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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

#### Sixty-first session

Geneva, 28 November-6 December 2022

Item 3 of the provisional agenda

#### Listing, classification and packaging

### Revision of the classification of tetramethylammonium hydroxide

Transmitted by the expert from the Netherlands\*

#### Introduction

1. At the fifty-ninth and sixtieth sessions of the Sub-Committee, three documents were presented (informal document INF.12 (fifty-ninth session), ST/SG/AC.10/C.3/2022/24 and informal document INF.22 (sixtieth session) to discuss a revision of the classification of tetramethylammonium hydroxide (TMAH). The available data on accidental human exposure and animal testing have been presented and thoroughly analysed in document ST/SG/AC.10/C.3/2022/24.

2. This led to a proposed new classification for TMAH based on human experience prioritized over animal test data, by assigning three packing groups to the TMAH solutions and to allow the toxic hazard take precedence over the corrosive hazard of TMAH. Two options were provided on the proper shipping names of the TMAH solutions, one with concentration limits and one without. Most delegates who provided comments during the sixtieth session preferred the option with concentration limits.

3. The views were divided on the concentration limit for TMAH solutions corresponding to packing group I. Some delegations supported the proposed 8.75 % concentration limit, while others preferred the concentration limit for packing group I to be 25 %.

#### Justification

4. Updating the classification of TMAH based on the most recent insights is necessary to ensure the safety of people, property and the environment. By doing so the Sub-Committee aligns itself with the Sustainable Development Goal 3: ensure healthy lives and promote well-being for all at all ages.

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\* A/75/6 (Sect.20), para. 20.51

## Discussion

5. The assignment of the packing group I concentration limit has been based on one lethal incident. Informal document INF.22 (sixtieth session) presented by the European Chemical Industry Council (Cefic) and the Dangerous Goods Advisory Council (DGAC) provided an additional analysis of that incident in which the victim was exposed to a mixture with, amongst others, 8.75 % TMAH and 10 % ethoxylated alcohol. As stated in that document it is likely that ethoxylated alcohol contributed to the lethal outcome of this incident, by hampering an adequate response to the TMAH exposure. However, this does not influence the toxic properties of TMAH solutions, nor does it influence the assignment of packing groups since the assignment of packing groups is based on the intrinsic hazardous properties of a substance and not on the timely manner of response and treatment to any accidental exposure.

6. At the sixtieth session of the Sub-Committee a few delegations questioned the assignment of the concentration limit based on solely one incident. Although the expert from the Netherlands agrees that multiple data points will provide more support for the proposed concentration limit it is however highly questionable to ignore a lethal incident.

7. The Model Regulations clearly state in paragraphs 2.6.2.2 and 2.8.3.2 that human experience shall be taken into account when assigning packing groups for toxic and corrosive substances. Although there are no quantitative criteria available to do this, it seems an arbitrary choice to consider a lethal incident as an outlier. Especially when coinciding factors that likely have influenced the outcome of this incident only seem to have affected the adequate response to the exposure and had no influence on the toxic properties of TMAH.

8. The Model Regulations have been developed, above all, to ensure the safety of people, property and the environment. Therefore, the expert from the Netherlands is of the opinion that a lethal outcome after accidental exposure is a highly significant outcome and cannot be considered an outlier for classification purposes. It is therefore proposed to maintain the TMAH concentration limit for packing group I at 8.75 %.

9. When preparing this document, it became clear that the acute toxicity test through the dermal route has been incorrectly used as classification data because it had been performed on rats instead of rabbits. Therefore, the 2.38% data was not applied correctly to assign Division 6.1 packing group II. However, this does not change the proposed concentration limit for packing group II, because there is data available on assigning concentration limits to packing groups I and III. The concentration limit for packing group II is then in between these limits. Additionally, for packing group II it was suggested to prioritize Division 6.1 over Class 8 which deviates from the precedence of hazards table. For these two reasons it is proposed to assign special provision 279 to packing group II as well.

10. Furthermore, during the sixtieth session there was a comment on the wording used in the proper shipping name of the packing group I and II entries. These comments have been taken into account and additionally, the wording of the packing group III entry has also been changed accordingly.

11. It was also mentioned that a transitional measure is needed for the proposed amendments to the Dangerous Goods List in the Model Regulations. This has also been taken into account in the revised proposal.

12. Finally, for solid TMAH the proposed classification and associated transport conditions should be reflected in the Guiding Principles. In table 4.2 of the Guiding Principles which deals with transport in intermediate bulk containers (IBCs) subject to approval by the competent authority (IBC99), UN 3423 TETRAMETHYLAMMONIUM HYDROXIDE, SOLID should be added to the table.

## Proposal

13. Taking into account the modifications proposed above, amend in 3.2.2 Dangerous Goods List as follows (new text is underlined, deleted text in ~~strike through~~):

UN No.	Name and description	Class or division	Subsidiary 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	<del>TETRAMETHYLAMMONIUM HYDROXIDE SOLUTION with not less than 8.75 % tetramethylammonium hydroxide</del>	<u>6.1</u>	<u>8</u>	I	<u>279 XXX</u>	<u>0</u>	<u>E5</u>	<u>P001</u>		<u>T14</u>	<u>TP2</u>
1835	<del>TETRAMETHYLAMMONIUM HYDROXIDE SOLUTION with more than 2.38 % but less than 8.75 % tetramethylammonium hydroxide</del>	<u>6.18</u>	<u>8</u>	II	<u>279 XXX</u>	<del>1 L</del> <u>100 ml</u>	<del>E2</del> <u>E4</u>	P001 IBC02		T7	TP2
1835	<del>TETRAMETHYLAMMONIUM HYDROXIDE SOLUTION with not more than 2.38 % tetramethylammonium hydroxide</del>	8		III	<u>223 XXX</u>	5 L	E1	P001 IBC03 LP01		T7	TP2
3423	<del>TETRAMETHYLAMMONIUM HYDROXIDE, SOLID</del>	<u>6.18</u>	<u>8</u>	II	<u>279 XXX</u>	<del>1 kg</del> <u>0</u>	<del>E2</del> <u>E5</u>	P002 <del>IBC08</del> <u>IBC99</u>	<del>B2, B4</del>	<del>T3 T6</del>	TP33

14. In 3.3 add a new special provision XXX to introduce a transitional period as follows:

“XXX 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.”

15. 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**

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