

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

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Item 2 (h) of the provisional agenda

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

Alternative proposal to INF.4: Proposed clarification of eye irritation sub-categorization

Transmitted by the expert from the United States of America

1. This informal document provides proposed editorial amendments to GHS Chapter 3.3 as an alternate approach to the proposal presented in UN/SCEGHS/38/INF.4 provided by Australia.
2. The proposed editorial amendments in Chapter 3.3 are presented below:

3.3.2.1.2 *Eye irritation (Category 2)/Reversible effects on the eye*

3.3.2.1.2.1 A single category (Category 2) is adopted for substances. Substances that have the potential to induce reversible eye irritation. Substances can should be classified in Category 2 where further categorization into Category 2A and sub-~~c~~Category 2B is not required by a competent authority or where data are not sufficient for further categorization. When a chemical is classified as Category 2, without further categorization, the classification criteria are the same as those for Category 2A.

3.3.2.1.2.2 For those authorities wanting more than one designation for reversible eye irritation, ~~categories~~ category 2A and sub-category 2B are provided:

(a) When data are sufficient and where required by a competent authority substances may be classified in Category 2A or sub-category 2B in accordance with the criteria in Table 3.3.2;

(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, sub-~~c~~Category 2B applies.

3.3.2.1.2.3 For those substances where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

Table 3.3.2: Reversible effects on the eye categories ^{a, b, c}

	Criteria
	Substances that have the potential to induce reversible eye irritation
Category 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.
Sub-Category 2B	Within Category 2A an eye irritant is considered mildly irritating to eyes (Sub-Category 2B) when the effects listed above are fully reversible within 7 days of observation.

^a The use of human data is addressed in 3.3.2.2 and in chapters 1.1 (para. 1.1.2.5(c)), and 1.3 (para. 1.3.2.4.7).

^b Grading criteria are understood as described in OECD Test Guideline 405.

^c Evaluation of a 4, 5 or 6-animal study should follow the criteria given in 3.3.5.3.