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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

25 November 2011

Sub-Committee of Experts on the Transport of Dangerous Goods

Fortieth session

Geneva, 28 November – 7 December 2011

Item 9 of the provisional agenda

Issues relating to 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

Twenty-second session

Geneva, 7 – 9 December 2011

Item 4 (c) of the provisional agenda

Cooperation with other bodies or international organizations 4 (c)

Work of the joint correspondence group on corrosivity criteria

Transmitted by the expert from the United Kingdom on behalf of the joint correspondence group

1. This informal document provides information in preparation for the meeting of the joint correspondence group on corrosivity criteria on 6th December, from 14:30 – 17:30 (Room XII).

2. The joint informal correspondence group was initiated at the 20th session of the GHS Sub-Committee, with the aim of considering further the harmonisation of corrosivity criteria in the transport Model Regulations and the GHS. The agreed terms of reference were as follows:

a. Verify the definition of "skin destruction" as mentioned in the Model Regulation on the transport of dangerous goods complemented with reference to the Organisation for Economic Co-operation and development (OECD) test guidelines. If the definition is not aligned with paragraph 3.2.2.4.1 in Chapter 3.2 of the GHS, propose appropriate improvements.
b. Identify and analyse the discrepancies between assignment to subcategories 1A, 1B and 1C, based on in vitro and in vivo testing and alternative approaches (bridging principles, mixtures calculations, pH…)
c. Identify differences in assignment to categories in lists provided by different regulations and guidance documents for a few representative common substances. Analyse the underlying data and origin of these differences and use these results for the work under paragraphs a, b and d.
d. Check the way OECD guidelines are referenced and their relevance.
e. Report findings and make recommendations that meet the need of all sectors with the aim of achieving consistent classification outcomes for skin corrosivity.

3. For the June/July sessions of the UNSCETDG/GHS the expert from the United Kingdom submitted informal document UN/SCEGHS/21/INF.6 – UNSCETDG/39/INF.14 setting out initial background information in relation to each of the above workstreams.

Work since the last TDG and GHS sub-committee's sessions has focused primarily on gathering information in relation to workstream c. above. Annexes 1-3 of this document contain three contributions in support of this workstream which have been received to date:

(a) A case study and summary table submitted by the Netherlands concerning the corrosivity classification of the substance diisopropylamine;

(b) A summary table submitted by the observer from Vietnam concerning the classification of a number of substances;

(c) Summary information submitted by the expert from Germany in relation to the substances potassium hydroxide, sulphuric acid and phosphoric acid.

5. The expert from Germany has also submitted a number of further relevant background documents. These have not been included in this informal document but have been circulated to the correspondence group and are available from the expert from the UK on request (Pierre.cruse@hse.gsi.gov.uk). A list of documents is given in Annex 3.

6. Annex 4 also contains for the information of the sub-committees a message distributed to UK GHS and TDG stakeholders requesting contributions to the work of the group, copied at Annex 3. The expert from the UK also invites further dissemination of the invitation to interest parties and welcomes further contributions and expressions of interest.

7. The expert from the UK also thanks the International Council of Chemical Associations (ICCA) for their contributions to workstreams b. and c., set out in informal documents UN/SCETDG/40/INF.9 – UN/SCEGHS/22/INF.12 and UN/SCETDG/40/INF.10 – UN/SCEGHS/22/INF.13.

8. A more detailed agenda for the meeting will be circulated in advance of the meeting, together with any further relevant information which is available in time for the meeting.

9. In addition to experts already on the joint correspondence group, the expert from the UK warmly invites further experts from either TDG or GHS sub-committees with an interest in the work to attend the meeting on 6th December.

Annex 1:

Summary table and case study on diisopropylamine submitted by the expert from the Netherlands

Template for information on classification of substances for the work of the joint working group on corrosivity criteria

Substance: DIISOPROPYLAMINE (UN 1158, CAS 108-18-9)

International or official national lists/databases	*List/database 1*	*List/database 2*	*List/database 3*	*List/database 4*
Identity of list/database or other source	**UN Dangerous goods list**	**Annex VI Regulation 1272/2008/EC (CLP) including the 1st and 2nd ATP (Regulations EC no 790/2009 and 286/2011)**	**GESAMP hazard profile**	
What is the process for agreeing classifications in this list/database?	**A proposal for classification is submitted to the UNSCETDG where a decision is taken**	**The classifications in Table 3.2 (Directive 67/548/EEC criteria) is based on a proposals submitted to TC C&L (European expert committee) which took a decision. The classification in Table 3.1 (CLP criteria) is based on a translation from the classification in Table 3.2.** **New additions to Annex VI is based on comparison with criteria and not translations.**	**An expert committee reviews hazard information and derives a classification**	
Corrosivity classification - For transport? - For supply?	**Transport or supply?** **Transport** **Classification is 3(8) PG II**	**Transport or supply?** **Supply** **Table 3.1: Skin Corr 1B** **Table 3.2: C; R34**	**Transport or supply?** **Transport** **Classification is Code 3 (without subdivision) which is equivalent to GHS Skin Corr 1 (without**	**Transport or supply?**

Substance: DIISOPROPYLAMINE (UN 1158, CAS 108-18-9)

International or official national lists/databases	*List/database 1*	*List/database 2*	*List/database 3*	*List/database 4*
			subdivision)	
Basis for classification, e.g. human experience, in vivo testing, in vitro testing, pH, read across, other experience, etc. Where testing is to a standard please specify	**Not known**	**Not known**	**Not known**	
What documentation/sources support this classification?		**Summary record from ECB ECBI/82/95_Add_00_Rev_01 No data is shown in this record. Other relevant records could not be located.**		
Date of classification (and any modifications)		**1995**		
Any general observations about the reasons for discrepancies in classifications of this substance in different international or official national lists/databases?	**As the underlying data for the classification has not yet been located, the reason for divergent classification is not known. Recently, the OECD carried out an analysis on divergent classifications for a few chemicals which are listed in Annex III of the Rotterdam Convention (see UN/SCEGHS/19/INF.3). The conclusion was that there are three main reason for divergent classifications:** • **different datasets are used to classify;** • **different interpretation of the data;** • **different application of the classification criteria.** **It is likely that the divergent classifications for diisopropylamine are for the same reasons.**			
Industry classifications for this substance/ classifications derived from currently available information	**Source 1 Publicly available data from the REACH registration dossier for diisoproplyamine**	**Source 2 Inventory of CLP classifications for hazardous substances on the European market**	**Source 3**	**Source 4**

Substance: DIISOPROPYLAMINE (UN 1158, CAS 108-18-9)

International or official national lists/databases	*List/database 1*	*List/database 2*	*List/database 3*	*List/database 4*
Source of classification, e.g. self-classification by supplier or consignor/ classification derived from current information ('derived classification').	**Self-classification by industry**	**Self-classification by industry**		
Corrosivity classification - For transport? - For supply?	**Transport or supply?** **Supply** **Industry self-classification is: Skin Corr 1A**	**Transport or supply?** **Supply** **The classifications Skin Corr 1A and Skin Corr 1B have been notified**	**Transport or supply?**	**Transport or supply?**
Basis for classification, e.g. human experience, in vivo testing, in vitro testing, pH, read across, other experience, etc. Where testing is to a standard please specify.	**In vivo data. The study used as the bases for classification is an OECD 404 study performed in 1983.**	**Not known**		
What documentation/sources support this classification?	**Robust study summaries from test reports with detailed description of methods and results**	**None**		
Date of classification (and any modifications)	**2010**			
Any general observations about the reasons for discrepancies in industry classifications/ derived transport vs supply classifications of this substance (as applicable)				

Substance: DIISOPROPYLAMINE (UN 1158, CAS 108-18-9)

International or official national lists/databases	***List/database 1***	***List/database 2***	***List/database 3***	***List/database 4***
Comments / observations on the differences between the substance classifications in international and official national lists, and industry/ derived classifications (as applicable).				

Case study:

Classifications and information on the corrosivity of diisopropylamine (CAS 108-18-9)

1. The Netherlands has searched for data and classifications on corrosivity for the chemical diisopropylamine (CAS 108-18-9, UN 1158) in a number of sources. This data search was not exhaustive so other data may be available from sources other than those used for this study. The sources that were searched and summary of the data that was found are included in the Annex to this document. The Netherlands did not perform a quality control on study methodology or results of the studies found in the sources.

2. This case study is divided into three parts. Part I presents the summary of the existing data that was found in the sources that were searched. Part II shows the existing classifications in several frameworks, and in Part III, the conclusions of the case study are presented.

3. It is pointed out that corrosivity is the only hazard property that was evaluated in this case study. Information on other hazard properties was not included in the information search. Also, in Part II, classifications other than those relating to corrosivity have not been listed.

Part I: Currently available data on corrosivity of diisopropylamine

4. A search for information on the corrosivity of diisopropylamine or the justification for current classifications was carried out in the following sources:

- Model Regulations on Transport of Dangerous Goods
- GESAMP Hazard Profiles
- Annex VI of Regulation EC No 1272/2008 (CLP)
- Publicly available REACH registration dossier for diisopropylamine
- Industry safety data sheet
- IUCLID file containing hazard information compiled for Regulation EC No 793/93

5. Below, a summary of the information on corrosivity that was located in each source is presented. More details and links to the data sources are located in the Annex to this document.

6. It has not yet been possible to locate any information on the corrosivity of diisopropylamine in the archives of UN TDG/UN GHS (for the listing in the Dangerous Goods List), GESAMP (for the listing in the GESAMP hazard profiles) and ECHA (for the listing in Annex VI of the CLP).

7. The publicly available REACH registration dossier provides four studies on the corrosive properties of diisopropylamine. Two of these studies are considered by the registrant to be reliable and useful for classification. The first study, which is also used as the basis for classification, is a well-documented OECD 404 guideline study from 1983. Full thickness destruction of the skin was observed after 3 minute contact time. Based on the data, the registrant concluded that diisopropylamine fulfilled the criteria for classification as Skin Corrosive 1A. The second study is from 1977 in which

diisopropylamine caused severe irreversible damage on the treated sites of the animals after an application time of 5 min, 2 hours and 4 hours.

8. A safety data sheet provided by industry concludes that direct contact with the chemical will cause irritation and burns to human skin if not washed immeditaly. In the safety data sheet, it is also concluded that diisopropylamine is corrosive, based on an OECD 404 study (3 minute contact time). It is not clear from the limited information provided whether this study is the same OECD 404 study as is documented in the REACH registration dossier.

9. The IUCLID file compiled for Regulation EC No 793/93 contained a reference to one study with limited information on study method and results. The reported conclusion is that the substance is moderately irritating. There is insufficient information available to assess whether this study is one of the studies that are in the REACH registration dossier.

Part II: Comparison of existing classifications

10. Table 1 shows the classification of diisopropylamine in the Dangerous Goods List (17th version), the GESAMP/EHS composite list (version 2010), Annex VI of Regulation EC no. 1272/2008 (CLP) and self-classifications from industry as notified to the Inventory of classifications of hazardous chemicals on the European market.

Table 1: Diisopropylamine classifications

Framework	***Classification***	***Data for classification (see Part I and Annex)***
Dangerous Goods List	3(8) PG II	Unknown
GESAMP/EHS	Skin Corr Cat 1	Unknown
Annex VI CLP	Skin Corr Cat 1B	Unknown
Notified classifications in Inventory*	i) Skin Corr 1A ii) Skin Corr 1B	i) OECD 404 study ii) Unknown

** This includes industry self-classification from the REACH registration dossier*

The Dangerous Goods List.

11. The Dangerous Goods List does not list all hazard classifications for a chemical but only the primary and secondary hazard according to the rules on precedence of hazard (Model Regulation Table 2.0.3.3). Diisopropylamine (UN1158) is listed in the Dangerous Goods List with the classification 3(8) PG II; the primary hazard is flammability and the subsidiary hazard is corrosivity. In order to determine the packing group for corrosivity, the flammability classification of diisopropylamine was examined. The available information suggests that the flammability classification for diisopropylamine is class 3, PG II and Flam Liq. Cat 2, using criteria of the Model Regulations and GHS, respectively. According to the rules on precedence of hazard, the corrosivity packing group is either PG II or PG III (Model Regulation Table 2.0.3.3)

The GESAMP hazard profile.

12. The GESAMP hazard profile classification for diisopropylamine is Skin Corr Cat 1. No sub-category 1A, 1B and 1C is provided. This means that the information available was not sufficient to make the assignment into category 1A, 1B or 1C.

European harmonized classifications in Annex VI of the CLP Regulation.

13. Diisopropylamine is listed with the classification Skin Corr 1B (CLP Regulation) in Table 3.1 and the classification C; R34 (Directive 67/548/EEC) in Table 3.2 on Annex VI of the CLP Regulation. The classification under Directive 67/548/EEC was discussed in the European Technical Committee on Classification and Labeling (TC C&L) in October 1995. The classification C; R34 of Directive 67/548/EEC was transposed into the CLP classification according to the transposition table given in Annex VII of the CLP Regulation. However, no distinction could be made between Skin Corr Cat 1B and Skin Corr Cat 1C. It is stressed that in order to change an entry in Annex VI, a proposal for a change in classification has to be prepared and submitted to the European Chemicals Agency (ECHA). In other words, updates in classifications due to new data that become available due to REACH are not automatically incorporated into Annex VI.

Self-classifications in the classification inventory.

14. Within the framework of the REACH Regulation, industry has collected data on corrosivity of diisopropylamine and used this information to classify the substance. The self-classification reported in the REACH registration dossier is a direct comparison of the data with the criteria and is not based on the transposition table in Annex VII of the CLP. For corrosivity, the CLP criteria are in all aspects identical to the GHS criteria.

Part III: Conclusions

15. The currently available data on the corrosive properties of diisopropylamine is of varying quality. The study which industry has used as the basis for the self-classification of diispropylamine in the REACH registration dossier is an OECD 404 study performed in 1983. The study pre-dates the GHS. Industry has concluded in the REACH registration dossier for diisopropylamine that this data supports the classification Skin Corrosive 1A. The CLP criteria for corrosivity are identical in all aspects to the GHS criteria

16. This study also illustrates that the classifications for diisopropylamine on existing lists differ for reasons that are not known since it has proven difficult to find the information that was used as the basis for the classification.

17. Recently, the OECD carried out an analysis on divergent classifications for a few chemicals which are listed in Annex III of the Rotterdam Convention (see UN/SCEGHS/19/INF.3). The conclusion of this analysis was that there are three main reasons for divergent classifications

- different datasets are used to classify;
- different interpretation of the data;
- different application of the classification criteria.

It is considered likely that the divergent classifications seen for diisopropylamine on different classification lists are due to these same reasons.

19. When for the sake of this case study, the currently available data are compared with the current criteria of the Model Regulations and GHS, the classification Class 8 PG I and Skin Corr 1A, respectively, are derived.

Available information on the corrosivity of diisopropylamine

A search for data on corrosivity of diisopropylamine was carried out in the following data sources

1) Model Regulations on Transport of Dangerous Goods
2) GESAMP Hazard Profiles
3) Annex VI of Regulation EC No 1272/2008 (CLP)
4) REACH registration dossier
5) Inventory on classifications of hazardous chemicals on the market in Europe
6) IUCLID file compiled for Regulation EC No 793/93
7) Industry Safety Data Sheet

1. Model Regulations on Transport of Dangerous Goods

Link to source:

http://www.unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev17/English/Rev17_Volume1.pdf

The transport classification of diisopropylamine (UN 1158) is 3(8) PG II in the Dangerous Goods List of the 17th edition of the Model Regulation. The GHS secretariat did carry out a search for old records, data sheets and other information that might shed light on the transport classification of diisopropylamine. No information has yet been located in the archives.

2. GESAMP Hazard Profiles

Link to source:

http://www.imo.org/OurWork/Environment/PollutionPrevention/ChemicalPollution/Documents/GESAMP-EHSCompositelistofhazardeprofiles.pdf

In the GESAMP-EHS Composite list (version 2010), diisopropylamine is classified with rating 3 in column D1 of the IBC code. Code 3 is equivalent to GHS Skin Corrosive Category 1. The GESAMP hazard profile lists no subcategory A, B or C. GESAMP did carry out a search for old records, data sheets and other information that might shed light on the GESAMP classification of diisopropylamine. No information has yet been located in the archives.

3. Annex VI of Regulation EC No 1272/2008 (CLP)

Link to source: http://apps.kemi.se/hclass/

The Kemi H-class database contains links to many documents of the technical committee on classification and labeling (TC C&L) which determined the European harmonized classification for chemicals under Directive 67/548/EEC. An electronic link is provided to document ECBI/82/95 Add 00 Rev 01 but no link is provided for the documents ECBI/31/95 Add 15, ECBI/31/95 Add 20, ECBI/31/95 Add 22 and ECBI/31/95 Add 23. The relevant entry for diisopropylamine from document ECBI/82/95 has been copied below.

ECBI/82/95 - Rev 1 : Commission Working Group on the Classification and Labelling of Dangerous Substances.Meeting at ECB Ispra, 9-11 October 1995.

Dipropylamine[1]; diisopropylamine [2] (612-048-00-5).

Proposed classification: F, R11; [Xn, R20/21/22]; [C, R35], Xi, R37; N, R51-53.

These substances are problematic for Austria in the Accession Treaty. The Austrian proposal suggests dividing the present entry into two. The classification for dipropylamine should include Xn; R20/21/22 and replacing Xi, R36/38 by C, R35, as well as the possible inclusion of S3, S36/37/39 and S51. The classification for diisopropylamine should include Xn; R20/22 and C, R35, as well as the possible inclusion of S3, S36/37/39 and S51 (i.e. this proposal does not include R21).

The Group accepted the Austrian proposal to split the entry into two, and agreed on the Austrian proposals for the addition of classification for acute toxicity. The Group accepted the Austrian proposal of C; R35 for dipropylamine, but felt that C, R34 was more appropriate for the diisopropylamine isomer. The Group agreed to delete Xi, R37 from the classification, and, instead, to include specific concentration limits which include R37 for preparations. The Group accepted the A proposal to include S36/37/39 for both isomers, but did not feel that S3 or S51 were justified for either isomer.

The Chairman pointed out that the proposal for N; R51-53 had been included by mistake.

Conclusion: The entry was modified by deleting diisopropylamine from this entry and introducing it as a new entry (612-128-00-X). The classification for this entry was agreed as F; R11, Xn; R20/22, C; R34, Symbols F, C, and S-phrases: (1/2-)16-26-36/37/39-45, and specific concentration limits. The classification for the remaining isomer (dipropylamine) was agreed as F; R11, Xn; R20/21/22, C; R35, Symbols F, C, and S-phrases: (1/2-)16-26-36/37/39-45, and specific concentration limits.

4. Publicly available REACH registration dossier

Link to source: http://apps.echa.europa.eu/registered/registered-sub.aspx#search, then search for diisopropylamine.

The REACH registration dossier for diisopropylamine contains data gathered by the European industry. The dossier contains four studies for skin corrosion. The studies have been evaluated by industry and given a reliability rating according to the system of Klimisch et al. (Reg Tox Pharmacolog 25:1-5, 1997) in which the data are given a reliability score of 1, 2, 3 or 4. Major national and international chemical hazard assessment programs have agreed that studies with reliability score 1 (‘Reliable without restriction’) and reliability score 2 (‘Reliable with restriction’) can be used for hazard and risk assessment. However, studies with reliability score 3 (‘Not reliable’) and reliability score 4 (‘Not assignable’) are not considered reliable and can not be used for hazard or risk assessment.

The executive summaries for the studies in the REACH registration dossier on diisopropylamine are copied here below.

OECD 404 study from 1983

Reliability 1: Reliable without restriction

Conclusion: Skin Corr 1A

Executive summary: The acute dermal irritation of diisopropylamine (DIPA) was evaluated in rabbits according to OECD 404 guideline and in compliance with the Good Laboratory Principles. DIPA was applied undiluted to the skin of 3 New-Zealand White albino rabbits

and held in contact for 3 minutes by means of a semi-occlusive dressing. Animals were then observed daily until day 14. Clear evidence of necrosis was observed within 24 h (brown-red and brown-green discoloration of treated skin sites), followed by dry and rough over time, associated with desquamation and/or open wound that ended in scar formation. The skin tissue became irreversibly damaged in total thickness. Erythema mean scores over 24, 48 and 72 hours were 2, 3 and 3 for animals 1, 2 and 3 respectively. Oedema mean scores over 24, 48 and 72 hours were 1, 0.67 and 1 for animals 1, 2 and 3 respectively. Skin damages were not reversible within the observation period. Under these experimental conditions, DIPA is considered as corrosive to rabbit skin.

In vivo study from 1977

Reliability 2: Reliable with restriction (pre-OECD 404 study)

Executive summary: In a study (1977), diisopropylamine (DIPA) was evaluated in rabbits according to OECD 404 guideline with some deviations. DIPA (1 ml) was applied undiluted to the skin of 2 New-Zealand White albino rabbits and held in contact for 5 min, 2 h and 4 h by means of a semi-occlusive dressing. Animals were observed for 8 days.

At 24 and 48 hours, both animals showed maximal erythema and severe oedema scores (4/4 and 2/2 respectively) that were not fully reversible within 8 days for every exposure time.

Under the experimental conditions of the test, DIPA caused severe irreversible damage on the treated sites of the animals after an application time of 5 min, 2 hours as well as of 4 hours.

Summary of a study report from 1977

Reliability 3: Not reliable

Executive summary: When exposures were terminated at four hours, all treated sites were gray in color; The sites subsequently became dry and slightly indurated. No structural changes in the skin were evident.

Abstract from an in vivo study from 1985

Reliability 4: Not assignable

Executive summary: The acute dermal irritation of Diisopropylamine (DIPA) was evaluated in rabbits. 0,5mL of DMIPA was applied during 4 or 24 hours and corrosion was observed.

Under these experimental conditions, DMIPA has to be classified as corrosive.

5. Inventory on classifications of hazardous chemicals on the market in Europe

Link to source: Not yet available.

The classifications Skin Corr 1B and Skin Corr 1A have been notified for the chemicals diisopropylamine to the European Chemicals Agency (ECHA). As no submission of experimental data is required, it is not known which information has been used to derive the classifications.

6. Industry Safety Data Sheet

Link to source: http://www.quickfds.com/out/16021-57701-21011-013234.pdf

“Skin contact: Causes severe burns.

- In humans : Direct contact with product:, Irritation and burns if not washed immediately
- In animals: Corrosive (OECD Guideline 404, rabbit, Exposure time: 3 min)”

7. IUCLID file compiled for Regulation EC No 793/93

Link to source:

http://esis.jrc.ec.europa.eu/doc/existing-chemicals/IUCLID/data_sheets/108189.pdf

The dossier is a compilation based on data reported by the European Chemicals Industry following Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document. The data have not undergone any evaluation by the European Commission. No relatibilty rating is provided.

Entry 1: Secondary reference from 1986

No reliability score is provided in the IUCLID

Executive summary: Prehled-Prumyslove-Toxicol-Orh-Latky-1986, pg 433, 1986 (85JCAB) through RTECS, 1994. 500 mg were applied for 24 h to rabbits. The reported conclusion is that the substance is moderately irritating.

No further information on study methodology or results is provided.

Annex 2: Summary information submitted by the observer from VietNam in relation to a number of substances

Template for information on classification of substances for the work of the joint working group on corrosivity criteria

Substances: …….

International or official national lists/databases	***List/database 1***	***List/database 2***	***List/database 3***	***List/database 4***
Identity of list/database or other source	Sulphuric acid oleum methyl phosphonic dichloride phenylphosphorus dichloride...	Iodine pentapluoride, Bromine pentafluoride, Bromine trifluoride...	Sodium/ Potassium hydroxide, Phosphorous acid, Zinc chloride...	Iodine monochloride, Vanadium trichloride, Thiophosgene, Thiophosphoryl chloride
What is the process for agreeing classifications in this list/database?	Toxic, fire, explosion	Oxidisers (Water-Reactive) Toxic, fire, explosion	Toxic, Corrosive, Non-combustible	Non - Combustible, Water-sensitive
Corrosivity classification - For transport? - For supply?	**Transport or supply?** For transport and supply	**Transport or supply?** For transport and supply	**Transport or supply?** For transport and supply	**Transport or supply?** For transport and supply
Basis for classification, e.g. human experience, in vivo testing, in vitro testing, pH, read across, other experience, etc. Where testing is to a standard please specify	Basic for classification: experience in vivo and vitro testing. Examination in laboratory of center.	Basic for classification: experience in vivo and vitro testing. Examination in laboratory of center.	Basic for classification: experience in vivo and vitro testing. Examination in laboratory of center.	Basic for classification: experience in vivo and vitro testing. Examination in laboratory of center.
What documentation/sources support this classification?	Vietnam and GHS-TDG documentations.	Vietnam and GHS-TDG documentations.	Vietnam and GHS-TDG documentations.	Vietnam and GHS-TDG documentations.
Date of classification (and any modifications)	From 2000 to 2010	From 2000 to 2010	From 2000 to 2010	From 2000 to 2010

Substances: …….				
International or official national lists/databases	***List/database 1***	***List/database 2***	***List/database 3***	***List/database 4***
Any general observations about the reasons for discrepancies in classifications of this substance in different international or official national lists/databases?	The reasons for discrepancies in classification of this substance: the different national list and international list.			

Template for information on classification of substances/mixtures for the work of the joint working group on corrosivity criteria

Mixture: …….				
International or official national lists/databases	***List/database 1***	***List/database 2***	***List/database 3***	***List/database 4***
Source of classification of mixture, e.g. official list, industry self-classification	Morpholine, aqueous mixture			
Corrosivity classification - For transport? - For supply?	**Transport or supply?** For transport and supply	**Transport or supply?**	**Transport or supply?**	**Transport or supply?**
Basis for classification, e.g. human experience, in vivo testing, in vitro testing, pH, read across, other experience, etc. Where testing is to a standard please specify	Basic for classification: experience in vivo and vitro testing. Examination in laboratory of center.			
What documentation/sources support this classification?	Vietnam and GHS-TDG documentations.			

Mixture: …….

International or official national lists/databases	***List/database 1***	***List/database 2***	***List/database 3***	***List/database 4***
Date of classification (and any modifications)	From 2000 to 2010			
Any general observations about the reasons for discrepancies in classifications of this substance in different international or official national lists/databases?	The reasons for discrepancies in classification of this substance: the different national list and international list.			

Annex 3: Summary information received from the expert from Germany in relation to potassium hydroxide, sulphuric acid and phosphoric acid

ECETOC
Technical Report 66
1995

	Erythema	Edema	Primary Irritation Index
Potassium hydroxyde (5% aq) Multipath study, 3 rabbits, 0.5 mL	Grade 2-4 Reaction outside application site	Grade 1-2	5.2
Potassium hydroxyde (10 % aq) Multipath study, 3 rabbits, 0.5 mL	Necrosis after 4.5 h Reaction outside application site	not evaluated due to severity of effects	not possible to calculate

The ECVAM International Validation Study on the In Vitro Tests for Skin Corrosivity.
Barratt et al. 1998
Tox in vitro 12: 471-482

	Corrosivity testing	Result	pH	Remarks
Sulfuric acid (10 % wt.)	3 min 1 hr 4h	nd pos nd	1.2	supporting data do not enable unequivocal classification
Phosphoric acid	3 min 1 hr 4h	neg pos pos	<1	
Potassium hydroxyde (10 % aq)			13.2	
Potassium hydroxyde (5% aq)			13.1	supporting data do not enable unequivocal classification

(nd – not determined)

Additional background documents submitted by the expert from Germany – circulated to the informal correspondence group and available on request from the expert from the UK (Pierre.cruse@hse.gsi.gov.uk)

M.D. Barratt (et al), The ECVAM International Validation Study on In Vitro tests for skin corrosivity, Toxicology in Vitro 12 (1998), 471-482

J. Scheel (et al), Classification and labelling of industrial products with extreme pH by making use of *in vitro* methods for the assessment of skin and eye irritation and corrosion in a weight of evidence approach, Toxicology in Vitro 25 (2011), 1435-1447

A.P. Worth (et al), An evaluation of the proposed OECD testing strategy for skin corrosion, ATLA 26 (1998), 709-720

J. R. Young (et al), Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without testing on animals, Toxicology in Vitro (1998) Vol 2 No 1, 19-26.

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Annex 4: Message sent by the expert from the UK to GHS and TDG stakeholders inviting contributions to the joint correspondence group on corrosivity criteria

GHS/TDG working group on corrosivity - invitation for input

Many of you will be aware that the UK is co-ordinating a joint working group at the UNSCEGHS/TDG related to harmonisation of corrosivity criteria between transport and supply. I am writing to ask whether members of our GHS stakeholder group and others would be willing to input into this work.

Background

The joint TDG/GHS corrosivity working group was initiated in December 2010 and has the following terms of reference:

a. Verify the definition of "skin destruction" as mentioned in the Model Regulation on the transport of dangerous goods complemented with reference to the Organisation for Economic Co-operation and development (OECD) test guidelines. If the definition is not aligned with paragraph 3.2.2.4.1 in Chapter 3.2 of the GHS, propose appropriate improvements.

b. Identify and analyse the discrepancies between assignment to subcategories 1A, 1B and 1C, based on in vitro and in vivo testing and alternative approaches (bridging principles, mixtures calculations, pH…)

c. Identify differences in assignment to categories in lists provided by different regulations and guidance documents for a few representative common substances. Analyse the underlying data and origin of these differences and use these results for the work under paragraphs a, b and d.

d. Check the way OECD guidelines are referenced and their relevance.

e. Report findings and make recommendations that meet the need of all sectors with the aim of achieving consistent classification outcomes for skin corrosivity.

The UK produced an informal document for the last GHS/TDG Subcommittee meetings (http://www.unece.org/fileadmin/DAM/trans/doc/2011/dgac10c4/UN-SCEGHS-21-inf06e_UN-SCETDG-39-inf14e.pdf). At the meeting it was agreed as the next step we should focus on workstream c), and look at the reasons why substances are classified in different ways in official lists and through industry self-classification - this work is currently underway and will be discussed at the next GHS/TDG meetings in December.

Since then there have also been two INF documents produced by ICCA for the next TDG/GHS Subcommittee meetings (http://www.unece.org/fileadmin/DAM/trans/doc/2011/dgac10c4/UN-SCEGHS-22-inf013e.pdf and http://www.unece.org/fileadmin/DAM/trans/doc/2011/dgac10c4/UN-SCEGHS-22-inf012e.pdf) which you may be interested to look at.

Self-classification on corrosive substances

One of our focuses is on classifications in official lists, but we are also interested in whether discrepancies could arise through direct application of the criteria in the GHS and TDG Model Regulations. In particular, we keen to find out whether self-classification of substances or simple mixtures that are not listed by name in the Dangerous Goods List or in CLP Annex VI (i.e. where generic or NOS entries are used) are likely to attract different corrosivity classifications.

To help find this out we are keen to find out how the corrosivity criteria are actually applied to such chemicals by supply and transport practitioners. We'd particularly like to get any specific examples of how such substances or mixtures have been self-classified for transport - and to the extent that it's already being applied, GHS - to identify any specific issues that have arisen.

In addition (to the extent that 'real' examples aren't available) we would also be interested in developing a few 'hypothetical' test cases, where practitioners in transport and supply apply the TDG and GHS criteria to example substances. This would also help to reveal whether there is an issue with self-classification in addition to the known issues with discrepancies between different lists.

Invitation for help

I would therefore like to ask whether anyone would be willing to contribute to this exercise. I would particularly like to invite:

(a) any suggestions as to relevant substances or simple mixtures to look at. Good examples would be corrosive substances or simple (say, two component) mixtures that are commonly transported/supplied but are neither included by name in the DGL nor in CLP Annex VI - in particular any cases where discrepancies are likely to arise.

(b) any details of actual classifications where you have identified a discrepancy (again other than the known cases in the DGL/CLP Annex VI), or volunteers to derive a 'hypothetical' classification as an illustrative test case;

(c) any other comments on whether and how discrepancies in GHS/TDG corrosivity classifications are likely to arise in relation to self-classified substances or mixtures.

For those attending, we will also discuss this at in our GHS stakeholder meeting on 22nd November, though feedback is welcome from anyone with an interest - please also forward this to anyone else not on our circulation list who may be interested.

In terms of timing we would like to get as much information together as we can before the informal group meets on 6th December between the UNSCETDG and GHS meetings. However, that is quite a short timescale so I anticipate this is something we would continue with after Christmas. However it would be good to get any initial comments and expressions of interest by the end of next week (25th November) and then we can take it from there.

Don't hesitate to contact me if you have any questions about this.

Best regards

Pierre Cruse

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