

## 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 Transport of Dangerous Goods

Thirty-fifth Session  
Geneva, 22 - 26 June 2009  
Item 10 of the provisional agenda

### ISSUES RELATING TO THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

#### Development of guidance for decisions not to classify substances and mixtures

#### Information about potential consequences for the classification of dangerous goods as an outcome of a discussion ongoing within the UN SCE GHS

#### Transmitted by the expert from Germany

1. Within the Sub-Committee of experts on the Globally Harmonized System of Classification and Labelling of Chemicals, currently a discussion is taking place on clarification of the bases for decisions not to classify under the GHS (see informal paper UN/SCEGHS/17/INF.3 as attached). Although there are already such indications in the current version of the GHS, the current discussion is intended to better clarify the situation and by that shows more evidence that there are certain issues apparently not or insufficiently taken into account at this stage.
2. Within the Sub-Committee of experts on the Transport of Dangerous Goods, currently a discussion is ongoing about a more detailed alignment of some health hazard criteria of the UN Model Regulation to those of the GHS. This is concerning class 8 for skin corrosion and also class 6.1 for acute toxicity. Also the parts of the criteria for aquatic environmental hazard taken over into the orange book will need to be kept continuously aligned with their development in the GHS to avoid discrepancies to arise again.
3. Although the work in the UN SCE GHS mainly concerns guidance on the application of the GHS and on the information to be included in the Safety Data Sheet (SDS), this work may have some consequences also on the application of the criteria for and on the classification of dangerous goods for transport. This gives a clear indication that the issues should be addressed in good co-operation of both Sub-Committees to achieve a solution applicable for all target audiences of the GHS including TDG.
4. If the provisions for a hazard class or category of the GHS are transferred and used in the transport sector as one important target audience for the GHS, the harmonized regulatory situation shall also ensure that classifications based on the same criteria shall lead to the same

classification in all sectors concerned, as this is one very important aim of the GHS. Otherwise, industry and authorities would not really benefit from the existence of the GHS. Therefore the expert from Germany would like to highlight some concerns for further consideration.

5. If in the GHS it is and will be permitted to distribute information that - e.g. due to a lack of data - classification of a substance or mixture is not possible and therefore not done, this touches the principle of self-classification in the Orange book. Currently only in certain classes a classification by a competent authority is required, for all other classes the consignor has to indicate the correct classification in the transport document and usually he is relying on data from others, e.g. manufacturer, importer or distributor. Furthermore the enterprise and personnel packing or filling dangerous goods have to rely on the correct classification to choose the correct packagings, IBC or tanks for transport.

6. Furthermore, it has to be recalled that in several classes, the UN model regulation declares not only that experience e.g. from accidental data or data on effects on humans shall be taken into account for classification, but that they have to prevail in cases, where they may lead to a more stringent classification than the one based on test data only. This aspect apparently has not been into account in the work ongoing in the UN SCE GHS up to now.

7. Permitting information about non-classification in the SDS by the GHS may lead to uncertainties for the transport sector and the logistical chains, although the SDS is not mandatory for transport. But it contains a section for transport information. And therein such information would be found in future. So it may lead to confusion for this target audience of the GHS, e.g.:

- a) for physical hazards, the classification is related to test methods and test results; so basically an indication like “not classified on the basis of test results according to test method ...” should not cause a general problem; but in the UN TDG list, there are dangerous goods listed, which are classified by listing. As the GHS does not provide for (a) list(s) of classified substances or mixtures and does not address classification by listing e.g. on the basis of accidental experience, there may be an inconsistency arising from that work;
- b) nevertheless for classification of dangerous goods of class 1 (explosives), class 4.1 (self-reactives) and class 5.2 (organic peroxides), classification by a competent authority is required for transport, as far as the substance or mixture is not already listed as classified in the orange book; in such cases, it is not appropriate that e.g. a manufacturer or consignor may be authorized to declare non-classification, because for transport he has to follow the classification by the competent authority and only that authority could declare something to be not classified; this situation is currently not reflected in the discussions within a working group of the SCE GHS working on that issue (see UN/SCEGHS/17/INF.3);
- c) furthermore for physical hazards classification derived e.g. by analogy from one tested substance or mixture to another – even with the same nominal composition, but e.g. with a different particle size – is not possible, the modified substance or mixture has to be submitted to testing for classification, this problem is likely to increase by a rising use of substances and mixtures composed of Nano particles;

- d) for acute toxicity, categories I to III, and for skin corrosion, categories 1a to 1c, relating to packing groups I to III in classes 6.1 and 8 of the orange book, there is no classification of a competent authority required, but non-classification is not indicated somewhere in the transport documents; only in very special cases some special provisions permit in the orange book to not classify e.g. a substance or a mixture of a substance with low concentration; in cases, where no sufficient data are available for classification, usually classification is made in analogy of classified dangerous goods and in taking account of precautionary points of view, therefore classification usually more follows a conservative approach;
- e) furthermore there are also dangerous goods of classes 3 and 6.1 listed in the TDG list, that are classified on the basis of expert judgement e.g. based on experience and differing from available data; so it could raise a problem for transport, if for example for a listed dangerous good somebody declares in an SDS something like “not classified according to data”;
- f) there could arise also a misleading situation within the application of the GHS and within classification for TDG, if for example for substance A the manufacturer has declared in an SDS something like “not classified for acute toxicity” or “not classified for skin corrosion” and another manufacturer has declared the same for substance B; thereby an enterprise mixing both for a new product for distribution including transport may be misled to think that there is no necessity to check his product for classification believing in the two independent SDS provided to him;
- g) the case mentioned under letter e) may even get worse if for (a) substance(s) it is indicated in an SDS, that it is “not classified for acute toxicity according to data in concentrations below X %”;
- h) even more misleading effects could arise from indications like “not classified according to lack of data”, this could encourage companies to a superficial data research and if no data are found at first glance, such indication may be given, thereby not only affecting safety by incorrect classification but also obliging enforcement authorities to do research on their own to prove this indication to be wrong;
- i) similar to acute toxicity and skin corrosions, the outcome may also affect the criteria for aquatic environmental hazard as far as used by the TDG provisions.

8. The Sub-Committee is invited to discuss the issues and to address the Sub-Committee of experts on GHS for careful consideration of the outcome of this discussion in developing its work further and to inform the SCE TDG about any further progress of that work before taking any decision.

## Annex

### UN/SCEGHS/17/INF.3

#### **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 LD<sub>50</sub> 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 pages 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*".

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