

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

Seventeenth session
Geneva, 29 June – 1 July 2009
Item 5 of the provisional agenda

DEVELOPMENT OF GUIDANCE ON THE APPLICATION OF GHS CRITERIA

Clarification of the bases for decisions not to classify under the GHS

Transmitted by the experts from the United States of America and Australia, on behalf of the informal working group on implementation issues

Background

1. At its sixteenth session, the Sub-Committee agreed with the proposal from the informal working group on GHS implementation issues to consider definitions for the terms "no data available," "not applicable," and "not classified." The United States offered to draft some text for consideration in the current biennium. (See ST/SG/AC.10/C.4/2008.22, Issue 1.4 in Paragraph 4.1, and UN/SCEGHS/16/INF.43, Paragraph 3(b).)
2. This paper reviews the issues and is intended as a discussion draft for use by the informal working group, with a view toward developing recommendations for Sub-Committee consideration at a subsequent session.
3. A draft of this informal paper was circulated to the Sub-Committee for comment. Comments were received from Germany, Sweden, the United Kingdom, and the Soap and Detergent Association. The paper has been revised to include points raised by commenters, without eliminating options for consideration by the group.

Issue

4. It may not be possible to assign a GHS health or environmental hazard class and category to a chemical for either of two reasons: (1) there are no or insufficient data upon which to base a classification, or (2) there are sufficient data and they show that the chemical does not meet the criteria for classification (e.g., an LD₅₀ of 6400 mg/kg for acute oral toxicity). This distinction may be important to chemical users and useful to include in safety data sheets (SDS).

5. This point is reflected in the current GHS. Chapter 1.5.3.3.1 (p. 37 of Rev 2, English version) states:

1.5.3.3.1 The SDS should provide a clear description of the data used to identify the hazards. If specific information is not applicable or not available under a particular subheading, the SDS should clearly state this.

6. The guidance on preparation of SDS in Annex 4 of the GHS document provides additional clarification that if data are not available to support classification for any of the health hazard classes (listed in A.4.3.11.1, p. 410 of Rev 2, English version), the hazard class should still be listed in Section 11 of the SDS, with a statement that data are not available.

Terms Used in the Current GHS Document (Rev. 2, all page numbers refer to English version)

7. A search for the specific terms cited in ST/SG/AC.10/C.4/2008.22 produced the following findings:

(a) "No data available".

This specific phrase does not appear in the GHS text. It appears only in the classification examples given in Annex 8 (p. 452, 455, 456) and in Annex 9 (A.9.2.4.2, p. 469).

A similar phrase "data are not available" is used, but in a different context, to explain the tiered approach to classification of mixtures. The health hazard chapters in particular note that "if data are not available" on the complete mixture, then bridging principles should be applied.

(b) "Not applicable".

This specific phrase appears in Chapter 1.5.3.3.1, quoted above. Annex 4 (A.4.3.11.4, p. 410) advises SDS preparers *not* to use this phrase because it might cause confusion, and again advises that "For health effects where information is not available, this should be clearly stated." The phrase also appears in Appendix III to Annex 9 (p. 525), where it is noted that a certain test method is not applicable in certain circumstances.

(c) "Not classified" and "classification not possible".

8. In the GHS text, most notably in the decision logics for classification of substances and mixtures at the end of each health hazard class, the current approach is to use the phrase "classification not possible" when sufficient data do not exist to permit a determination whether the classification criteria are met.

9. When there are data, and those data show that the criteria for classification are not met (i.e., the chemical does not present the hazard as defined by the GHS), the phrase used consistently in the health hazard chapter decision logics is "not classified. "

10. The decision logics for physical hazards and aquatic toxicity do not address the possibility that there will be insufficient data upon which to base a classification, and therefore do not use the phrase "classification not possible." Consistent with the health hazard chapters, they use the phrase "not classified" when the available data show that the criteria for classification for the hazard are not met.

11. The chapter on ozone depleting chemicals does not present the issue, since classification is based on listing under the Montreal Protocol and not on the classifier's own review of data to determine whether criteria are met.

Possible Clarifying Amendments to the GHS

12. From the findings discussed in Paragraph 5, it does not appear necessary to provide definitions for these phrases in Chapter 1.2, since the GHS document either advises against using them in preparing SDS (in the case of "not applicable") or they are used consistently and in accordance with their commonly understood meaning. One commenter noted the desirability of keeping changes to the text to the minimum necessary, and therefore supported retention of the terms "not classified" and "classification not possible" as they are now consistently used in the GHS text.

13. It would be possible to define (1) "classification not possible" or "no data available"; and (2) "not classified" so that the terms will be used uniformly on SDS. This would be of limited utility, however, since the SDS should be a stand-alone document. It cannot be assumed that readers of the SDS will have access to or knowledge of definitions in the GHS document. Therefore, it may be most useful to focus on giving further guidance to SDS writers, in terms of clear phrases that can be used in SDS and will be understood by users.

14. The informal working group may wish to consider whether it would be desirable to amend Chapter 1.5 and Annex 4 to make it clear not only when information is not available and therefore classification for a health or environmental effect is not possible (as indicated in A.4.3.11.1), but also when sufficient information is available, and the chemical has been found not to meet the criteria/present the hazard.

15. For example, clarifying amendments to make the discussion of SDS contents in Chapter 1.5 and Annex 4 consistent with the current use of "classification not possible" and "not classified" in the GHS health hazard chapters could include:

- (a) Table 1.5.2, Section 11 could be revised to add at the end:

Each health hazard class should be listed in this section. If no data, or insufficient data, are available for a health hazard class, that hazard class should be listed followed by the statement(s) ["Classification not possible"], ["no data available"], or ["insufficient data"].

The clearest option may be to combine the statements, (e.g. "Classification not possible: insufficient data"); otherwise readers might think there are other reasons, such as the limited expertise of the SDS writer, etc. Some reviewers supported this approach.

If sufficient data are available to permit a classification determination for a health hazard class, and the data show that the chemical does not meet the criteria for classification (and therefore does not present the hazard), the hazard class should be listed followed by the statement ["Not classified, based on available data"], or ["not (state hazard—not acutely toxic, not irritating, does not cause cancer, etc.) or [does not present that hazard] " or [does not meet classification criteria].

Reviewers who expressed a preference preferred "Not classified, based on available data" or "Not classified: does not meet classification criteria."

(b) A.4.3.11.1, last sentence could be revised to read:

If data for any of these hazards are not available, the hazard should still be listed on the SDS with a statement that data are not available. If data are available and show that the chemical does not meet the criteria for classification, the SDS should state that the chemical has been evaluated and found not to [meet classification criteria] [present the hazard].

16. One commenter on the draft discussion paper suggested that only those hazard classes for which a chemical has been classified need to be included on the SDS and expressed concern that listing all hazard classes could increase the length of the SDS. This approach would eliminate the need for the type of language suggested above. It would appear to be inconsistent with the intent of the GHS as adopted, however, and would not provide users of the SDS with information as to why a chemical is not classified.

17. If the length of the SDS is of concern, the group may wish to consider modifying the GHS to state that it is only necessary to include hazard classes for which the chemical is classified or for which insufficient data are available to make a classification determination. It is likely, however, that some SDS users would prefer to have more information, and that suppliers would prefer to include it if they have gone to the expense of developing data to assess whether their product meets the classification criteria

18. The informal working group may also wish to consider whether more detailed information should be provided for some hazard classes (e.g., as to the availability of data on acute toxicity for each exposure route for which the GHS prescribes criteria—oral, dermal, and by inhalation), and whether the information as to the reason for no classification should only be provided for health hazards. A similar approach could be taken for aquatic toxicity in Section 13 of the SDS and for physical hazards (which would require consequential changes, e.g., in the Chapter 4.1 decision logic).

Possible Miscellaneous Technical/Conforming Changes to Improve Consistency in Existing GHS Document

19. Decision logics 3.1.5.2 (p. 120), 3.8.2 (p. 197), and 3.9.2 (p.208): add the heading

Classification of mixtures on the basis of bridging principles or information/data on ingredients

20. Decision logic 3.2.2 (p. 130): amend the second box that points to "classification not possible" to read (proposed change is in italics):

Mixture: Does the mixture as a whole *or its ingredients* have data/information to evaluate skin corrosion/irritation?

21. Decision logics 3.2.2 (p.131) and 3.3.2 (p. 144): amend the heading to add "*bridging principles or*" before "*information/data on ingredients*".
