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**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

Fifteenth session
Geneva, 9-11 July 2008
Item 5 (c) of the provisional agenda

IMPLEMENTATION OF THE GHS

Other implementation issues

Reference to in vitro skin corrosion test
in the Model Regulations on the Transport of Dangerous Goods

Note by the secretariat ^{*/}

Background

1. At its thirty-second session, the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG Sub-Committee) considered a proposal to include a reference to OECD test guidelines 430, 431 and 435 in Chapter 2.8 of the United Nations Model Regulations on the Transport of Dangerous Goods (UN Model Regulations) as suitable in vitro skin corrosion methods to determine the classification of a substance into Class 8 (corrosive substances) for transport (see documents ST/SG/AC.10/C.3/2007/50, UN/SCETDG/32/INF.4, INF.5, INF.6 and INF.49).

^{*/} In accordance with paragraph 22 of the report of the Sub-Committee of experts on its fourteenth session (refer to ST/SG/AC.10/C.4/28).

2. The TDG Sub-Committee adopted provisionally the proposal in document ST/SG/AC.10/C.3/2007/50, as amended by INF.49 (see ST/SG/AC.10/C.3/64, Annex 1) but it was suggested that the text be checked by the GHS Sub-Committee.

3. Following the request of the TDG Sub-Committee, the GHS Sub-Committee examined the proposed amendments to paragraph 2.8.2.4 of the Model Regulations but could not take a decision since it was felt that additional background information on the scope and context of the proposal as well as more time was needed to consult with experts intersessionally. The GHS Sub-Committee asked the secretariat to submit an official document to its fifteenth session, including the proposed text together with all the relevant background information.

4. All experts were encouraged to ensure that the necessary consultations are conducted intersessionally in order to be in a position of making the appropriate recommendations to the TDG Sub-Committee.

Rationale for the proposal

5. According to paragraph 2.8.2.4 of the UN Model Regulations, allocation of substances and mixtures into a packing group within Class 8 shall be made taking into account human experience (in accordance with the criteria in 2.8.2.2 of the UN Model Regulations) in instances of accidental exposure and, in the absence of human experience, on the basis of data obtained from experiments in accordance with OECD Test Guideline 404 (Acute dermal irritation/corrosion).

6. The test method described in Test Guideline 404 requires the use of live animals and the proposal in document ST/SG/AC.10/C.3/2007/50 was intended to allow the use of in vitro skin corrosion tests (OECD Guidelines 430, 431 and 435) as an alternative to the “in vivo” test method in OECD Guideline 404.

7. The expert from the United States of America noted in INF.49 that only test method 435 provided test results suitable for the assignment of a Class 8 substance into a packing group for transport. However, he recognized that there is value in including also a reference to methods 430 and 431 since it is expected that substances which produce a negative result with these tests, will not produce a positive result with methods 404 or 435 (i.e.: if a substance has been tested for non-transport purposes according to tests 430 and 431 and a negative result is obtained, the substance is considered to be non-corrosive and will not have to be tested again according to test methods 404 or 435). He therefore proposed some amendments to the original proposal in document ST/SG/AC.10/C.3/2007/50.

8. In addition to the above, the expert from the Netherlands considered that the criteria and the classification procedures of the Model Regulations should be checked more thoroughly, in view of the GHS criteria, and said that he would prepare a document for the thirty-third session of the TDG Sub-Committee with respect to corrosiveness. The document has been circulated under the symbol ST/SG/AC.10/C.3/2008/48.

Action requested of the Sub-Committee

9. The Sub-Committee is invited to check that the amendment to paragraph 2.8.2.4 of the UN Model Regulations provisionally adopted by the TDG Sub-Committee is in conformity with the GHS.

Text provisionally adopted by the TDG Sub-Committee

10. Paragraph 2.8.2.4 of Chapter 2.8 of the UN Model Regulations, as amended (new text is underlined):

“2.8.2.4 In assigning the packing group to a substance in accordance with 2.8.2.2, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404¹ or 435². A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430³ or 431⁴ may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.”

¹ OECD Guidelines for testing of chemicals No. 404 “Acute Dermal Irritation/Corrosion” 1992.

² OECD Guideline for the testing of chemicals No. 435 “In vitro membrane barrier test method for skin corrosion” 2006.

³ OECD Guideline for the testing of chemicals No. 430 “In vitro skin corrosion: transcutaneous electrical resistance test (TER)” 2004.

⁴ OECD Guideline for the testing of chemicals No. 431 “In vitro skin corrosion: human skin model test” 2004.