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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 2 (b)(ix) of the provisional agenda

**Recommendations made by the Sub-Committee at its fifty-eighth,  
fifty-ninth and sixtieth sessions and pending issues: explosives and related matters**

### **Classification of nitrocellulose membrane filters for diagnostic and other life science applications**

**Submitted by the European Chemical Industry Council (Cefic) on  
behalf of the World Nitrocellulose Producers Association (WONIPA)\***

#### **Introduction**

1. Nitrocellulose membrane filters are used for diagnostic and other life science applications since several decades. Applications of these nitrocellulose (NC) membrane filters are rapid test devices for COVID-19 infections, pregnancy tests, infectious diseases like influenza, hepatitis, malaria, borreliosis and other diseases. In addition, NC membranes are used as substrates for bioanalytical test platforms for analysis of proteins and biomarkers and microorganisms: bacterial load of water, food and beverages, medical diagnostics for identification and separation of target proteins in human blood serum (HIV, BSE, etc.) via electrophoresis.

2. Nitrocellulose membrane filters UN 3270 with not more than 12.6 % nitrogen by dry mass, are classified in division 4.1 of the Model Regulations for the Transport of Dangerous Goods. For getting this classification, special provision 237 requests, that the NC membrane filters, including paper separators, coatings or backing materials etc., that are present in transport, shall not be liable to propagate a detonation as tested by one of the tests described in the *Manual of Tests and Criteria*, Part I, test series 1(a). In addition, the competent authority may determine based on the results of suitable burning rate tests taking account of the standard tests in the *Manual of Tests and Criteria*, Part III, subsection 33.2 that NC membrane filters in the form in which they are to be transported are not subject to the provisions of these Regulations applicable to flammable solids in division 4.1.

3. Cefic, on behalf of WONIPA, which represents in this case a group of manufacturers of NC membrane filters, which accounts for 80 % of the worldwide production of NC membrane filters for diagnostic and life science applications, presented in informal document INF.16 (sixtieth session of the Sub-Committee) a complete set of test results with UN 1(a) and UN N.1 tests for a group of NC membrane filters. These test results showed that NC-

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

membrane filters with a NC-content of up to 53 g/m<sup>2</sup> and a paper separator of minimum 80 g/m<sup>2</sup> can be excluded from division 4.1 of the Model Regulations by using the provisions of special provision 237.

4. The informal document INF.16 (sixtieth session) was discussed in the Working Group on Explosives (EWG) and the proposal was amended by the EWG. The Working Group on Explosives unanimously recommended to accept the proposal as amended (paragraph 11 and amendment 2 of the report of the EWG in informal document INF.44 (sixtieth session)). The TDG Sub-Committee requested that Cefic should submit the proposal in amendment 2 of the EWG report in an official document (paragraph 56 in ST/SG/AC.10/C.3/2022/R.1/Add.6), which is done in this document in paragraph 6 below. The EWG requested that additional single package testing should be made by Cefic using inner packaging configurations subjected to a burner that is used for airbags. The TDG Sub-Committee invited Cefic to provide an electronic copy of standard ISO 15105. The electronic copy of the standard ISO 15105 was sent to the TDG secretariat together with this working document.

5. Due to the short time before the deadline for the submission of a working document and the summer holiday season it will not be possible to finalize the additional single packaging tests and to send a working document before the deadline for the submission of official documents to the winter 2022 session of the Sub-Committee. Cefic plans to submit an additional informal document with the test results for the additional single package tests using inner packaging configurations subjected to a burner that is used for airbags timely before the Sub-Committee session in November/December 2022.

## Proposal

6. Add the following special provision to 3.3.1 of the Model Regulations:

“SPXXX Nitrocellulose (NC) membrane filters covered by this entry with NC content not exceeding 53 g/m<sup>2</sup> and a NC net weight not exceeding 300 g per inner packaging, are not subject to the requirements of this regulation if they meet the following conditions:

- (a) They are packed with paper separators of minimum 80 g/m<sup>2</sup> placed between each layer of NC membrane filters;
- (b) They are packed to maintain the alignment of the NC membrane filters and the paper separators in any of the following configurations:
  - (i) Rolls tightly wound and packed in plastic foil of minimum 80 g/m<sup>2</sup> or aluminium pouches with an oxygen permeability of equal or less than 0.1 % according to standard ISO 15105 part 1.
  - (ii) Sheets packed in cardboard of min. 250 g/m<sup>2</sup> or aluminium pouches with an oxygen permeability of equal or less than 0.1 % according to standard ISO 15105 part 1.
  - (iii) Round filters packed in disc holders or cardboard packaging of minimum 250 g/m<sup>2</sup> or single packed in pouches of paper and plastic material of total minimum 100 g/m<sup>2</sup>.”

7. In Chapter 3.2 Dangerous Goods List add SPXXX in Column 6 of the UN No. 3270 NITROCELLULOSE MEMBRANE FILTERS, with not more than 12.6 % Nitrogen, by dry mass.

8. If there are any questions on this document, please contact Werner Lange at: [dr.werner.lange@icloud.com](mailto:dr.werner.lange@icloud.com). An early email discussion of this document would be appreciated, so that as many questions as possible could already be clarified before the winter 2022 session of the Sub-Committee.

## **Justification**

9. Billions of COVID-19 rapid test devices are needed worldwide to control the spread of the COVID-19 pandemic. For the billions of COVID-19 rapid test devices, billions of NC membrane filters are needed as substrate. Cefic, respectively WONIPA, presents a packaging concept of the manufacturers of NC membrane filters which will simplify the transport of NC membrane filters. The simplification of the transport of NC membrane filters will improve the availability of the NC membrane filter for COVID-19 rapid test devices worldwide and by this improve the control of the COVID-19 pandemic. The new special provision will save a lot of work for the competent authorities worldwide, as they do not have to create competent authority decisions for each NC membrane filter type. Cefic plans to present a complete set of test results with the test results for the additional single package tests using inner packaging configurations subjected to a burner that is used for airbags for NC membrane filters in an additional informal document timely before the forthcoming 2022 session of the Sub-Committee.

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