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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-fourth session
Geneva,
Item 10 (h) 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-sixth session
Geneva,
Item 2 (a) of the provisional agenda
**Classification criteria and hazard communication:
Work of the Sub-Committee of Experts on the
Transport of Dangerous Goods on physical hazards**

Clarification of skin corrosion criteria for sub-categories 1A and 1B in GHS chapter 3.2 and for Packing Groups I and II in the Model Regulations paragraph 2.8.2.5

Transmitted by the International Paint and Printing Ink Council (IPPIC)[1]

Purpose

1.   The purpose of this paper is to initiate a discussion on the clarification in the criteria for the sub-categorization for skin corrosion in the GHS and allocation of the packing groups I and II in the Model Regulations in 2.8.2.5

Background

2.   Both regulations have been using a system based on exposure times and also on observation periods for assessing the potency and sub-grouping.

3.   Transport has been using since 1993 (8th revised edition of the United Nations Recommendations on the Transport of Dangerous Goods) exposure periods of up to 3 min

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[1]   In accordance with the programme of work of the Sub-Committee for 2013–2014 approved by the Committee at its sixth session (see ST/SG/AC.10/C.3/84, para. 86 and ST/SG/AC.10/40, para. 14).

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for Packing group (PG) I, of up to 60 min for PG II and of up to 4 h for PG III; observation periods of ≤ 1 h in connection with PG I and of ≤ 14 days have been used for PGs II and III. In other jurisdictions, e.g. in the European Union in Directive 67/548/EEC, an observation period for 3-min exposure has been applied as described in the OECD Test Guideline No. 404, i.e. "not fixed rigidly" (1992), or for up to 14 days (2002). In the development of the GHS criteria at OECD level (until 2001), the transport criteria concerning exposure times and observation periods were adopted, since the allocation to 3 sub-groups allowed a better differentiation of the severity of hazards than other systems (e.g. Directive 67/548/EEC with only two exposure time points, i.e. 3 min and 4 h). The criteria developed by the OECD were then adopted by the GHS Sub-Committee in 2002/2003 and are to be used for sub-categorization into 1A to 1C. However, no criterion for studies with only up to 3-min exposure and observation periods > 1 h up to 14 days according to internationally recognized scientific principles had been considered.

4.   Criteria in the GHS (Rev.5):

Table 3.2.1: Skin corrosion category and sub-categories

	Criteria
Category 1	Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure ≤ 4 h
Sub-category 1A	Corrosive responses in at least one animal following exposure ≤ 3 min during an observation period ≤ 1 h
Sub-category 1B	Corrosive responses in at least one animal following exposure > 3 min and ≤ 1 h and observations ≤ 14 days
Sub-category 1C	Corrosive responses in at least one animal after exposures > 1 h and ≤ 4 h and observations ≤ 14 days

5.   **The United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations** (18th revised edition) use identical criteria concerning exposure times and observation periods in chapter 2.8.2.5 and in Table 2.8.2.5 for allocating the Packing Group. Reference is made to OECD Test Guideline No. 404 (2002).

Test guidelines

6.   OECD No 404 describes an initial test in § 16 with up to three patches applied sequentially to the animal(s) for 3 min, 60 min and 4 hours. If the test follows strictly this stepwise procedure, a clear differentiation can be made between Cat. 1A/PG I and Cat. B/PG II. For tests performed only with 3-min exposure, the observation of the animal is " for 14 days unless corrosion develops at an earlier time point" (§ 18). In older studies with < 3 min, observation time points > 1 h had also been used.

7.   OPPTS 870.2500b Acute Dermal Irritation (US EPA; August 1998) also describes the stepwise procedure and refers to the observation period in § 6 as follows: "The duration of the observation period need not be rigidly fixed. It should be sufficient to fully evaluate the reversibility or irreversibility of the effects observed. It need not exceed 14 days after application."

8.   Thus the general procedure according to these internationally accepted test guidelines is to continue the observation period up to 14 days until corrosion is observed if at ≤ 1 h no corrosion developed: In other words, in a valid study for a suspected corrosive

chemical with an exposure of up to 3 min, corrosive responses were generally also recorded after the 1-hour observation period if no corrosion was observed at that time point.

9   In older studies that were not performed according to current test guidelines, observation periods > 1 h were generally also applied unless corrosion developed at an earlier time point.

Problem

10.   As mentioned before, in the GHS Rev.5 Table 3.2.1 and in 3.2.2.1.1.4 as well as in the Model Regulations in 2.8.2.5, there is an inconsistency/gap concerning chemicals which show corrosive responses only after an observation period of > 1 h up to 14 days following exposure up to 3 min. This causes uncertainties in the classification process of particular test results, which might lead to different classifications and might thus also have legal implications. Since allocation to PG I has a great impact on transport, unambiguous criteria are important for a distinct differentiation between PGI/Cat 1A and PG II/Cat 1B.

11.   The following practical examples of data on 2 test chemicals (TC) illustrate the issue:

Example:

Exposure Time: 3 min *TC*	*Clinical observation: dermal lesions/responses* *(abbreviated)*			*GHS Classification*	*Remarks*
	At 3 min	**At 1 h**	**After 10 days**		
TC 1	No Corrosive responses	Corrosive responses	No longer any observation, since corrosion already after 1 h	Category 1A	Criteria for Cat. 1A clearly fulfilled since corrosive responses after exposure = 3 min and during an observation period = 1 h
TC 2	No Corrosive responses	No Corrosive responses	Corrosive responses	?	Classification in Cat. 1A not possible since no corrosion at an observation period of 1 h. Classification in Cat. 1B according to the existing criteria not possible either, since exposure time not > 3 min. According to directive 67/548/EEC, TC 2 is classified as "Corrosive; R 35 = Causes severe burns", the severest sub-group in corrosivity.

For the 25th session, a preliminary informal document illustrating the issue was delivered (UN/SCEGHS/25/INF.19).

Proposal

12.　Since the classification criteria have to take the required duration of observation according to the test guidelines and testing schemes of older studies into account the following proposal for solving the problem is made:

Modification of the criteria for those test results based on exposures ≤ 3 min, but with corrosive responses at observation time points > 1 h up to 14 days in the following way: Since in any case allocation to sub-category 1A is restricted to an observation period of ≤ 1 h according to the accepted criteria, chemicals showing corrosive responses after observation periods > 1 h could be allocated to Cat. 1B and PG II without a break in the system (proposed amendments in bold):

13　For GHS 3.2.2.1.1:"….. sub-category 1A, where corrosive responses are noted following up to 3 minutes exposure and up to 1 hour observation; sub-category 1B, where corrosive responses are described following exposure greater than 3 minutes and up to 1 hour and observations up to 14 days **or following up to 3 minutes exposure and observations greater than 1 h and up to 14 days**; and sub-category 1C, where corrosive responses occur after exposures greater than 1 hour and up to 4 hours and observations up to 14 days. "

14.　**Criteria in the GHS (Rev.5):**

Table 3.2.1: Skin corrosion category and sub-categories

	Criteria
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Sub-category 1A	Corrosive responses in at least one animal following exposure ≤ 3 min during an observation period ≤ 1 h
Sub-category 1B	Corrosive responses in at least one animal following exposure > 3 min and ≤ 1 h and observations ≤ 14 days **or following exposure ≤ 3 min and observations > 1h ≤ 14 days**
Sub-category 1C	Corrosive responses in at least one animal after exposures > 1 h and ≤ 4 h and observations ≤ 14 days

15.　For the Model Regulations on the Transport of Dangerous Goods Chapter 2.8.2.5 (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 minutes but not more than 60 minutes or **within an observation period of more than 1 h up to 14 days starting after the exposure time of up to three minutes.**

Table 2.8.2.5: Summarizing the criteria in 2.8.2.5

Packing Group	Exposure Time	Observation Period	Effect
I	≤ 3 min	≤ 60 min	Full thickness destruction of intact skin
II	**≤ 3 min**	**> 1h ≤ 14 days**	Full thickness destruction of intact skin
	> 3 min ≤ 1 h	≤ 14 days	
III*	> 1 h ≤ 4 h	≤ 14 days	Full thickness destruction of intact skin

* Criteria for corrosion with reference to steel or aluminium omitted

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