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Sub-Committee of Experts on the Transport of Dangerous Goods

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Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals: corrosivity criteria

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Twenty-eighth session

Geneva, 10 – 12 December 2014
Item 2 (d) of the provisional agenda
Classification criteria and related hazard communication: work of the TDG-GHS working group on corrosivity criteria

Proposal for revision of Chapter 2.8 of the Model Regulations

Transmitted by the expert from the United States of America[1]

Introduction

1. During the forty-fifth session of the Sub-Committee of Experts on the Transport of Dangerous Goods and the twenty-seventh session of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals, the Netherlands on behalf of the joint TDG-GHS Working Group on corrosivity criteria submitted a progress report and a proposal for a revised Chapter 2.8 of the Model Regulations (ST/SG/AC.10/C.3/2014/25 –ST/SG/AC.10/C.4/2014/3; informal document INF.32 (45th TDG session – informal document INF.9 (27th GHS session).

2. The efforts of the joint TDG-GHS Working Group on corrosivity criteria to ensure the greatest possible consistency between the Transport Model Regulations and the GHS have received a great deal of support in principle within both the TDG and GHS Sub-Committees.

3. It is recognized that there is significant value to ensuring that the provisions of the Model Regulations allow for alternative methods for classification of corrosive materials

[1] In accordance with the programme of work of the Sub-Committee for 2013-2014 approved by the Committee at its sixth session (refer to ST/SG/AC.10/C.3/84, para. 86 and ST/SG/AC.10/40, para. 14).

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that provide an equivalent level of safety while allowing for greater flexibility and reducing the need for testing when appropriate. However it is equally recognized that there were significant concerns with some additional methods (such as the additivity method) that remain unresolved within the context of the joint TDG/GHS working group.

4. In the interest of ensuring additional validated methods are included within the Model Regulations to the greatest extent practicable at the present time, it is proposed that the methods generally accepted universally by the working group be incorporated consistent with the GHS text. Specifically, it is proposed that the Model Regulations be amended to permit (1) the use of extreme pH to classify substances and mixtures without further testing and (2) the use of bridging principles to classify mixtures under the conditions specified. The proposed amendments are substantively consistent with the GHS while ensuring transport terminology is used and that the text conforms to the format of the Model Regulations. Additional methods such as the additivity method requiring further work and review could be considered under future efforts as appropriate.

Proposal

5. It is proposed that Chapter 2.8 of the Model Regulations be amended to include a new section 2.8.2.6. The proposed new section authorizes alternatives to corrosivity assessments based on data obtained from experiments in accordance with OECD Test Guideline 404 or 435. In addition, a consequential amendment is proposed to section 2.8.2.4. The annex to this document reproduces the entire existing Chapter 2.8 of the Model Regulations with the proposed amendments included and underlined.

Annex

“Chapter 2.8

Class 8 – Corrosive substances

2.8.1 Definition

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 the means of transport.

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. 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 (LC_{50}) 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. Except as provided in 2.8.2.6, in the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404[1] or 435[2]. A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430[3] or 431[4] may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

[1] *OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2002.*

[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.*

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 2.8.2.5: 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 ºC when tested on both materials

2.8.2.6 Alternatives to assessments based on data obtained from experiments in accordance with OECD Test Guideline 404 or 435.

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

2.8.2.6.1 Unless the consideration of acid/alkaline reserve[5] suggests otherwise, a mixture with an extreme pH of ≤ 2 and ≥ 11.5 may be considered to meet the criteria of Class 8 and assigned to PG I without further testing.

2.8.2.6.2 Where a mixture has not been tested to determine its skin corrosion potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately classify the mixture, these data may be used in accordance with the following bridging principles.

(a) *Dilution*: If a tested mixture is diluted with a diluent which has an equivalent or lower skin corrosion packing group than the least corrosive original ingredient and which does not affect the corrosivity of other ingredients, then the new diluted mixture may be assigned to the same packing group as the original tested mixture.

(b) *Batching*: The skin corrosion potential of a tested production batch of a mixture may be assumed to be substantially equivalent to that of another untested production batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the skin corrosion potential of the untested batch has changed.

(c) *Concentration of mixtures of the highest corrosion packing group*: If a tested mixture meeting the criteria for inclusion in packing group I is concentrated, the more concentrated untested mixture may be assigned to packing group I without additional testing.

(d) *Interpolation within one packing group*: For three mixtures (X, Y and Z) with identical ingredients, where mixtures X and Y have been tested and are in the same skin corrosion packing group, and where untested mixture Z has the same active ingredients as mixtures X and Y but has concentrations of active ingredients intermediate to the concentrations in mixtures X and Y, then mixture Z is assumed to be in the same skin corrosion packing group as X and Y.

(e) *Substantially similar mixtures*: Given the following:

(i) Two mixtures: (X + Y) and (Z+Y);

(ii) The concentration of ingredient Y is the same in both mixtures;

(iii) The concentration of ingredient X in mixture (X+Y) equals the concentration of ingredient Z in mixture (Z+Y);

(iv) X and Z are the same skin corrosion packing group and do not affect the skin corrosion potential of Y.

If mixture (X+Y) or (Z+Y) is already classified based on test data, then the other mixture may be assigned to the same packing group.”

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[5] *Acid/Alkaline reserve may be determined e.g. by the methodology detailed in Young J.R., How M.J., Walker A.P., Worth W.M.H. (1988): Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without testing on animals. Toxicology in Vitro* ***2****, 19-26 and Young J.R., How M.J. (1994): Product classification as corrosive or irritant by measuring pH and acid / alkali reserve. In Alternative Methods in Toxicology vol. 10 - In Vitro Skin Toxicology: Irritation, Phototoxicity, Sensitization, eds. A.Rougier, A.M. Goldberg and H.I.Maibach, Mary Ann Liebert, Inc. 23-27.*