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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 Globally Harmonized System of Classification and Labelling of Chemicals

Seventeenth session,
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Item 6 (b) of the provisional agenda

COOPERATION WITH OTHER BODIES OR INTERNATIONAL ORGANIZATIONS

Work on the SCETDG on its 35th session

Corrosivity criteria

Comments on the proposal by the Netherlands (ST/SG/AC.10/C.3/2009/15)

Note by the secretariat

The secretariat reproduces hereafter the comments made several delegations on the proposal by the Netherlands based on the work of a correspondence group concerning the harmonization of the corrosivity criteria of the Model Regulations on the Transport of Dangerous Goods with those of the GHS.

COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the
Transport of Dangerous Goods

Thirty-fifth session
Geneva, 22 - 26 June 2009
Item 10 of the provisional agenda

ISSUES RELATING TO THE GLOBALLY HARMONISED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Comments on ST/SG/AC.10/C.3/2009/15 and UN/SCETD/35/INF 3. Suggested text for implementation of GHS criteria in Class 8 of the UN Model Regulations on the Transport of Dangerous Goods (Netherlands)

Transmitted by the expert from the United Kingdom

Introduction

1. The expert from the United Kingdom has strong concerns about the Netherlands proposals to implement the GHS corrosivity criteria in Class 8 of the UN Model Regulations.

2. The proposals to fully align transport with the GHS will complicate the regulations for the transport of corrosive substances for all those in the transport chain and inappropriately bring into scope more products, which is likely to lead to much more testing. The following paragraphs explain the reasons for the United Kingdom's reservations on implementing the corrosivity criteria.

Reasons

3. In the GHS, pH can be used to indicate corrosivity. It should be noted that pH is not the only or major criterion for corrosivity. However as measurement of pH is a quick, simple and inexpensive way to get an answer, it is often used to assess a product. A substance/mixture is considered corrosive if it has a pH value of less than or equal to 2 (acidic end of the scale) or greater than or equal to 11·5 (basic/alkaline end of the scale).

4. However pH is not necessarily a good indicator of corrosivity and the threshold values set will mean a potential increase in the range of products caught such as propriety cleaners. For example, a 0·1N (Normal) solution of sodium carbonate with a pH of 11·6 would be caught (sodium carbonate is a very common substance and is used as a food additive, in cleaning products, soaps and detergents).

5. Some other examples where extreme pH values would lead to an inappropriate transport classification are: -

(a) Product A contains 0·96% sulphuric acid and would be regarded as non-dangerous for transport. However by extreme pH (1·75) this equates to Category 1A which is aligned with packing group I.

(b) Product B contains 2·5% benzalkonium chloride and 8% lactic acid and would be regarded as non-dangerous for transport. However again by extreme pH (1.3-2.3) it would equate to Category 1A which is aligned with packing group I.

(c) Product C contains 8% phosphoric acid. Extreme pH (0.8-1.5) would put this in Category 1A which equates to packing group I. However tests carried out previously showed that phosphoric acid wasn't packing group III until 10%.

(d) Product D contains 9% sulphamic acid and some surfactant. Extreme pH (0.6) would put this in Category 1A which equates to packing group I. Tests carried out have shown that sulphamic acid is not corrosive for transport until above 10%.

(e) Product E contains 2% ethanolamine and at this concentration would not be regarded as corrosive for transport. However extreme pH (11·9 – 12·4) pushes it into Category 1A which would equate to packing group I.

6. Assessment of acid or alkali reserve, if possible, is preferable to pH. However even if this parameter suggests a substance or mixture may not be corrosive despite the low or high pH value, further testing needs to be carried out to confirm this – leading to considerably more assessment and testing of a wide range of products hitherto not being regarded as corrosive for transport.

7. In the annex to ST/SG/AC.10/C.3/2009/15, the proposed new second sentence in 2.8.2.2 refers off to 2.8.3.4 which corresponds to the GHS criteria for the classification for skin corrosion.(see section 3.2.1 in GHS) This would mean inappropriate wholesale testing for new substances particularly mixtures as more products come onto the market. It could also lead to allocation of a packing group not in line with:

(a) Those of existing entries, in the case of new products assigned to new entries that are added to the Dangerous Goods List of Chapter 3.2;

(b) Those of existing products, in the case of new products assigned to the same existing generic or n.o.s. entries.

8. This would lead to an unbalanced classification system not only for corrosives, but would also affect other classes. For substances with a corrosive hazard and (an) other hazard(s), an inappropriate classification could result from the precedence of hazard characteristics. Allocation to a lower packing group (indicating a higher danger) is a likely outcome and for products with more than one hazard possibly inappropriate primary classification. This would result in unjustified harsher and more costly conditions of carriage throughout the transport chain.

9. For classification of mixtures as corrosive under GHS, generic trigger levels are given for the individual and the sum of all the ingredients of a mixture. These levels are typically concentrations of 1% or more and 5% or more of the mixture. However for transport, in the UN Model Regulations, varying trigger levels are given for various substances as follows: -

Sulphuric acid > 3%
Formic acid ≥ 5%
Alkyl and aryl sulphonic acids > 5%
Ammonia solution > 10%
Acetic acid > 10%
Propionic acid > 10%
Formaldehyde solution > 25%.

10. These values are given in the lower case text of the name and description of various UN entries in the Dangerous Goods List in Chapter 3.2. In RID/ADR/ADN Special Provisions in the series SP500 – 654 usually confirm that lower concentrations of these substances are not subject to the regulations.

11. For mixtures containing several potential corrosive ingredients, the situation is more complex, but mixtures containing, say, one of the above substances in excess of the trigger levels under GHS but below the concentrations given in the UN Model Regulations would be regarded as corrosive if GHS is followed.

12. The sub-categorization of corrosivity in relation to exposure times and observation periods for animal testing in GHS are the same as those referred to in the UN Model Regulations for assignment of packing group. However GHS makes reference to “responses” being noted following the particular exposure time within the relevant observation period. The types of corrosive reaction are listed and it would seem that this would lead to more substances, including mixtures, being caught by the criteria. To avoid this and problems of interpretation, reference to “full thickness destruction of skin” as in the current UN text would be preferable.

13. As reflected in paragraph 110 of the report of the 34th session of the UNSCOE (ST/SG/AC.10/C.3/68), the Netherlands explained that there was no intent to bring any change to the current scope of the UN Model Regulations in relation to the classification criteria for corrosivity. However as illustrated above we believe that by direct implementation of the GHS criteria as they currently stand, considerable changes will result which would be inappropriate to the transport sector.

Conclusion

14. The UNSCEGHS will be carrying out an editorial review of GHS Chapters 3.2 (skin corrosion/irritation) and 3.3 (serious eye damage/eye irritation) in this biennium. Because of the serious problems we believe would be created by fully embracing the current criteria, it is recommended that alignment of the UN Model Regulations with the GHS corrosivity criteria is deferred at least until this review has been carried out. This would enable further work to be done to establish systematically the differences between the existing transport and supply criteria and the scale of the problems that would arise in practice if transport adopted GHS.

15. Then a review of the criteria for corrosivity should enable them to be adapted to meet the needs of both supply and transport while still maintaining the building block approach of the GHS.

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UN/SCETDG/33/INF.21

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
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ISSUES RELATING TO THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Comments on ST/SG/AC.10/C.3/2009/15 and UN/SCETD/35/INF 3. Suggested text for implementation of GHS criteria in Class 8 of the UN Model Regulations on the Transport of Dangerous Goods (Netherlands)

Transmitted by the International Association of the Soap, Detergent and Maintenance Products Industry (A.I.S.E.)

Introduction

1. A.I.S.E. has considerable concern about the proposals of the Netherlands to implement GHS corrosivity criteria into Class 8 of the UN Model Regulations. We agree with the points made by the United Kingdom in UN/SCETDG/35/INF.12 and wish to emphasise the following for further discussion.

Discussion

2. The amended text for 2.8.3.2 in 2009/15 includes “If consideration of alkali/acid reserve suggests the substance may not be corrosive despite the low or high pH value, then further testing shall be carried out to confirm this, preferably by use of an appropriate validated *in vitro* method.” But as has been pointed out pH gives no indication of degree of danger and neither does alkali/acid reserve. So if alkali/acid reserve does indicate corrosive further testing will be required to assign packing group.

3. If it were made clear that “data” in 2.8.3.2 included the Dangerous Goods List that would substantially reduce the need for testing.

Conclusion

4. A.I.S.E. invites the Sub-Committee not to make sweeping changes to Chapter 2.8 until UNSCEGHS has carried out its review of GHS Chapters 3.2 (skin corrosion/irritation) and 3.3 (serious eye damage).

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ISSUES RELATING TO THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Comments to ST/SG/AC.10/C.3/2009/15 and INF.3(Netherlands)

Transmitted by CEFIC

Introduction

1. Document UN/SCETDG/35/INF.3 from the expert of the Netherlands proposes a revised text for implementing the GHS criteria as far as possible into the transport regulations. Comments have meanwhile been provided in document UN/SCETDG/35/INF.12 (United Kingdom), UN/SCETDG/35/INF.21 (AISE) as well as UN/SCETDG/35/INF.25 (Netherlands). Changes to paper INF.3 are proposed to prevent potentially wrong classification decisions which could happen by applying this text.

2. The decision logic, especially for mixtures, was based on the assumption that no data are available. In the case of a mixture of well known substances, the decision logic has to be changed to prevent unnecessary costs and wrong classifications.

3. Therefore CEFIC is of the opinion that the dominant usage of the pH value especially for the classification of mixtures could lead to wrong classifications for substances and mixtures of substances with no extreme pH-value. In general we would propose a sequence that existing data will be checked first before interpretation of less significant data.

Proposal

4. Subsection 2.8.3.2 should be modified (sentence 3 to 6):

" … on the skin. In some cases enough information may be available from structurally related compounds to make classification decisions. ~~Likewise, pH extremes like < 2 and > 11.5 may indicate skin effects, especially when buffering capacity is known, although the correlation is not perfect. Generally, such agents are expected to produce significant effects on the skin. If consideration of alkali/acid reserve suggests the substance may not be corrosive despite the low or high pH value, then further testing shall be carried out to confirm this, preferably by use of an appropriate validated *in vitro* method.~~ If there are no data available further testing may be carried out, preferably by use of an appropriate

validated in vitro method or by the use of bridging principles. Although the correlation is not perfect, extreme pH-value <2 and > 11,5 under consideration of the buffering capacity may indicate skin effects. This may be considered if no other data is available. It also stands….."

5. Figure 2.8.1 should be replaced by two new Figures 2.8.1A and 2.8.1B as follows in order to take account of the availability of validated data. The corresponding reference in ST/SG/AC.10/C.3/2009/15 has been put between brackets.

Figure 2.8.1: Tiered testing and evaluation of skin corrosion potential
Table A: If validated data for substances or mixtures are available

Step	Parameter		Finding		Conclusion
1a (1a)	Existing human or animal experience[(f)] ↓ Not corrosive or no data ↓	→	Corrosive	→	Classify as corrosive[(a)]
1b (1b)	Existing human or animal experience ↓ No data ↓	→	Not corrosive	→	No further testing, not classified
2 (4)	Existing skin data in animals indicate no need for animal testing[(d)] ↓ No indication or no data ↓	→	Yes	→	Possibly no further testing may be deemed corrosive
3a (6)	In vivo skin corrosion test (1 animal) ↓ Negative response or no data ↓	→	Positive response	→	Classify as corrosive[(a)]
3b (6)	In vivo skin corrosion test (1 animal) ↓ No data ↓	→	Not corrosive	→	No further testing, not classified
4a (5)	Valid and accepted in vitro skin corrosion test[(e)] ↓ Negative response or no data ↓	→	Positive response	→	Classify as corrosive[(a)]
4b (-)	Valid and accepted in vitro skin corrosion test[(e)] ↓ No data ↓	→	Not corrosive	→	No further testing, not classified
5 (-)	Bridging principles (for mixtures) ↓ Not indication or no data ↓	→	Corrosive	→	Classify as corrosive[(a)]
6a (-)	Calculation method (for mixtures) ↓ Not corrosive, not applicable or no data ↓	→	Corrosive	→	Classify as corrosive[(a)]
6b (-)	Calculation method (for mixtures) ↓ No indication, not applicable or no data ↓	→	Not corrosive	→	No further testing, not classified

7 (2a)	Structure-activity relationships or structure- property relationships[(b)] ↓ Not corrosive or no data ↓	➔	Corrosive	➔	Classify as corrosive[(a)]
8 (3)	pH with buffering[(c)] ↓	➔	pH < 2 or > 11.5	➔	Classify as corrosive[(a)]
	Not as above	➔	No further testing	➔	No further testing, not classified as corrosive

Table B: No validated data for the substance or components available

Step	Parameter		Finding		Conclusion
1 (3)	pH with buffering[(c)] ↓ No indication or no data ↓	➔	pH < 2 or > 11.5	➔	Classify as corrosive[(a)], possibly further testing
2 (2a)	Structure-activity relationships or structure- property relationships[(b)] ↓ Not corrosive or no data ↓	➔	Corrosive	➔	Classify as corrosive[(a)], possibly further testing
3a (5)	Valid and accepted in vitro skin corrosion test[(e)] ↓ Negative response or no data ↓	➔	Positive response	➔	Classify as corrosive[(a)]
3b (-)	Valid and accepted in vitro skin corrosion test[(e)] ↓ No indication or no data ↓	➔	Not corrosive	➔	No further testing, not classified
4 (4)	Existing skin data in animals indicate no need for animal testing[(d)] ↓ No indication or no data ↓	➔	Yes	➔	Possibly no further testing may be deemed corrosive
5a (6)	In vivo skin corrosion test (1 animal) ↓ Negative response or no data ↓	➔	Positive response	➔	Classify as corrosive[(a)]
5b (6)	In vivo skin corrosion test (1 animal) ↓ No indication or no data ↓	➔	Not corrosive	➔	No further testing, not classified
6a (1a)	Existing human or animal experience[(f)] ↓ Not corrosive or no data ↓	➔	Corrosive	➔	Classify as corrosive[(a)]
6b (1b)	Existing human or animal experience	➔	Not corrosive	➔	No further testing, not classified

6. It is proposed to change footnote (c) from:

Measurement of pH alone may be adequate, but assessment of acid or alkali reserve is preferable; methods are needed to assess buffering capacity; If consideration of alkali/acid reserve suggests the substance may not be corrosive despite the low or high pH value, then further testing shall be carried out to confirm this, preferably by use of an appropriate validated in vitro method;

Into:

Measurement of pH alone is no valid classification criteria. It has to be estimated together with the buffering capacity by determination of the alkali/acid reserve. It could only be an indication. Further testing should be carried out, preferably by use of an appropriate validated in vitro method or by the use of bridging principles or for mixtures methods described in 2.8.4.2 and the concentration limits described in 2.8.4.3.

7. It is further proposed to amend paragraph 2.8.4.1.2 as follows:

2.8.4.1.2 … classification of substances for skin corrosion to help ensure an accurate classification, as well as avoid unnecessary animal testing. ~~A mixture is considered corrosive if it has a pH of 2 or less or a pH of 11.5 or greater. If consideration of alkali/acid reserve suggests the substance or mixture may not be corrosive despite the low or high pH value, then further testing needs to be carried out to confirm this, preferably by use of an appropriate validated *in vitro* test~~. In case of missing data or bridging principles according 2.8.4.2 or concentration limits according 2.8.4.3 are not possible further testing may be carried out, preferably by use of an appropriate validated in vitro test. The measurement of pH alone is no valid classification criteria. It has to be estimated together with the buffering capacity by determination of the alkali/acid reserve. It could only be an indication. Further testing may be carried out, preferably by use of an appropriate validated in vitro method or by the use of bridging principles or, for mixtures, methods described in 2.8.4.2 and the concentration limits described in 2.8.4.3. See also decision logic in 2.8.5.

8. Furthermore it is proposed to amend paragraph 2.8.4.3.4 as follows:

Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. ~~The approach explained in .8.4.3.1 and 2.8.4.3.2 might not work given that many of such substances are corrosive at concentrations < 1%~~.Due to the fact that the approach explained in 2.8.4.3.1 and 2.8.4.3.2 might not work given that many substances are corrosive at concentrations < 1%, for substances which have corrosive properties also below the concentration limits named in Table 2.8.3, these specific limits have to be taken for classification of a mixture.

9. It is also proposed to delete Table 2.8.4 as Category 1 on its own does not exist in the transport regulations classification. Classification on the basis of the pH can never lead to a specific grouping or packing group.

10. As a result of these changes it is proposed to remove the two references to 2.8.4 from 2.8.4.3.5.

11. Finally it is proposed to amend the heading of 2.8.5 by removing "/ irritation" and by inserting the new decision logic (amended Figure 2.8.1).

Justification

12. Due to the fact that some substances which are corrosive on skin have no extreme pH-value (like quaternary ammonia compounds), a predominant status of this criterion is not applicable.

13. As pointed out in 2.8.3.2 an extreme pH-value might indicate skin effects when the buffering capacity is known, "although the correlation is not perfect". In contrast to this statement this will be the dominant criteria for mixtures according subsection 2.8.4.3.4 and Table 2.8.4 . The pH could only be an indication but not a definitive criterion because the real criterion is the acid or alkali capacity. Therefore in opposite to the text in 2.8.4.3.4 the concentration with a specific threshold limit is the better indicator instead of the pH value. It could be also no instrument for grouping because there is no detailed judgement related with the pH.

14. Because of the national / regional implementation of the GHS in many regions, including the implementation of regional or country specific lists of chemicals with specific threshold limits, these will be the dominant classification criteria under GHS instead of the pH (e.g. Japan and also EU for well known substances).

15. The implementation of this new rules makes only sense if GHS is implemented in most countries otherwise these direct links would lead to a regulation which is not in force in many regions (like the U.S.). This causes deviations in the classification which could not be the target of an international system. The standard implementation way of TDG might be too quick in this way and brings a deharmonization. On the other hand the classification of corrosive substances is still in discussion for GHS.

16. The decision logic named in 2.8.5 is not legally binding and just for orientation. Therefore it should not be used in a derived document.

17. The decision logic should clearly express that first of all well known validated data have to be used. Therefore this has to be taken into account. After it is checked that no valid data is available the decision tree which is already named should be added. Otherwise this data will probably be ignored or unnecessary tests will be carried out.

18. Above all however, as mentioned in INF.12 by the expert of the United Kingdom and INF.21 from A.I.S.E, CEFIC is of the opinion that it is appropriate to wait for further decisions until the review of the GHS Chapters 3.2 and 3.3 have been carried out. A correspondence working group of UN-SCEGHS is currently working on this and CEFIC is contributing to this work. As this is only the first meeting of the biennium, there is no reason why the discussion, based upon the output of GHS, could not take place at a later stage.

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ISSUES RELATING TO THE GLOBALLY HARMONISED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Reaction on Information paper 12 of the United Kingdom and INF. 21 of AISE: Comments on ST/SG/AC.10/C.3/2009/15 and UN/SCETD/35/INF 3. Suggested text for implementation of GHS criteria in Class 8 of the UN Model Regulations on the Transport of Dangerous Goods (Netherlands)

Transmitted by the expert from the Netherlands

Introduction

1. In information paper 12 the expert from the United Kingdom expressed strong concerns about the Netherlands proposals to implement the GHS corrosivity criteria in Class 8 of the UN Model Regulations. The expert from AISE supports the concerns expressed by the United Kingdom.

2. In this information paper the expert from The Netherlands will present a reaction on the input from the expert from the United Kingdom and from AISE.

pH is not the perfect indicator of Corrosivity

3. We agree with the expert from the United Kingdom that the pH value is not the perfect indicator of the corrosive properties of a substance or mixture. However, the way the GHS classification criteria are set up, the pH is only one of the possible indicators which may be used if other information on the corrosive properties of the substance/mixture is not available.

4. In the case valid information from human experience or animal testing is available; this information prevails over the classification based on a pH measurement. The tiered testing and evaluation of skin corrosion potential for substances is illustrated in figure 2.8.1 of the proposed Chapter 2.8 (Annex of ST/SG/AC.10/C.3/2009/15).

5. The classification of mixtures is explained in paragraph 2.8.4 of the proposal. Also for mixtures classification based on pH is possible if no other information on the mixture exists.

Description of the corrosive reaction

6. The expert of the UK has some doubt whether corrosivity as defined in the UN GSH criteria is comparable with the criteria as presently used in the Transport Recommendations. In line with

the UN GHS criteria paragraph 2.8.4.3.4.1 of the proposed chapter 2.8 describes; “A corrosive substance is a test material that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 test animals after exposure up to a 4-hour duration’.

GHS classification criteria enhance data availability

7. One of the driving forces of the harmonization of the classification criteria is the reduction for testing and evaluation of chemicals. The hazard information of the substance/mixture can be used throughout the life cycle of the substance. This benefit of the harmonization will only ‘pay off’ after implementation of the GHS criteria in the different (inter)national legal instruments, recommendations, codes and guidelines.

8. The GHS corrosivity classification criteria are already implemented in different (inter)national legal instruments throughout the world, for example Japan, New Zealand and the European Union. Alignment of the UN recommendations on TDG with the GHS will enable optimal use of available information on a substance or mixture. In this context it is not understood that “much more testing” as suggested by the expert of the United Kingdom in par. 2 of INF. 12 is necessary as compared with the present criteria in the UN Model Regulations.

9. The Expert of the United Kingdom suggests that the number of substances/mixtures classified based on corrosive properties may increase due to the implementation of the UN GHS criteria. However this increase, if any, will not be due to ‘inappropriate classification’ but due to increased availability of information on the properties of the substance/mixture.

Dangerous Goods List

10. The common practice regarding the substances/mixtures listed by name in the Dangerous Goods List. will not change by the implementation of the GHS classification criteria. The transport conditions as defined for listed substances/mixtures are leading.

Conclusion

11. The expressed concerns of the Expert of the United Kingdom and AISE are not shared by the Expert of the Netherlands. We do not believe that the alignment with the UN GHS criteria will dramatically change the transport classification, nor that transport should be treated as a special case in the chain of supply, use and transport

12. In line with the expressed unanimous support for the need for harmonisation with the UN GHS (report par. 108 of ST/SG/AC.10/C.3/68 December 2008 meeting), the alignment of the corrosivity criteria need not to await the editorial review as proposed by the UN GHS.

13. The use of available knowledge on the hazardous properties of the substances/mixtures will increase by the implementation of the GHS classification criteria for corrosivity allowing safe transport and handling.

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