



**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****Fiftieth Session**

Geneva, 28 November-6 December 2016

Item 2 (c) of the provisional agenda

**Recommendations made by the Sub-Committee
on its forty-seventh, forty-eighth
and forty-ninth sessions and pending issues:
listing, classification and packing****Packagings for infectious substances****Transmitted by the expert from Germany¹****Introduction**

1. At the last session several proposals (ST/SG/AC.10/C.3/2016/9, informal documents INF.10, INF.51 and INF.52 48th session) were submitted on packagings for infectious substances. A lunchtime working group discussed several aspects but could not reach a final solution (see informal document INF. 75).

2. Germany has reviewed all the arguments and approaches concerning packagings for clinical waste category A from the forty-ninth session. The lunchtime working group concluded that the new provisions should not interfere with requirements for the usual transport of class 6.2 Category. Therefore a new UN number for clinical waste category A and a separate packaging instruction for this number have been incorporated in the revised proposal to allow a clear differentiation. It is proposed to use a name based on the wording as for UN 3291 with the addition of "Category A". Consequential amendments are necessary in Chapter 1.4 and Chapter 2.6. The proper shipping name of UN 3291 should be amended accordingly to allow a clear differentiation between Category A and Category B wastes.

¹ In accordance with the programme of work of the Sub-Committee for 2015–2016 approved by the Committee at its seventh session (see ST/SG/AC.10/C.3/92, paragraph 95 and ST/SG/AC.10/42, para. 15).

3. The proposed packing instruction is a triple packaging and stipulates that the waste may be considered as solid if sufficient absorbent material is packed with the waste. Provisions for disinfecting the inner packagings before placing them in the outer packaging have been added as an additional requirement in the packing instruction. How and to which extent disinfection is necessary should be decided with the Competent Public Health Authority, as this is more an operational question and also influenced by the packaging types used for the different layer, e.g. plastic bags are difficult to disinfect and the material may be affected by the disinfection substance.
4. The packagings shall be tested and approved according to Chapter 6.3. Chapter 6.3 has been specially developed for Category A substances and 6.3 refers to an accident scenario and not to normal conditions of transport. This implies a 9 metre drop test, special preparation for the drop test (e.g. cold conditioning for plastic packings) and a puncture test. Germany sees no justification to apply a less stringent test regime for clinical waste of Category A. The only problem with Chapter 6.3 is the required filling with water for the drop test, but with filling material corresponding to the properties of the waste packagings may pass the test. The 9 m drop test is absolutely necessary to prove the capability of packagings for infectious waste of category A. However, as testing facilities for such a drop height might be limited, it is suggested allowing alternative methods with the approval of the competent authority, this would allow to replace the drop test for example by a calculation through a mass drop height relation.
5. Consequentially, the marking provisions of Chapter 6.3 should be amended to allow a differentiation between packagings tested for solid wastes of category A and packagings tested for liquid. The information of the gross mass in the marking will help to avoid overfilling.
6. It should be noted that the approval of packagings for the transport of infectious substances category A is only one element of the process of transporting wastes of category A. Such transports are always under the regime of the competent public health authority. The public health authority has to decide whether the public risk is justifiable and if such transports may take place and to require further safety and security measures. Their decisions will be made in consideration of the local and regional circumstances.
7. This proposal does not interfere with existing national regulations. Some comments pointed out that the existing waste packagings for category A wastes would not comply with the new regulations. However, they also do not comply with the existing Model Regulations. Such packagings may continue to be used for national transport, if necessary. The majority of such transports are probably national and, in accordance with the local circumstances and facilities less stringent regulations may be continue to be applied due to national regulations.

Proposal

8. 1.4.3.1.2: Amend the text of table 1.4.1 related to infectious substances to read as follows (new text underlined):
“Division 6.2 infectious substances of Category A (UN Nos. 2814 and 2900), medical or clinical waste of Category A (UN No. 35XX)“
9. Amend 2.6.3.2.1 to read as follows (new text underlined):
“2.6.3.2.1 Infectious substances shall be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN3291, UN 3373 or UN 35XX, as appropriate.“

10. Amend sub-paragraph (a) of 2.6.3.2.3.9 as follows (new text underlined):
“(a) Medical waste (UN 3291 and UN 35XX)”
11. Amend paragraph 2.6.3.5.1 to read as follows (new text underlined, old text ~~stricken through~~):
“2.6.3.5.1 Medical or clinical wastes containing Category A infectious substances shall be assigned to ~~UN 2814 or UN 2900~~UN 35XX as appropriate. Medical or clinical wastes containing infectious substances in Category B shall be assigned to UN 3291.”
12. Amend the note in 2.6.3.5.2 as follows (new text underlined):
“**NOTE:** The proper shipping name for UN 3291 is “CLINICAL WASTE, CATEGORY B, UNSPECIFIED, N.O.S” or “(BIO) MEDICAL WASTE N.O.S” or “REGULATED MEDICAL WASTE, N.O.S”. The proper shipping name for UN 35XX is CLINICAL WASTE, CATEGORY A, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, CATEGORY A, N.O.S. or REGULATED MEDICAL WASTE, CATEGORY A, N.O.S.”
13. Add the new UN No. 35XX to the dangerous goods list in 3.2.1 and modify the proper shipping name for UN 3291 accordingly:

UN No.	Name and description	Class or division	Subsidiary risk	UN packing group	Special provisions	Limited and excepted quantities		Packagings and IBCs		Portable tanks and bulk containers	
						(7a)	(7b)	Packing instruction	Special packing provisions	instructions	special provisions
(1)	(2)	(3)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9)	(10)	(11)
	3.1.2	2.0	2.0	2.0.1.3	3.3	3.4	3.5	4.1.4	4.1.4	4.2.5 / 4.3.2	4.2.5
35XX	CLINICAL WASTE, CATEGORY A, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, CATEGORY A, N.O.S. or REGULATED MEDICAL WASTE, CATEGORY A, N.O.S.	6.2				0	E0	P62X			

Amend the proper shipping name of UN 3291 as follows: CLINICAL WASTE, CATEGORY B, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, CATEGORY B, N.O.S. or REGULATED MEDICAL WASTE, CATEGORY B, N.O.S.

14. Add the new UN No. 35XX to Appendix A (List of generic and N.O.S. proper shipping names):

<i>Class or Division</i>	<i>Subsidiary Risk</i>	<i>UN No</i>	<i>Proper Shipping Name</i>
DIVISION 6.2			
Specific entries			
6.2		35XX	CLINICAL WASTE, CATEGORY A, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, CATEGORY A, N.O.S. or REGULATED MEDICAL WASTE, CATEGORY A, N.O.S.

Amend the proper shipping name of UN 3291 as follows: CLINICAL WASTE, CATEGORY B, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, CATEGORY B, N.O.S. or REGULATED MEDICAL WASTE, CATEGORY B, N.O.S

15. Add the new UN No. 35XX to the alphabetical index of substances and articles:

<i>Name and description</i>	<i>Class</i>	<i>UN No.</i>
CLINICAL WASTE, CATEGORY A, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, CATEGORY A, N.O.S. or REGULATED MEDICAL WASTE, CATEGORY A, N.O.S.	6.2	35XX

Amend the proper shipping name of UN 3291 as follows: CLINICAL WASTE, CATEGORY B, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, CATEGORY B, N.O.S. or REGULATED MEDICAL WASTE, CATEGORY B, N.O.S

16. Add the new packing instruction P62X:

62X	PACKING INSTRUCTION	62X
This instruction applies to UN No.35XX		
<p>The following packagings are authorized provided that the general provisions of 4.1.8 are met: Packagings meeting the requirements of Chapter 6.3 and approved accordingly consisting of</p> <p>(a) An inner packaging comprising:</p> <ul style="list-style-type: none"> (i) a leakproof primary receptacle; (ii) a leakproof secondary packaging; (iii) sufficient absorbent material to absorb the entire amount of liquid present; <p style="padding-left: 40px;">Each secondary packaging shall contain only one primary receptacle. The primary receptacle and the secondary packaging shall be of metal or plastics.</p> <p>(b) A rigid outer packaging:</p> <ul style="list-style-type: none"> Drums (1A2, 1B2, 1N2, 1H2) Boxes (4A, 4B, 4N, 4H2) Jerricans (3A2, 3B2, 3H2) 		
<p>Additional requirement:</p> <ol style="list-style-type: none"> 1. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa. 2. The exterior surface of the primary and secondary packagings shall be disinfected before being packed into the outer packaging respectively as recommended by the Competent Public Health Authority. 3. Before being contained in the primary packaging, sharp objects such as broken glass and needles shall be contained in a packaging resistant to puncture and able to retain liquids under the performance test conditions for packing group II in Chapter 6.1. 		

17. Amend 6.3.4 as follows:

Insert two new paragraphs 6.3.4.2 (d) and (e):

“(d) For packagings tested for solid infectious substances only, the maximum gross mass in kilograms;

(e) For packagings tested for solid infectious substances only, the letter "S";”

The remaining entries of the list in 6.3.4.2 change from (d) – (g) to (f) – (i) respectively. In 6.3.4.3, replace “6.3.4.2 (a) to (g)” with “6.3.4.2 (a) to (i)”.

Amend 6.3.4.4 as follows:

6.3.4.4 Examples of marking

4G/CLASS 6.2/06 as in 6.3.4.2 (a), (b), (c) and (f)

S/SP-9989-ERIKSSON as in 6.3.4.2 (g) and (h)

4G/CLASS 6.2/15/S/06 as in 6.3.4.2 (a), (b), (c), (d) and (e)

S/SP-9989-ERIKSSON as in 6.3.4.2 (g) and (h)

18. In 6.3.5.1.6 g) replace “6.3.4.2 (a) to (f)” with “6.3.4.2 (a) to (h)” and “6.3.4.2 (g)” with “6.3.4.2 (i)”.
19. Amend 6.3.5.2.1 to read as follows (new text underlined):
- “6.3.5.2.1 Samples of each packaging shall be prepared as for transport except that a liquid or solid infectious substance shall be replaced by water or, where conditioning at -18 °C is specified, by water/antifreeze. Each primary receptacle shall be filled to not less than 98 % of its capacity. In deviation from this primary receptacles of packagings for clinical waste of category A (UN No. 35XX) maybe filled with solids to the maximum gross mass at which they may be used.”
20. Amend 6.3.5.3.1 to read as follows (new text underlined):
- “6.3.5.3.1 Samples shall be subjected to free-fall drops from a height of 9 m onto a non-resilient, horizontal, flat, massive and rigid surface in conformity with 6.1.5.3.4. The competent authority may permit equivalent evaluation methods.”
21. Amend 6.3.5.3.5 to read as follows (new text underlined):
- “6.3.5.3.5 Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by cushioning/adsorbent material in the secondary packagings. For packagings for clinical waste of category A (UN No. 35XX), the entire contents are retained by the inner receptacle, even if the closure while retaining its containment function, is no longer sift-proof.”
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