labelled in Australia. This was not the intention of the competent authority at the time of implementation.

14. While these issues can be partially addressed by amending local legislation and by competent authorities providing guidance to classifiers, it is unlikely that this approach would fully resolve the confusion duty holders are experiencing as classifiers will still refer directly to the GHS text when classifying chemicals across markets.

Proposal

15. To clarify the sub-categorization of Category 2 eye irritation, it is proposed to adopt the approach to the presentation of the criteria for eye irritation based on that already in place for Category 1 skin corrosion in Chapter 3.2 of the GHS.

16. This approach would remove Category 2/2A terminology in Chapter 3.3 and replace it with a new 'Category 2', while Sub-Categories "2A" and "2B" would be presented as separate, non-overlapping sub-categories.

17. The proposal does not change the scope of the classification criteria for Category 2 eye irritation, rather it presents the category in the same manner as for other sub-categorization schemes in the GHS.

18. 'Category 2' would capture eye irritation that is reversible with 21 days (as is the case now), while 'Sub-Category A' would capture eye irritation that is reversible between 8 to 21 days, and 'Sub-Category B' would capture effects that are reversible within 1 to 7 days.

19. A proposal for the categorization of Category 2 eye irritation is shown below:

	Criteria
	Substances that have the potential to induce reversible eye irritation
Category 2	Substances that produce in at least 2 of 3 tested animals a positive response of: (a) corneal opacity \geq 1; and/or (b) iritis \geq 1; and/or (c) conjunctival redness \geq 2; and/or (d) conjunctival oedema (chemosis) \geq 2 calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material, and which fully reverses within an observation period of normally 21 days.
<u>Sub-Category 2A</u>	An eye irritant is considered irritating to eyes when the effects listed above <u>are fully reversible within an observation period of greater than 7 days and not more than 21 days</u> . are fully reversible within 8 to 21 days of observation.
<u>Sub-Category 2B</u>	An eye irritant is considered mildly irritating to eyes when the effects listed above are fully reversible <u>within an observation period of seven days</u> . within 7 days of observation

20. The criteria proposed are identical to those set out in chapter 3.3 currently, with the exception that sub-categories 2A and 2B do not overlap. Authorities may still choose to use either Category 2 or Sub-Categories 2A and 2B. However, the proposed approach would provide clarity both where authorities do not require sub-categorization and also where sub-categorization is required where supported by data.

21. It is expected that only minimal changes to section 3.3.2 of the GHS would be needed to clarify the classification criteria and refine the terminology. Consequential changes to Annexes 1 and 3 would also be required.

Next steps

22. The expert from Australia welcomes any comments on the proposal, including any alternative proposals.

23. If the Sub-Committee is supportive of this approach, the expert from Australia will prepare a formal paper for agreement at the 39th session. This document would include the complete changes needed to implement this proposal.