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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

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Item 2 (d) of the provisional agenda
Classification criteria and related hazard communication: Work of the TDG-GHS working group on corrosivity criteria

Comments regarding existing proposals and an alternative proposal for revision of Chapter 2.8 of the Model Regulations

Transmitted by the expert from Canada

Purpose

1. To discuss challenges with other proposals submitted to both the TDG and GHS Sub-Committees of Experts for changes to Chapter 2.8 of the TDG Model Regulations and to present an alternative proposal that addresses these challenges.

Introduction

2. Reference is made to documents:

(a) ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12;

(b) ST/SG/AC.10/C.3/2014/99–ST/SG/AC.10/C.4/2014/18;

(c) ST/SG/AC.10/C.3/2014/104; and,

(d) UN/SCETDG/46/INF.15–UN/SCEGHS/28/INF.7.

3. The efforts of the joint TDG-GHS Working Group on corrosivity criteria have led to several proposals for revisions to Chapter 2.8 of the Model Regulations. Significant support, in principle, exists within both the Transportation of Dangerous Goods (TDG) and Globally Harmonised System (GHS) Sub-Committees to revise the existing Chapter 2.8 and to advance new principles for addressing the transportation of Class 8 – Corrosive Substances.

4. This proposal builds on the work of the referenced proposals above and further elaborates considerations for the transport of corrosive materials. It focuses on the classification and packing group assignment of corrosive materials for transport, and presents proposed text in keeping with the generally established structure and regulatory format of chapters found in the Model Regulations. The proposal also echoes the significant concerns with some additional methods (such as the additivity method) outlined in ST/SG/AC.10/C.3/2014/99–ST/SG/AC.10/C.4/2014/18 that remain unresolved within the

context of the joint TDG/GHS working group and addresses them (by omission) in the proposed text.

Discussion

Structure of the Proposed Text

5. The United Nations (UN) TDG Model Regulations are generally drafted for adoption as regulatory text. The structure of the Model Regulation chapters is generally consistent, defines key terms up-front, and then leads into the packing group assignment criteria for transportation. It is important that the text be written clearly and in a regulatory style as many member states adopt the text, as written, into their regulations or incorporate them by reference. The text presented in ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12, adapted from the GHS, is problematic since it does not follow the generally accepted format of the Model Regulations and is not written as regulatory text. This paper builds on the alternative text presented in ST/SG/AC.10/C.3/2014/99–ST/SG/AC.10/C.4/2014/18 and proposes adapted text that is aligned with the generally accepted format and presented as regulatory text; key definitions are presented first followed by the criteria for packing group assignment.

Introduction of Sub-classifications

6. Canada supports the general comments made in paragraph 5 of UN/SCETDG/46/INF.15–UN/SCEGHS/28/INF.7.

7. The introduction of sub-categories (8A, 8B, 8C) in ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12, adapted from the GHS, is a concept from the GHS that is foreign to the TDG Model Regulations. The introduction and use of this classification system in the Model Regulations would create a lot of confusion amongst transportation stakeholders and introduce new concepts that have not been carried over from the GHS in other sections of the Model Regulations. The alternative text proposed below removes this sub-category schema from the proposed Chapter 2.8 text in favour of immediate packing group determination, but maintains the text from the proposed 2.8.3.3. that allows the correlation of packing group assignments from the GHS classification schema where products were previously classified as sub-category 8A, 8B, or 8C. This is intended to simplify cross-functionality between the GHS and TDG Model Regulations, and uses previous classifications under the GHS for transportation where possible.

8. Echoing paragraph 9 of UN/SCETDG/46/INF.15–UN/SCEGHS/28/INF.7 and limiting classification to the assessment on the intrinsic property of corrosivity, the assignment of packing groups based on animal testing or *in vitro* test data (if applicable) has to remain part of the proposed Chapter 2.8.3. This proposal does allow for the use of GHS sub-classifications for direct packing group assignment where products have previously been classified into the GHS sub-classifications as per 2.8.3.3.1 in the attached Annex 1.

Generic Concentration Limits

9. Tables 2.8.3 and 2.8.4 of the proposed text in ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12 are problematic because they attempt to assign (generic) concentration limits for determining packing group of mixtures in Class 8A and Class 8 without sub-classification respectively. Concentration is not an appropriate selection criterion for assigning packing group. Concentration is linked to pH for Brønsted-Lowry acids/bases; it can be a useful parameter to infer the corrosivity of a strong Brønsted-Lowry acid/base. Weaker Brønsted-Lowry acid/bases are governed by their dissociation into a

liquid and this dissociation will vary with each weaker acid/base – generic concentration limits for determining corrosivity become very problematic due to the huge variation possible for weaker acids/bases. A concentration threshold is also problematic when considering corrosivity of Lewis acids/bases (an alternative acid/base definition) and other compounds outside of the varying definitions for acids/bases.

10. Given the huge variation in the types of potentially corrosive acids/bases and other substances that exist, determining generic concentration limits for corrosive substances becomes problematic and risks under- or over-classifying many types of corrosives that may be transported. It also does not take into account the effect of the corrosive substance's solvent, which may amplify or mitigate corrosivity – a generic concentration threshold may properly classify a specific corrosive substance in one solvent but not in another. For example, the presence of surfactants in solutions of certain household cleaning products has been found to affect the corrosivity of these products; when surfactants are contained in a product, some otherwise corrosive products no longer meet the corrosive criteria and would then be classified as irritants.[1]

Acid/Alkaline Reserve

11. The consideration of acid/alkaline reserve is raised in the proposed text of most submissions. Canada supports the consideration of acid/alkaline reserve but would raise several issues with the proposed text and the references to published papers such as *Young et al. (1988)*:[2]

(a) While the references mentioned in the GHS[3] present peer-reviewed approaches to quantifying acid/alkaline reserve, they are not standardised approaches consistent with other standards referenced in the Model Regulations for use in classification. The lack of a standardised approach for determining acid/alkaline reserve presents a significant challenge in ensuring consistent, reproducible, and reliable results for classification of corrosive substances, and in the verification for enforcement of classification from a member state perspective. Significant variation in acid/alkaline reserve data was witnessed in *Craan et al. (1997)* between industry data and the experimental test data obtained by Health Canada as part of the study.[4] While this may be a result of issues in the quality of data taken from Material Safety Data Sheets, the lack of a formal standard for determination of acid/alkali raises issues of reproducibility and consistency of data.

(b) More recent work on acid/alkaline reserve has built on the works referenced in the GHS. For example, the *Craan et al. (1997)*[5] paper has built on and furthered

[1] *Craan A. J., Sanfaçon G., Walker R. H. (1997): The use of pH and acid/alkaline reserve for the classification and labelling of household cleaning products: data from a poison control center. International Journal for Consumer Safety Vol. 4, Iss. 4, 191-213.*

[2] *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.*

[3] Ibid.

[4] Ibid.

[5] *Craan A. J., Sanfaçon G., Walker R. H. (1997): The use of pH and acid/alkaline reserve for the classification and labelling of household cleaning products: data from a poison control center. International Journal for Consumer Safety Vol. 4, Iss. 4, 191-213.*

the body of work on acid/alkaline reserve. Of note, *Craan et al. (1997)* proposes an alternative definition for corrosives incorporating pH and acid/alkaline reserve based on thresholds and varying the acid/alkaline reserve ranges based on whether the substance is a solid or liquid. As well, it makes note of the impact additives (e.g., surfactants) can have in altering the validity of these ranges and revealed an asymmetric distribution along the pH axis of six classes of consumer products, which deviates from the proposal presented in *Young et al. (1988)*.[6]

12. Consideration of acid/alkaline reserve is maintained in the proposal below 2.8.3.1.2 but stated as optional text. The GHS references concerning acid/alkaline reserve could be updated to reflect recent work in this area. They may also need to be revised, and the considerations around non-standardised approaches and variability in acid/alkaline reserve between data sets would need to be addressed before the consideration of acid/alkaline reserve could reasonably be incorporated into the Model Regulations – failure to do so may create inconsistent approaches, enforcement issues, and inconsistent classification for some products.

Additivity and Dilution

13. The additivity approach presented in 2.8.2.3.3.2 of ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12 is problematic since it does not account for potential synergistic effects between corrosive substances in a mixture. The additivity approach presented in the GHS assumes a simple additive relationship between components, which may not be the case; mixtures of components may result in a corrosivity that is greater than or less than the sum of the individual components. Additional investigation of these interactions needs to be conducted and quantification of interactions needs to be developed (along with guidance on impacting factors) before this approach could successfully be brought into a regulatory context.

14. The dilution approach presented in 2.8.2.3.2.2 of ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12 (from the GHS) states that a corrosive substance diluted with another corrosive substance that has an equivalent or lower corrosivity classification would be classified as equivalent to the original corrosive substance; this does not take into account the potential additivity impacts as discussed in paragraph 0. The proposed text in Annex 1 revises the proposed text to specify dilution as the process of diluting a corrosive with a non-corrosive, and would need to account for the impact of additives in the diluent as discussed in paragraph 0. Dilution with another corrosive may raise additivity issues and should be considered separately as to the mixing of corrosives and the subsequent classification / packing group assignment.

Default Packing Group Assignment

15. Proposal ST/SG/AC.10/C.3/2014/104 would revise the default packing group assignment of corrosives classified as Class 8 without sub-classification in the GHS to from Packing Group I to Packing Group II.

16. Paragraph 2 of ST/SG/AC.10/C.3/2014/104 cites work done the Joint TDG-GHS Working Group, specifically the ratio for the assignment of packing groups in Class 8. While these ratios represent the number of UN Nos. assigned to transport in the specified packing group, they do not reveal any information about the volumes of corrosives transported and their packing groups. In making a determination of the risk in transporting

[6] *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.*

corrosives, accounting for the volumes transports instead of the ratio of UN Nos. would represent a better basis for making such a determination. That said, the distribution of packing groups transported by volume will vary considerably between member states; defaulting to packing group II when no sub-classification test has been conducted may raise the risk in some jurisdictions and could be an unintended consequence of such a determination.

17. As well, the UN Nos. cited in ST/SG/AC.10/C.3/2014/104 are not relevant examples from which to draw parallels for corrosives. UN Nos. 3175, 3243, and 3244 were intended to handle the transport of solids containing dangerous goods such as rags soiled with substances in Class 3, 6.1 or 8. The risks inherent to transporting soiled rags differ significantly from those of transporting corrosives, and these UN Nos. do not form a basis of relevant evidence from which to draw an analogous comparison representative of risk and the original context in which these UN Nos. were intended.

18. The proposed text in Annex 1 does maintain in 2.8.3.3.1 that products with a GHS sub-category should be assigned to the corresponding TDG packing group; and that those products without a GHS sub-category should be assigned to Packing Group I. Default assignment to PG I should only be done for substances that are known corrosives based on peer-reviwed litterature.

Proposal

19. It is proposed that Chapter 2.8 of the Model Regulations be replaced with the text in the attached annex to this document. The proposed section is aligned with the general format and approach utilised in the Model Regulations, and focuses on the packing group assignment of corrosive materials for transport.

20. New text is underlined in the proposal and deleted text is crossed-out.

21. Canada is seeking comments on the proposal and points raised in the Discussion section of this paper. These comments and feedback would form the basis for a formal proposal in the next bi-ennium.

Annex

"Class 2.8

Class 8 – Corrosive Substances

2.8.1 Definition and general provisions

2.8.1.1 *Class 8 substances (corrosive substances)* are substances which, by chemical action, will cause ~~severe~~ irreversible 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.

2.8.1.2 For substances and mixtures that are corrosive to skin, hazard classification is determined using criteria in section 2.8.2, where they will be assigned to a packing group. A substance is corrosive to skin when it produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure for up to 4 hours. Hazard classification can alternatively be determined using section 2.8.3 for mixtures.

2.8.1.3 Liquids and solids which may become liquid during transport, which are judged not to be skin corrosive shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.2 (c) (ii).

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* 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 (3) 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 (3) 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 four (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 2.8.2.1: Table summarizing the criteria in 2.8.2.1

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

2.8.2.2 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 2.8.2.1; alternatively the criteria in 2.8.3 can also be used.

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 2.8.3, 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.

2.8.3 Alternative hazard classification of mixtures corrosive to skin

2.8.3.1 Hazard classification of mixtures when data when data are available for the complete mixture

2.8.3.1.1 The mixture shall be classified using the criteria for substances as illustrated in Table 2.8.2.1.

2.8.3.1.2 [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.

[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.*

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

[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.*]

2.8.3.2 Hazard classification of mixtures when data are not available for the complete mixture: bridging principles

2.8.3.2.1 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*: [Unless the consideration of synergistic or antagonistic effects suggests otherwise,] if a tested mixture is diluted with a diluent which does not meet the criteria for Class 8 ~~has an equivalent or lower skin corrosion packing group than the least corrosive original ingredient~~ and ~~which~~ does not affect the packing group 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."

2.8.3.3 *Hazard classification of mixtures as per the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*

2.8.3.3.1 Substances and mixtures not listed by name in the Dangerous Goods List that have been classified in one of the GHS three sub-categories 1A, 1B or 1C for skin corrosion can be assigned to packing groups as follows (see Table 3.2.1 of GHS for definitions of sub-categories 1A, 1B, and 1C):

(a) Substances and mixtures classified as Class 8, sub-category 1A are assigned to packing group I;

(b) Substances and mixtures classified as Class 8, sub-category 1B are assigned to packing group II;

(c) Substances and mixtures classified as Class 8, subcategory 1C are assigned to packing group III;

(d) Substances and mixtures classified as Class 8 without a sub-category, as per GHS criteria below in Table 2.8.3.3.1, are also assigned to packing group I.

Table 2.8.3.3.1: GHS skin corrosion hazard sub-categories[a]

	Criteria
Class 8, no sub-category	Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure ≤ 4 h from peer-reviewed test data
Class 8, sub-category 1A	Corrosive responses in at least one animal following exposure ≤ 3 min during an observation period ≤ 1 h
Class 8, sub-category 1B	Corrosive responses in at least one animal following exposure > 3 min and ≤ 1 h and observations ≤ 14 days
Class 8, sub-category 1C	Corrosive responses in at least one animal after exposures > 1 h and ≤ 4 h and observations ≤ 14 days

[a] *The use of human data is addressed in GHS 3.2.2.2 and in GHS chapters 1.1 (par. 1.1.2.5 (c)) and 1.3 (par. 1.3.2.4.7).*

NOTE: *The sub-categories 1A, 1B and 1C do not constitute divisions in Class 8. "*