
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

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Item 3 of the provisional agenda

Listing, classification and packing

Response to ST/SG/AC.10/C.3/2022/72 - Revision of classification of tetramethylammonium hydroxide

Transmitted by the expert from the Netherlands

Introduction

1. Document ST/SG/AC.10/C.3/2022/68 presented by the expert from the Netherlands proposes a new classification for tetramethylammonium hydroxide (TMAH). Cefic and DGAC have presented an alternative classification approach for TMAH in document ST/SG/AC.10/C.3/2022/72.
2. The expert from the Netherlands is of the opinion that document ST/SG/AC.10/C.3/2022/72 contains aspects and deviations from the Model Regulations that need to be brought to the attention of the Sub-Committee. This regards the use of human experience, the species of test animals used for classification, and the proposed differentiation between TMAH aqueous solutions and TMAH mixtures.

Human experience

3. The Model Regulations require that when available, human experience shall be used for assigning packing groups for Division 6.1 and Class 8 substances (paragraphs 2.6.2.2.2, 2.6.2.2.3 and 2.8.3.2); in the absence of human experience, data obtained from animal experiments shall be used. While the authors of document ST/SG/AC.10/C.3/2022/72 acknowledge that “animal test data should be used to refine and not override data from human experience”, the proposed concentration limits in document ST/SG/AC.10/C.3/2022/72 (paragraph 25) are nevertheless based on animal test data as calculated in paragraph 17 of that document and not on human experience. The approach behind these proposed concentration limits is therefore not in line with the principles of the Model Regulations.

Animal species

4. As there is a significant amount of human experience available, animal data should not be used for deriving the classification of TMAH. Nevertheless, the authors of document ST/SG/AC.10/C.3/2022/72 make use of animal data in their classification. Furthermore, while the Model Regulations (paragraph 2.6.2.1.2) require acute dermal toxicity testing to be performed on albino rabbits, the authors use rat data. Allowing a different test species than the albino rabbit for classification of dermal toxicity will set a precedent that affects the classification of not only TMAH but also many other dangerous goods. If the Sub-Committee

is of the opinion that these types of data are suitable for classification purposes, then this issue should be addressed first, before using it for actual classification purposes.

TMAH aqueous solutions and mixtures

5. Document ST/SG/AC.10/C.3/2022/72 proposes to distinguish between aqueous TMAH solutions and TMAH mixtures. Aqueous solutions are mixtures, and the toxicity of a mixture depends on the composition of the mixture. One incident with a TMAH mixture is used for distinguishing between an aqueous solution and a mixture. This mixture contained no other substances than TMAH that meet the toxicity criteria of the Model Regulations. While one of the other substances was a surfactant which increases dermal uptake of other substances, it must be noted that TMAH by itself is easily absorbed through the skin, by means of its structure and corrosive properties. Document ST/SG/AC.10/C.3/2022/24 of the 60th session details the severe health effects (death) of TMAH, even after short exposure times (<1 min). The resulting health effects from exposure to this specific mixture are therefore mainly determined by TMAH, especially since the victim died due to TMAH poisoning according to the autopsy report, and the results can therefore also be considered representative for aqueous TMAH solutions. Therefore, the expert from the Netherlands is of the opinion that from a safety point of view, the concentration limit for packing group I should be 8.75 % for both aqueous TMAH solutions and TMAH mixtures.

Discussion

6. The expert from the Netherlands believes that the abovementioned issues should be considered when discussing the proposed new classification for TMAH.
