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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**

#### **Forty-seventh session**

Geneva, 22 – 26 June 2015

Item 10 (e) of the provisional agenda

**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-ninth session**

Geneva, 29 June – 1 July 2015

Item 2 (c) of the provisional agenda

**Classification criteria and related hazard communication:  
Corrosivity criteria**

## **Proposal for revision of Chapter 2.8 of the Model Regulations and follow-up questions**

**Transmitted by the expert from Canada<sup>1</sup>**

### **Purpose**

1. Following up on the discussions of the forty-sixth session of the Sub-Committee of Experts on the Transport of Dangerous Goods, to propose changes to Chapter 2.8 of the United Nations Model Regulations to the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG Sub-Committee).
2. To refer, for clarification and further investigation, questions relating to the Globally Harmonised System (GHS) approaches to classification of corrosives to the Sub-Committee of Experts on the Globally Harmonised System (GHS Sub-Committee).

### **Introduction**

3. Reference is made to documents:

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<sup>1</sup> In accordance with the programme of work of the Sub-Committee for 2015–2016 approved by the Committee at its seventh session (see ST/SG/AC.10/C.3/92, paragraph 95 and ST/SG/AC.10/42, para. 15).

- (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;
- (d) Informal document INF.15 (TDG, 46<sup>th</sup> session) – INF.7 (GHS, 28<sup>th</sup> session);
- (e) Informal document INF.35 (TDG, 46<sup>th</sup> session) – INF.20 (GHS, 28<sup>th</sup> session);
- (f) Informal document INF.46 (TDG, 46<sup>th</sup> session) – INF.21 (GHS, 28<sup>th</sup> session);
- (g) Informal document INF.60 (TDG, 46<sup>th</sup> session) – INF.24 (GHS, 28<sup>th</sup> session);
- (h) Informal document INF.61 (TDG, 46<sup>th</sup> session) – INF.25 (GHS, 28<sup>th</sup> session);
- (i) Informal document INF.71 (TDG, 46<sup>th</sup> session) – INF.29 (GHS, 28<sup>th</sup> session);

4. 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 TDG and GHS Sub-Committees to revise the existing Chapter 2.8 and to advance new principles for addressing the transport of Class 8 – Corrosive substances.

5. This proposal builds on the work of the referenced proposals above and the discussions that took place at the forty-sixth session of the TDG Sub-Committee. 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.

6. This proposal also removes references to some additional methods (such as the additivity method), as an interim measure, until the issues outlined in ST/SG/AC.10/C.3/2014/99 – ST/SG/AC.10/C.4/2014/18, informal document INF.46 (TDG 46<sup>th</sup> session) – INF.21 (GHS 28<sup>th</sup> session), and raised at the forty-sixth session can be discussed and resolved.

7. This proposal requests clarification from the GHS Sub-Committee to address the significant concerns with some additional methods identified for corrosives classification and proposed previously in the proposals, including ST/SG/AC.10/C.3/2014/69 – ST/SG/AC.10/C.4/2014/12, of the forty-sixth session of the TDG Sub-Committee.

## **Discussion and questions for the GHS Sub-Committee**

### **Structure of the proposed text**

8. In line with the comments raised previously in informal document INF.46 (TDG 46<sup>th</sup> session) – INF.21 (GHS 28<sup>th</sup> session), this proposal 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.

9. Paragraph 5 of informal document INF.71 (TDG 46<sup>th</sup> session) – INF.29 (GHS 28<sup>th</sup> session) identifies that the use of the GHS text is “included with the aim of optimal global harmonization of criteria now and in the future. Despite the non-legislative style of the GHS text, several examples of successful implementation in jurisdictions exist.”

10. While the expert from Canada recognises the intent, the “*Guiding Principles for the Development of the UN Model Regulations*”<sup>2</sup> state that the one of the purposes of presenting the Recommendations on the Transport of Dangerous Goods in the form of a model regulation is “To ‘recommend’ the Recommendations on the Transport of Dangerous Goods to modal organizations, regional bodies and national governments (in particular those governments considering the development of national regulations affecting the transport of dangerous goods) in a form [*original emphasis*] that can be adopted with little or no modification directly into modal, regional or national regulations.”

11. It is with this understanding that the emphasis on developing regulatory text remains the primary purpose of this proposal and of work towards incorporating further criteria for the classification of corrosives in the Model Regulations. While principles and guidance are useful in discussing concerns relating to regulatory provisions, they do not readily form text that can be incorporated into regulation and that can be readily enforced.

#### **Introduction of sub-classifications**

12. 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 Model Regulations. The introduction and use of this classification system in the Model Regulations would create a lot of confusion amongst transport stakeholders and introduce new concepts that have not been carried over from the GHS in other sections of the Model Regulations.

13. Informal document INF.46 (TDG 46<sup>th</sup> session) – INF.21 (GHS 28<sup>th</sup> session) originally proposed text under 2.8.3.3.1 that would allow packing group assignment for substances that have been classified in one of the GHS sub-categories 1A, 1B, or 1C for skin corrosion. This element has been removed from the current proposal – several questions remain regarding uncertainties with the GHS classification of a Class 8 without sub-classification.

#### **Generic concentration limits**

14. 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 and informal document INF.71 TDG (46<sup>th</sup> session) – INF.29 (GHS 28<sup>th</sup> session) attempt to assign (generic) concentration limits for determining packing group of mixtures in Class 8A and Class 8 without sub-classification respectively. Concentration alone is not an appropriate selection criterion for assigning packing group. Concentration is linked to pH for Brønsted-Lowry acids/bases and 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 in dissociation possible for weaker acids/bases. A concentration threshold is also problematic when considering corrosivity of Lewis acids/bases (an alternative acid/base definition).

15. 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 and additives in solution, which may amplify or mitigate corrosivity – a generic

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<sup>2</sup> [http://www.unece.org/fileadmin/DAM/trans/danger/publi/unrec/GuidingPrinciples/Guiding\\_Principles\\_Rev18.pdf](http://www.unece.org/fileadmin/DAM/trans/danger/publi/unrec/GuidingPrinciples/Guiding_Principles_Rev18.pdf)

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,<sup>3</sup> the opposite may also be true.

16. This paper poses the following questions to the GHS Sub-Committee, to aid in developing revised text regarding concentration limits:

- (a) How does the GHS schema account for the wide range of dissociation potential for weak acids/bases when determining generic concentration limits?
- (b) How does the GHS account for potentially synergistic effects between the corrosive substance and its solvent which may vary considerably based on the chosen solvent?

#### **Acid/Alkaline reserve**

17. The consideration of acid/alkaline reserve is raised in the proposed text of most previous submissions. Canada supports the consideration of acid/alkaline reserve but would raise several issues with the text originally proposed in ST/SG/AC.10/C.3/2014/69 – ST/SG/AC.10/C.4/2014/12 and the references to published papers such as *Young et al. (1988)*:<sup>4</sup>

- (a) While the references mentioned in the GHS<sup>5</sup> 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.<sup>6</sup> While this may be a result of issues in the quality of data taken from Safety Data Sheets, the lack of a formal standard for determination of acid/alkali raises issues of reproducibility and consistency of data.

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<sup>3</sup> *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.*

<sup>4</sup> *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.*

<sup>5</sup> *Ibid.*

<sup>6</sup> *Ibid.*

(b) More recent work on acid/alkaline reserve has built on the works referenced in the GHS. For example, the *Craan et al. (1997)*<sup>7</sup> paper has built on and furthered 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)*.<sup>8</sup>

18. 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.

19. This paper poses the following questions to the GHS Sub-Committee to aid in developing revised text that would address issues relating to acid/alkaline reserve:

(a) Has the GHS Sub-Committee of Experts undertaken a review of the new literature on acid/alkaline reserve since its original incorporation in the GHS? Would the GHS Sub-Committee consider such a review with the intention of updating the current knowledge on acid/alkaline reserve?

(b) Would the GHS Sub-Committee consider the development or adoption of a standardised test method(s) for the determination of acid/alkaline reserve (e.g., similar to ASTM D1121-11)?<sup>9</sup>

(c) What methods exist in the GHS to account for the effects/synergies of additives that may impact on the validity of pH ranges and contributions of acid/alkaline reserve? Is the GHS Sub-Committee aware of ways in which these issues could be addressed and that could be incorporated into the GHS?

### **Additivity and dilution**

20. 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 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

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<sup>7</sup> 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.*

<sup>8</sup> *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.*

<sup>9</sup> *ASTM D1121-11, Standard Test Method for Reserve Alkalinity of Engine Coolants and Antirusts, ASTM International, West Conshohocken, PA, 2011, www.astm.org.*

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.

21. 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 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 20. The proposed text in the annex revises the text originally submitted in ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12 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 15. 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.

22. This paper poses the following questions to the GHS Sub-Committee to aid in developing revised text that would address the issues of additivity:

- (a) Has the GHS Sub-Committee considered the effects of dilution of one corrosive with another corrosive? What methods exist to account for these potential synergistic effects when applying the classification principles outlined in 3.2.3.2.2. of the GHS?

## Proposal

23. The questions raised in this proposal and directed at the GHS Sub-Committee are meant to stimulate discussion on issues that, if resolved, may lead to further harmonisation proposals of the Model Regulations with the GHS criteria for classification of corrosives.

24. 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. It focuses on the packing group assignment of corrosive materials for transport, reviews work conducted in the previous biennium, and proposes a first step towards better harmonisation with Chapter 3.2 of the GHS.

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

## Annex

### Proposal for revision of Chapter 2.8 of the Model Regulations for harmonization with the GHS

#### CHAPTER 2.8

#### CLASS 8 – CORROSIVE SUBSTANCES

##### 2.8.1 Definition and general provisions

2.8.1.1 ~~Class 8 substances (e~~ *Corrosive substances*~~)~~ are substances which, by chemical action, will cause irreversible damage to the skin 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 leads to the 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~~ mixtures of Class 8 are divided among the three packing groups according to their degree of hazard in transport ~~as follows~~, in accordance with the following criteria:

- (a) ~~Packing group I: Very dangerous substances and preparations~~ is assigned to substances and mixtures 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: substances and preparations presenting medium danger~~ is assigned to substances and mixtures 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: Substances and preparations presenting minor danger~~ is assigned to substances and mixtures 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**

<i>Packing Group</i>	<i>Exposure Time</i>	<i>Observation Period</i>	<i>Effect</i>
<u>I</u>	<u>&lt; 3 min</u>	<u>&lt; 60 min</u>	<u>Full thickness destruction of intact skin</u>
<u>II</u>	<u>&gt; 3 min ≤ 1 h</u>	<u>≤ 14 d</u>	<u>Full thickness destruction of intact skin</u>
<u>III</u>	<u>&gt; 1 h &lt; 4 h</u>	<u>≤ 14 d</u>	<u>Full thickness destruction of intact skin</u>
<u>III</u>	<u>=</u>	<u>=</u>	<u>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</u>

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 2.8.2.14; alternatively the criteria in 2.8.3 can also be used. 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 2.8.2.5 (e) (ii).

2.8.2.3 A substance or preparation meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC<sub>50</sub>) 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<sup>10</sup> or 435<sup>11</sup>. A substance which is

<sup>10</sup> OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2002.

<sup>11</sup> OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006.



determined not to be corrosive in accordance with OECD Test Guideline 430<sup>12</sup> or 431<sup>13</sup> 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 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 (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:~~

~~(a) — 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~~

~~(b) — 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-elad, 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**

<i>Packing Group</i>	<i>Exposure Time</i>	<i>Observation Period</i>	<i>Effect</i>
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

<sup>12</sup> OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.

<sup>13</sup> OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2004.

## **2.8.3 Alternative hazard classification of mixtures corrosive to skin**

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

2.8.3.1.1 Where sufficient data is available for classification, the mixture shall be classified using the criteria for substances in 2.8.2.1 as illustrated in Table 2.8.2.1, if data is appropriate.

2.8.3.1.2 [Unless the consideration of acid/alkaline reserve<sup>14</sup> suggests otherwise,] a mixture with an extreme pH of  $\leq 2$  and  $\geq 11.5$  may be considered to meet the criteria of Class 8 and assigned to PG I without further testing.

### **2.8.3.2 Hazard classification of mixtures when data are not available for the complete mixture**

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 and 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. If the latter occurs, a new classification is necessary.

(c) *Concentration of mixtures of packing group I*: 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:

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<sup>14</sup> [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.]*

- (i) Two mixtures: (X + Y) and (Z+Y);
- (ii) The concentration of ingredient Y is essentially 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) Data on skin corrosion for X and Z are available and substantially equivalent, i.e. they are in the same 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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