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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 Transport of Dangerous Goods

Thirty-seventh session Geneva, 21–30 June 2010

Item 10 of the provisional agenda

Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Alignment with GHS, Proposal of amendment to Chapter 2.8

Transmitted by the expert from the Netherlands¹

Background

- 1. In order to align the criteria for corrosivity of Chapter 2.8 of the Model Regulations with those of Chapter 3.2 of the GHS, the expert from the Netherlands volunteered to prepare a proposal of amendments to Chapter 2.8 of the Model Regulations reflecting the outcome of the Working Group on corrosivity criteria at the thirty-sixth session of the Sub-Committee in December 2009.
- 2. The expert from the Netherlands has prepared this proposal taking into account the report of the working group as reported in Annex V to ST/SG/AC.10/C.3/72, including the conclusions and terms of reference as reported in paragraph 12 stating that "As a conclusion, the working group considered that
- (a) There was no need to reproduce in full the GHS text in the United Nations Model Regulations because the criteria contained therein were in line with the GHS;
- (b) Chapter 2.8 of the United Nations Model Regulations should be amended to underline the correlation between transport packing groups I, II and III and GHS subcategories 1A, 1B and 1C;

¹ In accordance with the programme of work of the Sub-Committee for 2009-2010 approved by the Committee at its fourth session (refer to ST/SG/AC.10/C.3/68 para. 118(b) and ST/SG/AC.10/36, para. 14).



- (c) Notes should be included to explain the applicability and limitations of the use of extreme pH values, calculation methods for mixtures and bridging principles to deduce classification and their relationship with transport criteria.".
- 3. On the understanding that the different classification methods as presented in Chapter 3.2 of GHS are not separate blocks in the building block approach, the methods indicated in GHS Chapter 3.2 are taken into account in the proposal for revision of Chapter 2.8. The proposal reflects a clear preference for the use of results from in vivo and/or in vitro testing. However in absence of the results from in vivo and/or in vitro testing, the use of GHS-defined methods based on alternative information to allocate a packing group is obligatory.
- 4. A draft proposal was circulated to experts of the TDG and GHS sub-committees in February 2010. Written comments were received from experts from Canada, Germany, Switzerland, the United Kingdom, the United States of America, Dangerous Goods Advisory Council and France. Numerous suggestions for improvements were received during the informal written round, of which several have been included in the current proposal. Some remarks received were considered beyond the scope of the current task of harmonising the corrosivity criteria between the Model Regulations and GHS such as the discussion on the definition of 'substances', which applies to all chapters of the Model Regulations.
- 5. The following major amendments to Chapter 2.8 are proposed:
 - (a) The definition of Class 8 substances is extended to explicitly include solutions and mixtures, and consequently the reference to mixture/preparation is deleted where possible;
 - (b) The GHS definitions of 'skin corrosion' and 'corrosion to metals' are included in the definitions section;
 - (c) The table to paragraph 2.8.2.5 as adopted by the Sub-Committee on its thirty-sixth session and reported in Annex I to ST/SG/AC.10/C.3/72 is included;
 - (d) Section 2.8.3 has been added to Chapter 2.8. In this section, the applicability and limitations of the use of extreme pH values, calculation methods for mixtures and bridging principles are explained;
 - (e) In section 2.8.3 it is furthermore clarified that the results of *in vivo* and *in vitro* testing prevail over the results of the alternative methods;
 - (f) The correlation between transport packing groups I, II and III and GHS subcategories 1A, 1B and 1C is clarified by introducing a table in the new paragraph 2.8.3.1;
 - (g) An amendment put forward in the written consultation round is presented in square brackets. The amendment aims at accepting the assignment of a packing group based on extreme pH only. As this was not a conclusion from the working group meeting the amendment presented in square brackets.

Proposal

6. The annex to this document contains the proposed amended Chapter 2.8 of the Model Regulations, with proposed modifications indicated with strike-out style for deleted text, and underlining for new text.

Annex

Proposed amendments to Chapter 2.8 of the United Nations Model Regulations on the Transport of Dangerous Goods

Chapter 2.8

Class 8 – Corrosive substances

2.8.1 Definitions

Class 8 substances (corrosive substances) are substances which, by chemical action, will cause severe damage when in contact with living tissue, or, in the case of leakage, will materially damage, or even destroy, other goods or means of transport and include solutions and mixtures of these substances.

Skin corrosion is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours.

A substance or a mixture that is *corrosive to metals* is a substance or a mixture which by chemical action will materially damage, or even destroy, metals.

2.8.2 Assignment of packing groups

- 2.8.2.1 Substances and preparations of Class 8 are divided among the three packing groups according to their degree of hazard in transport as follows:
 - (a) Packing group I: Very dangerous substances and preparations;
 - (b) Packing group II: Substances and preparations presenting medium danger;
 - (c) Packing group III: Substances and preparations presenting minor danger.
- 2.8.2.2 Allocation of substances listed in the Dangerous Goods List in Chapter 3.2 to the packing groups in Class 8 has been made on the basis of experience taking into account such additional factors as inhalation risk (see 2.8.2.3) and reactivity with water (including the formation of dangerous decomposition products). New substances, including mixtures, can be assigned to packing groups on the basis of the length of time of contact necessary to produce full thickness destruction of human skin in accordance with the criteria in 2.8.2.4, 2.8.2.5 an if necessary 2.8.3. Liquids, and solids which may become liquid during transport, which are judged not to cause full thickness destruction of human skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.2.5 (c) (ii).
- 2.8.2.3 A substance or preparation meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC50) in the range of packing group I, but toxicity through oral ingestion or dermal contact only in the range of packing group III or less, shall be allocated to Class 8 (see note under 2.6.2.2.4.1).
- 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 Guideline 404² or 435³. A substance which is determined not to be corrosive in accordance with OECD Test Guideline 43⁴ or OECD Test Guideline 431⁵ may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

- 2.8.2.5 Packing groups are assigned to corrosive substances in accordance with the following criteria:
 - (a) Packing group I is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period up to 60 minutes starting after the exposure time of three minutes or less;
 - (b) Packing group II is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than three minutes but not more than 60 minutes;
 - (c) Packing group III is assigned to substances that:
 - (i) cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or
 - (ii) are judged not to cause full thickness destruction of intact skin tissue but which exhibit a corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials. For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR (1.0144 resp. St 44-3), ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for testing aluminium, non-clad, types 7075–T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the Manual of Tests and Criteria, Part III, Section 37.

Note: Where an initial test on either steel or aluminium indicates the substance being tested is corrosive the follow up test on the other metal is not required.

Table summarizing the criteria in 2.8.2.5

Packing Group	Exposure Time	Observation Period	Effect
I	≤ 3 min	≤ 60 min	Full thickness destruction of intact skin
II	> 3 min ≤ 1 h	≤ 14 d	Full thickness destruction of intact skin
III	> 1 h ≤ 4 h	≤ 14 d	Full thickness destruction of intact skin
III	-	-	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials

² OECD Guideline for the testing of chemicals No. 404 "Acute dermal irritation/Corrosion" 1992.

OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006.

⁴ OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.

OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2004.

2.8.3 Alternative methods to allocate a packing group for skin corrosion

2.8.3.1 The criteria for skin corrosion listed in 2.8.2.5 are included in Chapter 3.2 of the GHS. In addition the GHS describes methods to determine if a substance meets the criteria for skin corrosion based on alternative information. These additional GHS classification methods shall be used to assign the packing group in cases where the information mentioned in 2.8.2.4 is not available for the substance or mixture. A classification based on results from *in vivo* and *in vitro* methods prevails over a classification derived using the alternative methods.

The relationship between packing groups and GHS skin corrosion categories is as follows:

Packing group I	Skin corrosion sub-category 1A	
Packing group II	Skin corrosion sub-category 1B	
Packing group III	Skin corrosion sub-category 1C	

2.8.3.2 In the application of the classification methods for skin corrosivity in Chapter 3.2 of the GHS for transport purposes the following should be noted:

Extreme pH

GHS classification criteria allow a substance or a mixture to be classified as skin corrosive based on its pH. A substance is considered corrosive if it has a pH < 2 or a pH > 11.5. However, it is not possible to assign a GHS sub-category or packing group based on pH. To assign a packing group, an *in vitro* or *in vivo* test has to be performed. Where results from *in vitro* or *in vivo* tests are available, a classification based on these results prevails over a classification based on pH. [If data are not available it is permitted to assign packing group I based on extreme pH.]

The absence of an extreme pH is not proof of absence of skin corrosive properties.

Bridging principles

The bridging principles using data on similar tested mixtures and individual ingredients can be applied when data are not available for the actual mixture. Whether a packing group can be assigned using the bridging principles depends on the available information on the ingredients Where results from *in vitro* or *in vivo* tests on the actual mixture are available, a classification based on these results prevails over a classification derived from the bridging principles.

Mixture calculations

In the absence of test data on the actual mixture or similar tested mixtures, a classification based on the mixture calculations as included in Chapter 3.2 of GHS should be performed. Whether a packing group can be assigned using the mixture calculations depends on the available information on the ingredients. Where results from *in vitro* or *in vivo* tests on the actual mixture are available, a classification based on these results prevails over a classification derived from mixture calculations.

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