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| **UN/SCETDG/61/INF.54** 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 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**1. 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 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**1. 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 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**1. 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** 1. The expert from the Netherlands believes that the abovementioned issues should be considered when discussing the proposed new classification for TMAH.

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| **Committee of Experts on the Transport of Dangerous Goodsand on the Globally Harmonized System of Classificationand Labelling of Chemicals****Sub-Committee of Experts on the Transport of Dangerous Goods 1 December 2022****Sixty-first session**Geneva, 28 November-6 December 2022Item 3 of the provisional agenda**Listing, classification and packing** |

 Revision of classification of tetramethylammonium hydroxide

 Submitted by the European Chemical Industry Council (Cefic) and Dangerous Goods Advisory Council (DGAC)

 I. Introduction

1. Earlier in the week, following the discussion in plenary of documents ST/SG/AC.10/C.3/2022/68, ST/SG/AC.10/C.3/2022/72, INF.19, and INF.21, dealing with the reclassification of tetramethylammonium hydroxide (TMAH), the topic was referred to an informal working group under the leadership of the expert from Belgium. Due to the complexity of the issue and the multiple views and options, it was felt that an informal discussion could possibly yield a way forward. This document captures our understanding of the majority views coming out of the informal working group and presents a modified proposal accordingly.

2. There was little support for assigning concentration limits to all packing groups on the basis of the incident involving the 8.75% TMAH solution. Although there was some support for Option 2 of INF.21, a preference for Option 1 emerged during the discussions and we have based this revised proposal on Option 1 accordingly.

3. The following revisions to Option 1 have been made in response to concerns raised during the informal working group and related discussions:

 (a) The concentration limit for PG I aqueous solutions has been revised to include 25%.

 (b) Proposed SP XXX in paragraph 5 has been modified to include provisions based on human experience for the classification of formulations that are not aqueous solutions and contain a surfactant in a concentration > 1%.

 (c) Provisions for a transitional period have been introduced in a new SP ZZZ in paragraph 6.

 (d) SP 279 has been assigned to the entries for aqueous solutions to reflect they have been classified on the basis of human experience.

 (e) A consequential amendment to the Guiding Principles has been incorporated in paragraph 8.

4. As reported to the plenary session, there was also discussion in the informal working group about revising the cut-off value between PG II and III from 2.5% to 2.38%. The representative from DGAC promised to consult with technical experts within DGAC and Cefic about this. After consultation, we learned that this would cause greater problems than anticipated so we have retained 2.5% as we originally proposed.

 II. Proposal

5. In 3.3, add a new special provision XXX as follows:

“XXX This entry applies only to aqueous solutions comprised of water, tetramethylammonium hydroxide (TMAH), and no more than 1 % other constituents. Other formulations containing tetramethylammonium hydroxide must be assigned to an appropriate generic or n.o.s. entry (e.g., UN 2927, Toxic liquid, corrosive, organic, n.o.s., etc.), except as follows:

other formulations containing a surfactant in a concentration > 1% and with not less than 8.75% tetramethylammonium hydroxide must be assigned to UN 2927, TOXIC LIQUID, CORROSIVE, ORGANIC, N.O.S., PG I, and

other formulations containing a surfactant in a concentration > 1% and with more than 2.38% but less than 8.75% tetramethylammonium hydroxide must be assigned to UN 2927, TOXIC LIQUID, CORROSIVE, ORGANIC, N.O.S., PG II.”

6. In 3.3 add a new special provision ZZZ to introduce a transitional period as follows:

“ZZZ The provisions of 3.2.2 from the twenty-second revised edition of the Recommendations on the Transport of Dangerous Goods, Model Regulations may continue to be applied until 31 December 2026.”

7. Modify the entries for UN 1835 as follows (new text is underlined, deleted text strikethrough):

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| **UN No.** | **Name and description** | **Class****or division** | **Subsi-diary hazard** | **UN packing group** | **Special provisions** | **Limited and excepted quantities** | **Packagings and IBCs** | **Portable tanks and bulk containers** |
| **Packing instruction** | **Special packing provisions** | **Instructions** | **Special provisions** |
| 1835  | TETRAMETHYLAMMONIUM HYDROXIDE AQUEOUS SOLUTION with not less than 25 % tetramethylammonium hydroxide  | 6.1  | 8  | I  | 279XXXZZZ | 0  | E5  | P001   |   | T14  | TP2  |
| 1835  | TETRAMETHYLAMMONIUM HYDROXIDE AQUEOUS SOLUTION with more than 2.5 % but less than 25 % tetramethylammonium hydroxide  | 8 | 6.1  | II  | 279XXXZZZ | 1 L  | E2  | P001 IBC02  |   | T7  | TP2  |
| 1835  | TETRAMETHYLAMMONIUM HYDROXIDE AQUEOUS SOLUTION with not more than 2.5 % tetramethylammonium hydroxide  | 8  |   | III  | 223XXXZZZ | 5 L  | E1  | P001 IBC03 LP01  |   | T7  | TP2  |
| 3423 | TETRAMETHYLAMMONIUMHYDROXIDE, SOLID | 6.1~~8~~ | 8 | I~~I~~ | 279ZZZ | ~~1 kg~~ 0 | ~~E2~~ E5 | P002~~IBC08~~IBC99 | ~~B2, B4~~ | ~~T3~~ T6 | TP33 |

8. Add to table 4.2 in the Guiding Principles the following line (new text is underlined):

**Table 4.2: Substances allowed for transport in IBCs subject to approval by the competent authority**

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| **UN**  | **Name**  | **Class/Div.**  | **PG**  | **Subsidiary hazard(s)**  |
| 3423  | TETRAMETHYLAMMONIUM HYDROXIDE, SOLID | 6.1 | I | 8  |