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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

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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-sixth session

Geneva, 4 – 6 December 2013

Item 2 (c) of the provisional agenda

Classification criteria and hazard communication: Corrosivity criteria

Harmonisation of the skin corrosion classification criteria in the UN Model Regulations with those in GHS

Transmitted by the European Chemical Industry Council (CEFIC)

Basis for this document

1. Based on the Informal documents

UN/SCETDG/43/INF.26 / UN/SCEGHS/25/INF.9 from CEFIC

and UN/SCETDG/43/INF.42 / UN/SCEGHS/25/INF.11 from the United Kingdom

and on the commitment in the forty-third session of the Sub-Committee of Experts on the Transport of Dangerous Goods together with the results of the joint TDG/GHS Working Group on 1 July 2013 during the twenty-fifth session of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals it was agreed that it needs to be ensured that the harmonization of the skin corrosion classification criteria in the UN Model Regulations with those in GHS should not lead to an ungraded worse case scenario for the transport conditions. On the other hand the well established safety level for the transport conditions should be preserved. Reason for the often used worse case approach according GHS are no downstream consequences for supply and use.

Background

2. Unexpected problems were raised w hen discussing the harmonization of the Globally Harmonized Systems of Classification and Labeling of Chemicals (GHS) with the Regulations for the Transport of Dangerous Goods (TDG), especially the intended one-to-one relation of the GHS sub-categories 1A, 1B and 1C for skin corrosivity with the assignment of Packing Group (PG) I, II and III for transportation of Class 8 substances and mixtures. Such a simplified approach for the harmonization of the classification criteria implies an upgrade to PG I for numerous chemicals and generates much stricter transport conditions without adequate safety-related justification or benefit. The reason is that the classification in almost each case is not based on in vivo data, but based on derived data

as new in vivo tests need the permission of the competent authorities, in order to reduce animal testing. For supply and use the ratio of substances assigned to the highest sub-category seems always to be significantly higher than the ratio in transport. To move most of the products into the highest packing group PG I is not necessary as transports are conducted safely today, but it will reduce the perception of the hazard.

3. The joint informal correspondence group has noted that:

(a) The hazard categories skin corrosion 1A, 1B, 1C do not have to be adopted in all jurisdictions;

(b) One of the PGs I, II or III is always assigned for transport of a corrosive substance or mixture, together with other packaging conditions as appropriate;

(c) Any sub-categorisation of the hazard class skin corrosion or Class 8 does not lead to differentiation in hazard communication for supply and use.

(d) Some experts were of the opinion that the current classification scheme provided harmonized results for all sectors when based on in vivo data, and that the inconsistencies occurred when classification results were derived either from translation of previous classification results into GHS hazard classes/categories or from using alternative classification methods, which usually led to over-classification. Taking into account that the over-classification of corrosive substances had a direct impact on transport and storage conditions the working group concluded that the outcomes should not lead to reclassification of Class 8 substances in transport, and should not default to more severe classification or assignment to a more onerous packing group than appropriate.

(e) Several experts favoured option 6 out of UN/SCETDG/43/INF.42 / UN/SCEGHS/25/INF.11 as the best compromise to address the needs of all sectors and recognized that further work was needed to define the conditions under which alternative methods (including those which did not result in sub-categorization such as pH and non-additivity methods) could be used while ensuring that the results were consistent with the requirements for transport. Options 2 and 5 also received support.

(f) On the use of expert judgement and weight of evidence, the group noted that a positive result under human exposure should always supersede the results obtained from test methods and agreed that the concept of expert judgement needed to be further clarified.

Way forward

4. Following these principles with regard to both, hazard and risk, PG I would be assigned exclusively to very critical Class 8 substances as currently done in the DGL which would also apply to mixtures containing a considerable amount of such substances.

5. The already available possibility to classify a substance or mixture as corrosive to skin in Category 1 without sub-categories according to GHS should be pointed out.

6. The general classification approach and assignment of PG or sub-categories should be divided into three steps.

Step 1 – Human data:

If human data are available they have to be used for substances and mixtures.

For GHS sub-categories may be assigned accordingly.

For TDG packing groups have to be assigned accordingly.

Step 2 - Test results (in vivo / in vitro)-:

If test results are available and no human data they have to be used for substances and mixtures

For GHS sub-categories may be assigned accordingly.

For TDG packing groups have to be assigned accordingly.

Step 3 - Alternative methods -:

For GHS: Classification as corrosive, no sub categories assigned.

For TDG: Classification as corrosive, packing groups has to be assigned to define transport conditions.

7. Based on the favoured option 6 out of **UN/SCETDG/43/INF.42 / UN/SCEGHS/25/INF.11** the next steps could be proposed. Options 2 and 5 which have been supported too, are mostly included in option 6 or could be integrated so that the following proposal should imply these three options.

<table>
<tr><td colspan="2"></td><td colspan="2">Classification</td><td colspan="2"></td></tr>
<tr><td colspan="2">Classification criteria</td><td>GHS</td><td>Transport</td><td colspan="2">Other transport conditions</td></tr>
<tr><td>Exposure ≤ 3 min
Observation ≤ 1 hour</td><td>Test data</td><td>Skin Corrosive 1A</td><td>Class 8 PG I</td><td colspan="2" rowspan="3">Special packing provisions, limited and excepted quantities and downstream transport provisions</td></tr>
<tr><td>Exposure > 3 min ≤ 1 hour
Observation ≤ 14 days</td><td>Test data</td><td>Skin Corrosive 1B</td><td>Class 8 PG II</td></tr>
<tr><td>Exposure > 1 hour ≤ 4 hour
Observation ≤ 14 days</td><td>Test data</td><td>Skin Corrosive 1C</td><td>Class 8 PG III</td></tr>
<tr><td colspan="2" rowspan="3">Alternative methods</td><td rowspan="3">Evaluated as
Skin corrosive 1</td><td rowspan="3">Class 8</td><td>PG I</td><td rowspan="3">Special packing provisions, limited and excepted quantities and downstream transport provisions</td></tr>
<tr><td>PG II</td></tr>
<tr><td>PG III</td></tr>
</table>

Alternative methods according to this proposal are:

– Bridging principles (= Assignment of a packing group based on reference mixtures)

– Additivity approach

– Non-additivity approach (based on pH-value, may also be applied for substances)

Proposal

8. To enable a harmonised approach for classification a change to GHS and to TDG is required. The following general way forward is proposed. Details on the new text in the

TDG and the assignment of the packing groups need to be further discussed. The proposal reflects the general approach as this needs to be agreed on.

9. Amendments to GHS:

As the sub-categories 1A, 1B, 1C do not have any effect on the communication of the corrosion to skin hazard they should be removed from chapter 3.2 in GHS in case of usage of alternative methods.

Changes:

– 3.2.2.1.1.3 When data are sufficient and where required by a competent authority substances may be classified in one of the three sub-categories 1A, 1B or 1C in accordance with the criteria in table 3.2.1 **if the determination of skin corrosion is based on an appropriate validated in vitro test, relevant animal data and human data.**

– **Delete the NOTE under Table 3.2.3 (together with footnote 6 in table 3.2.5.2)**

10. Amendments to the UN Model Regulations on the transport of dangerous goods:

The UN Model regulations should implement the following elements / principles in chapter 2.8 to harmonize with GHS:

(a) Expert judgement and total weight of evidence as a principle for classification

(b) Bridging principles

(c) Additivity approach for mixture with the limits as prescribed in the GHS

(d) Non additivity approach for mixture containing certain ingredients or ingredients with an extreme pH-value for which the additivity approach is not applicable (decision based on expert judgement and weight of evidence). The assignment of the packing group is based on the packing group of the relevant ingredient(s).

The assignment of the packing group of ingredients is strictly limited to the transport list or to test data. The proposed tables in the Annex (see 4 and 5) need to be amended with the appropriate text based on the GHS but amended for TDG.

a) Expert judgement and total weight of evidence

This means that all data and information for a substance need to be considered validated and judged on and the most appropriate classification needs to be assigned to the substance or mixture. This is quite similar to the text in subchapter 2.8.2.2 – 2.8.2.4 but needs to be extended to the newly implemented methods. Therefore it makes sense to use the text which is already available in GHS.

In the GHS the definitions of expert judgement and total weight of evidence are as follows.

If it will be implemented for several classes (6.1, 8 and environmentally hazardous substances) it has to be implemented under 2.0.1.X. If it should only implemented for corrosive substances it has to be implemented under 2.8.2.X and all reference to other classes (like exposure routes, etc.) can be deleted.

(This text is the original text from GHS and based on the 5th edition of GHS. Eventually this text needs to be amended for TDG.)

– Expert judgement:

The approach to classifying mixtures includes the application of expert judgement in a number of areas in order to ensure that the existing information can be used for as many

mixtures as possible to provide protection for human health and the environment. Expert judgement may also be required in interpreting data for hazard classification of substances, especially where weight of evidence determinations are needed.

– Total weight of evidence:

For some hazard classes, classification results directly when the data fulfil the applicable criteria. For others, classification of a substance or a mixture is made on the basis of the total weight of evidence. This means that all available information on the determination of toxicity *(if only implemented in class 8 needs to be changed into "corrosivity")* is considered together, including the results of valid in vitro tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.

The quality and consistency of the data are important. Evaluation of substances or mixtures related to the material being classified should be included, as should site of action and mechanism or mode of action study results. Both positive and negative results are assembled together in a single weight of evidence determination.

Positive effects which are consistent with the criteria for classification in each chapter, whether seen in humans or animals, will normally justify classification. Where evidence is available from both sources and there is a conflict between the findings, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification. Generally, data of good quality and reliability in humans will have precedence over other data. However, even well-designed and conducted epidemiological studies may lack sufficient numbers of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness and quality of both the human and animal data relative to the expected frequency of occurrence of effects and the impact of potentially confounding factors.

Route of exposure, mechanistic information and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubts about relevance in humans, a lower classification may be warranted. When it is clear that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified. *(May be not necessary if only implemented into class 8.)*

Both positive and negative results are assembled together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

b) Bridging principles

If it should only implemented for corrosive substances it has to be implemented under 2.8.2.X in the UN Model regulations on the transport of dangerous goods.

(This text is adopted from GHS and based on the 5th edition of GHS. It may be that this text needs to be amended for TDG.)

Classification of mixtures when data are not available for the complete mixture: bridging principles:

Where the mixture itself 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 characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

– Dilution:

If a tested mixture is diluted with a diluent which has an equivalent or lower skin corrosivity classification than the least skin corrosive original ingredient and which is not expected to affect the skin corrosivity of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture.

– Batching:

The skin corrosion potential of a tested production batch of a mixture can 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

– Concentration of mixtures of the highest packaging group:

If a tested mixture classified in the highest packaging group for skin corrosion is concentrated, the more concentrated untested mixture should be classified in the highest corrosion packaging group without additional testing.

– Interpolation within one hazard:

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same skin corrosion packaging group, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same skin corrosion packaging group as A and B.

– Substantially similar mixtures:

Given the following:

(a) Two mixtures: (i) A + B;

(ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

(d) Data on skin corrosion for A and C are available and substantially equivalent, i.e. they are in the same packaging group and are not expected to affect the skin corrosion potential of B.

If mixture (i) or (ii) is already classified based on test data, then the other mixture can be classified in the same packaging group.

(c) Additivity approach

(Should be implemented under 2.8.2.X in the UN Model regulations on the transport of dangerous goods.)

Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture:

In order to make use of all available data for purposes of classifying the skin corrosion hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach:

The “relevant ingredients” of a mixture are those which are present in concentrations ≥ 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases), unless there is a

presumption (e.g. in the case of corrosive ingredients) that an ingredient present at a concentration < 1% can still be relevant for classifying the mixture for skin corrosion.

In general, the approach to classification of mixtures as corrosive to skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each skin corrosive ingredient contributes to the overall corrosive properties of the mixture in proportion to its potency and concentration. The mixture is classified as corrosive or irritant to skin when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

The classification of mixtures based on the composition and the classification of the ingredients according to the UN Model Regulations on the transport of dangerous goods have to be carried out under the following principles:

– If the sum of ingredients which are corrosive to the skin are $\geq$ 5 %, the mixture has to be classified into class 8.

– Assignment of packing groups:

More than 5% of corrosive substances leads to a classification into class 8, to assign the PG a different approach is needed. This is the introduction of an additional X. This limit X has been set with 50%. This is based on the substances listed by name in the UN Model Regulations, assigned to PG I. 29 substances are listed with PG I, 5 with specific concentration limits between 37 % and 70%)

Assignment to PG I:

a) If in the mixture the specific concentration limits of the substances listed in sub-chapter 3.2.1 in PG I are exceeded, the mixture has to be assigned to PG I.

b) If in the mixture 50 % of ingredients are assigned to PG I in sub-chapter 3.2.1 without specific threshold limits.

c) If in the mixture 50 % of ingredients not listed by name in sub-chapter 3.2.1, but based on test data assigned to PG I.

Assignment to PG II:

If the mixture is not assigned to PG I and:

a) in the mixture the specific concentration limits of the substances listed in sub-chapter 3.2.1 in PG II are exceeded, the mixture has to be assigned to PG II

b) in the mixture 50 % of ingredients are assigned to PG I + PG II in sub-chapter 3.2.1 without specific threshold limits.

c) in the mixture 50 % of ingredients not listed by name in sub-chapter 3.2.1, but based on test data assigned to PG I + II.

Assignment to PG III:

If the mixture is not assigned to PG I or PG II and:

a) in the mixture the specific concentration limits of the substances listed in sub-chapter 3.2.1 in PG III are exceeded, the mixture has to be assigned to PG III

b) the sum of ingredients which are corrosive to the skin is $\geq$ 5 % .

Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. A mixture containing corrosive ingredients that cannot be classified based on the additivity approach due to chemical

characteristics that make this approach unworkable, should be classified as into class8 if it contains ≥ 1% of a corrosive ingredient.

If there are data showing that (an) ingredient(s) may be corrosive to skin at a concentration of < 1% (corrosive), the mixture should be classified accordingly.

The assignment into the packaging groups should be carried out as named above.

d) Non-additivity approach

(Should be implemented under 2.8.2.X in the UN Model regulations on the transport of dangerous goods.)

Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive to skin if it has a pH ≤ 2 or a pH ≥ 11.5. However, if case of consideration of acid/alkaline reserve the substance may not be corrosive despite the low or high pH value,

When considering testing of the mixture, classifiers are encouraged to use a tiered weight of evidence approach as included in the criteria for classification of substances for skin corrosion to help to ensure an accurate classification, as well as to avoid unnecessary animal testing. In the absence of any other information, a mixture is considered corrosive to skin if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the mixture may not be corrosive despite the low or high pH value, this needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.

The assignment to the packaging groups should be carried out according the same principles and threshold limits as used for the additivity approach.

If there is no other data available, the substance or mixture should be assigned to PG II.

11) Decision logic for mixtures

For an easier usage the decision logic for the classification and assignment of Packaging Groups for mixtures should be implemented as shown below.

Classification and assignment of PG for mixtures

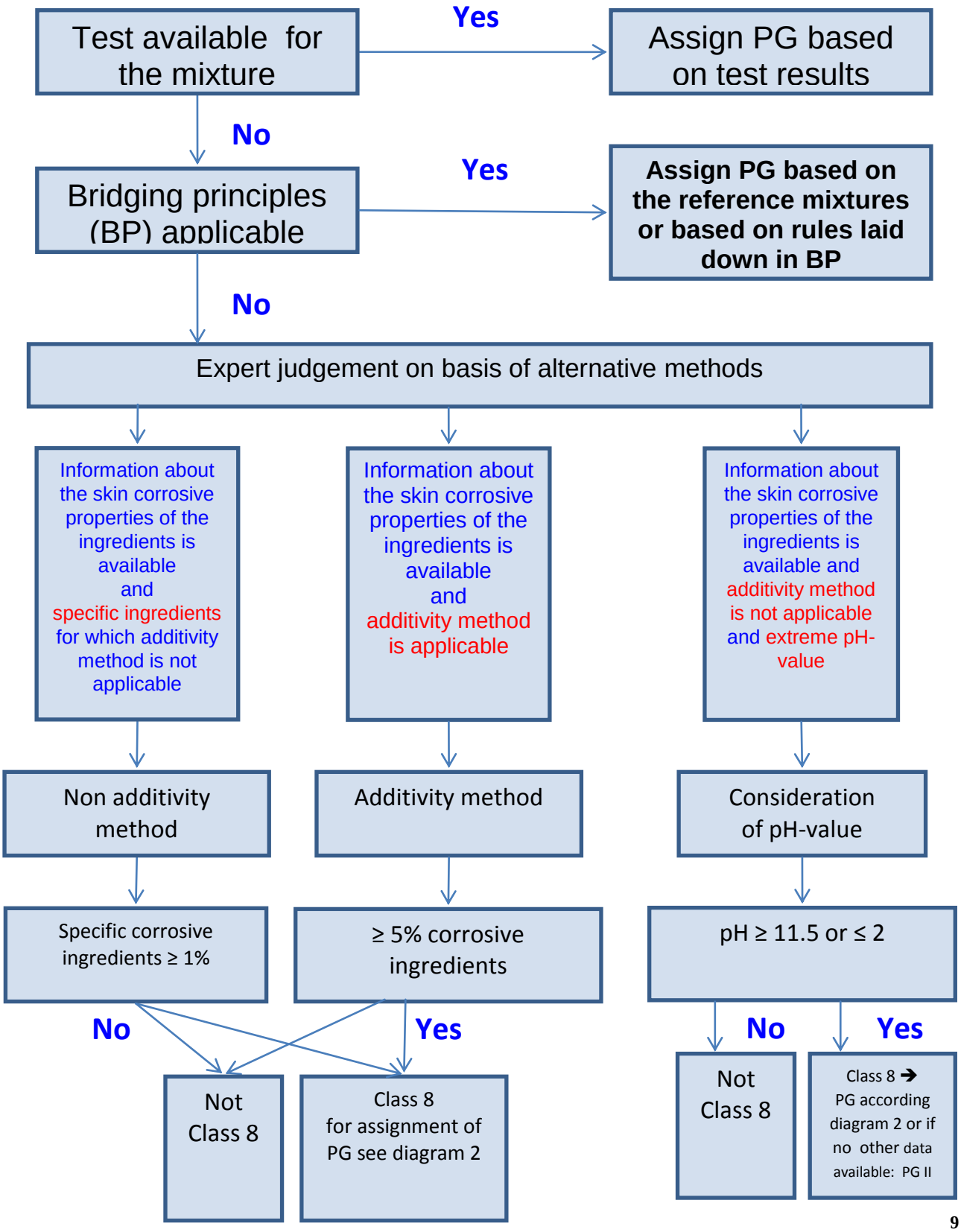
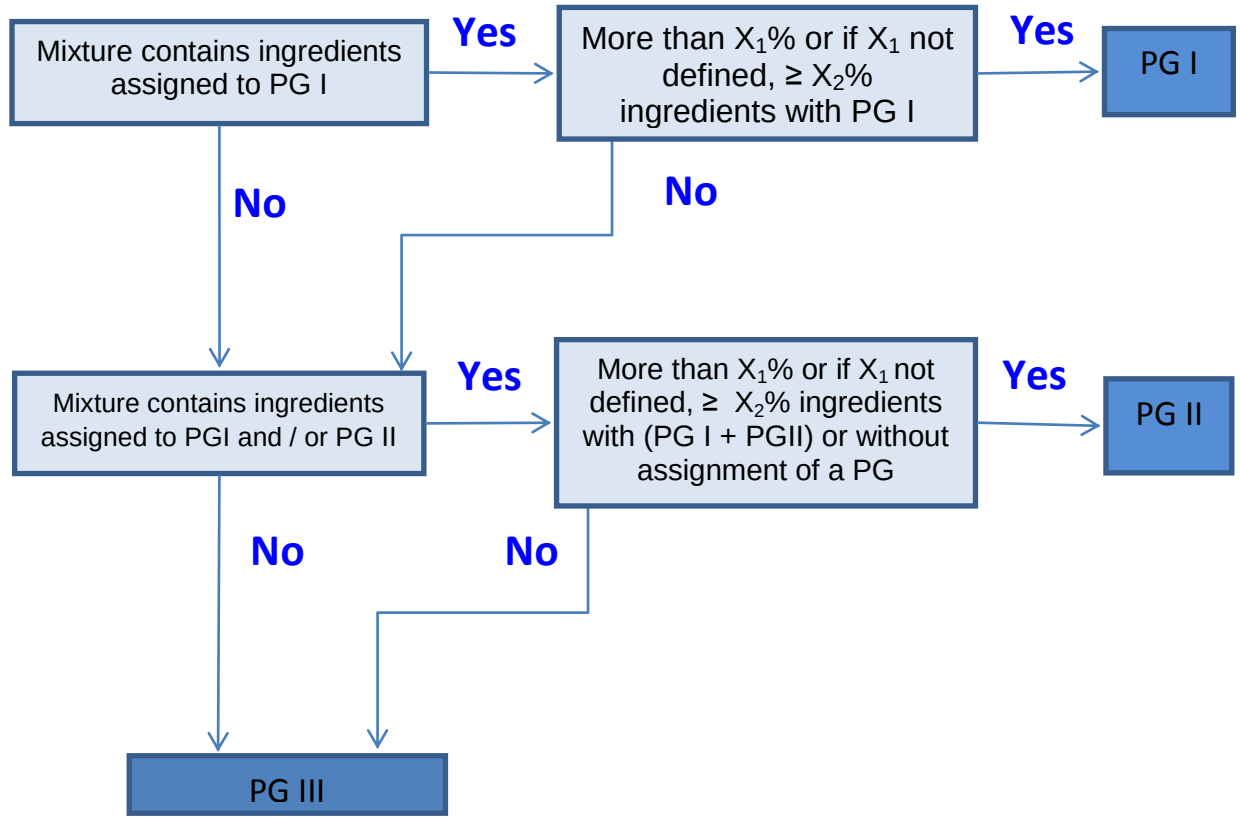


Diagram 2



Explanation of X:

X_1 = specific concentration limits as listed in the UN Model Regulations
X_2 = general concentration limit (e.g. 50 %), in case no SCL listed in the UN Model Regulations

Justification

11. The subcategories have been implemented to GHS to harmonize with the transport regulations. As this is now causing problems and the subcategories are not used for any purpose in GHS, they can be deleted.

12. It makes no difference in classification or any other aspect in supply systems based on GHS whether a corrosive substance is sub-category 1A, 1B or 1C as the symbol, signal word and hazard statement are all the same (see Table 3.2.5 in GHS). Indeed Table 3.2.1 in GHS, second column makes it clear that these sub-categories for corrosivity only apply to some authorities. In transport, assigning or changing the Packing Group is particularly significant as it determines the requirements for the containment and downstream consequences relating to the transport operation.

13. Implementing alternative methods in the transport regulations strengthens the harmonisation with GHS. The assignment of packing groups only in the TDG allows adjusting the assignment based on the safety aims and needs for transport. A deletion of the assignment of sub-categories in GHS and the resulting national lists of chemicals all over the world, the discrepancies between GHS and TDG are reduced to an absolute minimum without loss of information or safety.