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

20 June 2014

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Geneva, 2 – 4 July 2014
Item 3 (g) of the provisional agenda
Classification criteria and hazard communication:
Miscellaneous

Proposal for additional guidance in Chapter 3.2 Skin Corrosion/Irritation

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

Introduction

1. IPPIC had previously submitted a proposal to clarify the issue concerning (older) skin corrosivity studies with only up to 3 minutes exposure and observation periods greater than 1 hour up to 14 days (see INF.19 (GHS 25th session), and ST/SG/AC.10/C.4/2013/8 - ST/SG/AC.10/C.3/2013/68). Substances which had been tested according to such schemes cannot easily be allocated to a sub-category according to Table 3.2.1.

	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

Table 3.2.1: Skin corrosion category and sub-categories

2. At the 26th session of the Sub-Committee there was general agreement not to change the criteria in Table 3.2.1, but rather to deal with this issue through appropriate guidance. IPPIC was invited by the Sub-Committee to develop such guidance for consideration at a future session (ST/SG/AC.10/C.4/52, para. 13, 14). This document presents a first proposal for the new guidance, on which the comments of the Sub-Committee are invited.

Proposal

3. Add a new sub-section in 3.2.5 as follows:

"3.2.5.4 Guidance on use of test data

- 3.2.5.4.1 Classification criteria for allocation to skin corrosion sub-categories 1A, 1B and 1C are based on the duration of exposure and the duration of the subsequent observation periods (for details see 3.2.2.1.1.4 and table 3.2.1).
- 3.2.5.4.2 Classification in sub-category 1A is based on corrosive responses (see definition in 3.2.1.1) following ≤ 3 min exposure during an observation period ≤ 1 h, whereas classification in sub-category 1B is based on > 3 min and ≤ 1 h exposure during observations ≤ 14 days. However the criteria do not specify how to classify corrosive responses based on existing data from tests with ≤ 3 min exposure and an observation period > 1 h and ≤ 14 days.
- 3.2.5.4.3 Test results with corrosive responses following ≤ 3 min exposure, but only after observation > 1h up to 14 days, should generally lead to sub-category 1B, since for sub-category 1A the upper observation period is definitely limited to a maximum of 1 h according to the established criteria. In cases with unclear results at 1 h, or where the observation had only been performed after 1h and thus skin corrosion at the 1 h observation limit for sub-category 1A cannot clearly be excluded, an allocation to sub-category 1A should be considered using expert judgement."

2