



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

Sixtieth session

Geneva, 27 June-6 July 2022

Item 2 (i) of the provisional agenda

Explosives and related matters: miscellaneous

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 and also 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 UN 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 *UN 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 *UN 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 the Worldwide Nitrocellulose Producers Association (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, presents in this document first test results for a group of NC

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

membrane filters, which show that this group of NC membrane filters can be excluded from division 4.1 of the UN Model Regulations by using the provisions of special provision 237.

4. Due to the COVID-19 pandemic not all tests could be finalized before the deadline for the submission of working documents to the summer 2022 session of the Sub-Committee. Cefic plans to submit an additional informal document with comprehensive test results timely before the Sub-Committee session and will make a proposal based on those comprehensive tests to create a new special provision for this group of clearly defined NC membrane filters, which excludes this group from division 4.1 in the informal document. This 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 and will additionally improve the availability of the NC membrane filters (including rapid test devices for COVID-19 infections) worldwide, as the transport of these filters is facilitated. A detailed description of the NC membrane filter packaging configurations, a compilation of the test results now available as well as detailed test descriptions and results can be found in annexes I to III.

Test description and test results

5. All tests were performed by the German competent authority “BAM” according to the methods specified in the Manual of Tests and Criteria, seventh revised edition, 2019.

6. NC membrane filters are delivered in different product packaging configurations. Please find an overview of the NC membrane filter packaging configurations in Annex I. They are produced from a master roll of NC membrane filter, from which the different forms (round filters, sheets and small rolls) are achieved by cutting the master roll into round filters, sheets and rolls.

7. 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 type 1(a). All test samples, NC membrane filters with Polyethylene terephthalate (PET) film backing, NC membrane filters without PET film backing, NC membranes on rolls, NC membrane in sheet form, NC membrane filters as round filters and NC membrane filters in Leporello form were tested in round cut outs with a diameter of 38 mm in their packaging configuration for transport with the UN 1(a) test to determine if those NC membrane filters are liable to propagate a detonation or not. All NC membrane products contained paper separators with a weight of 80 g/m². Please find a compilation of the product configurations and the test results of the samples 1 to 5 in Annex II.

8. All NC membrane filters are packed for transport in a primary packaging, e.g. plastic bags or cardboard boxes. The NC membrane filters are wrapped for transport in this primary packaging (cardboard or plastic film). It is important that the sequence of NC membrane filters and paper separators is fixed and that it is ensured that the layers lie closely upon the other. This is achieved by tightly wrapping the NC membrane filters and the paper separators with the primary packaging.

Test results

9. Section 1 in Annex III shows the detailed result of the UN 1(a) test for sample No. 1 i.e. NC membrane filter UniSart® backed with PET film. The test result was “negative”. The tests with samples No. 2 to No. 5 showed all a “negative” test result: the steel tube was not fragmented completely, and no hole has been punched in the witness plate. The witness plate was only domed. The evaluation of BAM for all tested NC membrane filters was that they were considered not to be able to propagate a detonation, because neither the steel tube has been fragmented completely nor a hole has been punched in the witness plate.

10. 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. BAM has chosen the UN test N.1 to determine the burning rate of the NC membrane filters.

11. As the NC membrane filters are delivered in different configurations, these configurations were taken into account for the tests. Burning rate tests were performed using stampings for round filters, strips for NC membrane sheets and rolls as they were delivered.

12. In section 2 in Annex III the detailed test description and test results for the test with “NC membrane filter UniSart® CN140 backed (19501)” in the round filter configuration are given. The BAM evaluation for all five samples of NC membrane round filters described in the table in Annex II is that they are no flammable solids of class 4.1.

13. In section 3 in Annex III the detailed test description for the test with “NC membrane filter UniSart® CN140 backed (19501)” in the sheet configuration is given. NC membrane filters in sheet form are packed for transport closely together in cardboard boxes or plastic film with a paper separator between each sheet. To ensure that the UN test N.1 corresponds as closely as possible to this transport configuration, strips of 250 mm length (including paper separators between each NC membrane filter strip) were packed together as in the transport packaging. The burning times were determined for this configuration packed in cardboard or plastic film. For the NC membrane filter Type 114H6Z, the UN test N.1 was not performed with strips, as these are only transported in Leporello packaging. The BAM evaluation of tests with all four samples was that they are no flammable solids because the combustion did not propagate along the 200 mm measuring distance when packed in PET film as well as in cardboard.

14. In section 4 in Annex III the detailed description for the tests with NC membrane filter rolls is given. The BAM evaluation of a test with an NC membrane roll backed with a PET FILM with paper separators (UniSart® CN 140 backed (19501)) and a test with an NC membrane roll unbacked (UniSart® CN 140 unbacked (11301)) with paper separators is that both NC membranes on rolls are not flammable solids because the combustion did not propagate along the measuring distance and the burning rate was less than 2.2 mm/s.

15. The test results now presented in this document show, that it is possible to exclude a group of NC membrane filters from the division 4.1 flammable solids. Due to the COVID-19 pandemic not all tests for the definition of this group of NC membrane filters could be finalized before the deadline for submission of official documents for the summer 2022 session of the Sub-Committee. The complete set of test results will be presented in an additional informal document timely before the summer 2022 session.

Proposal

16. As stated above, not all tests for the definition of this group of NC membrane filters could be finalized before the submission deadline of official documents for the summer 2022 session. Cefic plans to present the complete set of test results and a proposal for a special provision for a clearly defined group of NC membrane filters, which can be excluded from the division 4.1 flammable solids in an additional informal document for consideration by the Sub-Committee.

17. If there are any questions concerning this document, please contact Werner Lange at: 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 summer 2022 session of the Sub-Committee.

Justification

18. 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. Cefic plans to present a complete set of test results for NC membrane filters timely before the forthcoming summer 2022 session of the Sub-Committee in an additional informal document. In that informal document a proposal for a special provision will be made for a defined group of NC membrane filters, that can be excluded from the transport division 4.1 flammable solids, which will simplify the transport of the NC membrane filters.

Annex I

Overview of NC membrane filter product packaging configurations

NC membrane flat filter sheets	
NC membrane filter rolls	
NC membrane round filters	
NC membrane filters in Leporello – package (A Leporello (fanfold) is a zigzag-folded endless packaging made of bags with individually packed round filters which are sealed and folded on top of each other)	

Annex II - Compilation of product configurations and test results

Sample	Product description		Configuration of product in primary packaging							Test configuration	Test results
	Name	Description	product dimension	NC weight per area [g NC/m ² membrane]	NC weight in primary packaging [g]	Backing? y/n	Thickness backing [µm]	Interleaf paper? y/n	Weight per area of interleaf paper [g/m ²]		
UN 1(a) test											UN 1(a) test
1	CN140 (19501) backed	NC membrane roll in plastic bag	25 mm x 100 m	40	100	y	100	y	80	400 mm stack of a diameter of Æ 38 mm cut outs	"_"
2	CN140 (11301) unbacked	NC membrane roll in plastic bag	25 mm x 100 m	37	92.5	n	-	y	80		"_"
3	11327-230-220-N	NC membrane sheets in cardboard box	L x W = 220 mm x 230 mm	53	268.2	n	-	y	80		"_"
4	13005-50-N	NC membrane round filters, 100 pieces in cardboard box	Æ 50 mm	46	9	n	-	y	80		"_"
5	114H6Z-50-SCM	NC membrane round filters, Leporello bags only	Æ 50 mm	44	9	n	-	Leporello			"_"
UN test N.1 - NC membrane round filter											UN-test N.1
1	CN140 (19501) backed	NC membrane roll in plastic bag	25 mm x 100 m	40	100	y	100	y	80	250 mm stack of Æ 38 mm cut outs	not class 4.1
2	CN140 (11301) unbacked	NC membrane roll in plastic bag	25 mm x 100 m	37	92.5	n	-	y	80		not class 4.1
3	11327-230-220-N	NC membrane sheets in cardboard box	L x W = 220 mm x 230 mm	53	268.2	n	-	y	80		not class 4.1
4	13005-50-N	NC membrane round filters, 100 pieces in cardboard box	Æ 50 mm	46	9	n	-	y	80		not class 4.1

5	114H6Z-50-SCM	NC membrane round filters, Leporello bags only	Æ 50 mm	44	9	n	-	Leporello			not class 4.1
UN test N.1 - NC membrane in sheet form											
1	CN140 (19501) backed	NC membrane roll in plastic bag	25 mm x 100 m	40	100	y	100	y	80	a) wrapped with cardboard	not class 4.1
										b) wrapped with PET foil	not class 4.1
2	CN140 (11301) unbacked	NC membrane roll in plastic bag	25 mm x 100 m	37	92.5	n	-	y	80	a) wrapped with cardboard	not class 4.1
										b) wrapped with PET foil	not class 4.1
3	11327-230-220-N	NC membrane sheets in cardboard box	L x W = 220 mm x 230 mm	53	268.2	n	-	y	80	a) wrapped with cardboard	not class 4.1
										b) wrapped with PET foil	not class 4.1
4	13005-50-N	NC membrane round filters, 100 pieces in cardboard box	Æ 5 mm	46	9	n	-	y	80	a) wrapped with cardboard	not class 4.1
										b) wrapped with PET foil	not class 4.1
UN-test N.1 - NC membrane on rolls											
1	CN140 (19501) backed	NC membrane roll in plastic bag	25 mm x 100 m	40	100	y	100	y	80	roll (20 mm x 100 m)	not class 4.1
2	CN140 (11301) unbacked	NC membrane roll in plastic bag	25 mm x 100 m	37	92.5	n	-	y	80		not class 4.1

Annex III

Detailed test results

Section 1 — UN 1(a) test description and test results

The following figure shows the result of the UN 1(a) test for sample 1 = NC membrane filter UniSart® backed with PET film.

	1. Trial	2. Trial
Mass of the sample:	377.1 g	374.6 g
Remained part of the steel tube:	16 cm	17 cm
Fragmented part of the steel tube:	24 cm	23 cm
Residue of the sample:	0*	0*
Witness plate:	Domed	Domed



Note*: Spread out in the test chamber

Evaluation of UN 1(a) test by BAM: The sample “NC membrane filter type UniSart® CN 140 backed (19501)” is considered not be able to propagate a detonation, because neither the steel tube has been fragmented completely nor a hole has been punched in the witness plate.

BAM evaluation of UN 1(a) test for samples 2 to 5: The samples 2 to 5 are considered not be able to propagate a detonation, because neither the steel tube has been fragmented completely nor a hole has been punched in the witness plate

Section 2 — UN test N.1 description and test results for the tests with round filters



The NC membrane round filters were fixed with their paper separators, as they are configured for transport in a holding device to get a measuring distance of 250 mm. They were ignited and the burning speed was measured.

Test results for “NC membrane filter UniSart® CN140 backed (19501)”

In the preliminary test the round filters could be ignited after 43 seconds, but the flame went out after 42 minutes without propagating the combustion along the necessary measuring distance of 200 mm. Due to the clear result, the main test could be waived.

BAM evaluation of this UN test N.1: The sample “NC membrane filter type UniSart® CN140 backed (19501)” is not a flammable solid because the combustion did not propagate along the 200 mm measuring distance.

BAM evaluation of UN test N.1 for samples 2 to 5: The samples are not a flammable solid because in the preliminary screening tests the burning time for propagation of the combustion along the 200 mm measuring distance was longer than 2 minutes.

Section 3 — UN test N.1 with strips from NC membrane filters in sheet form

NC membrane filters are also transported in sheets, which are packed closely together in cardboard or plastic film, with an interleaf layer between each sheet.

To ensure that the UN test N.1 corresponds as closely as possible to this configuration, strips of 250 mm length (including interleaf papers between each NC membrane filter strip) were packed together as in the transport packaging. The burning times were determined for this configuration packed in cardboard or plastic film.

The UN test N.1 was not performed with strips of the NC membrane filter type 114HZ because these are transported only in Leporello packaging.



Stripes packed in PET film



Stripes packed in cardboard

Test result for “NC membrane filter type UniSart® CN 140 backed (19501)” (223/090921/07)

The NC membrane filters packed in PET film (with interleaf paper) could be ignited in the preliminary screening test, but the flame went out after 2 minutes without propagating the combustion along the measuring distance of 200 mm.

The NC membrane filters packed in cardboard (with interleaf paper) could be ignited in the preliminary screening test, but the flame went out after 30 seconds without propagating the combustion along the measuring distance of 200 mm.

As the result was quite clear, the main test could be waived for both configurations.

BAM evaluation of UN test N.1: The sample “NC membrane filter type UniSart® CN140 backed (19501)” is not a flammable solid because the combustion did not propagate along the 200 mm measuring distance when packed in PET film as well as packed in cardboard.

BAM evaluation of UN tests N.1 with sample 2 to 4: The samples 2 to 4 are not flammable solids because the combustion did not propagate along the 200 mm measuring distance when packed in PET film as well as packed in cardboard.

Section 4 — UN test N.1 with NC membrane filters in roll form

NC membrane filters are also shipped in big quantities in rolls with paper separators between each layer of NC membrane filter, for example for COVID-19 rapid test devices. For this reason, the UN test N.1 was also performed with NC membrane filters in roll form.

Test with “NC membrane filter type UniSart® backed (19501)”

For this NC membrane sample (No.1) a preliminary test was performed with strips, by cutting strips of 250 mm length from a roll of the same NC membrane material with a width of 20 mm. These strips were then stacked together with paper separators between each NC membrane strip until a height of 10 mm was reached. Then they were tightly wrapped in PET film or cardboard.

In this preliminary screening test, it was not possible to maintain a measuring distance of 200 mm with NC membrane filters from the rolls.

Trial 1:



The NC membrane roll was ignited on one side with a gas flame (measuring distance 198 mm), after 54 seconds the flame went out, over a measuring distance of 52 mm the NC membrane filter was carbonized. The burning time for the measuring distance of 52 mm was 126 seconds, resulting in a burning rate of 0.41 mm/s.

Trial 2:



The roll was ignited on one side with a gas flame (measuring distance 65 mm corresponds to the radius of the roll), after 28 seconds the flame went out, over a measuring distance of 52 mm the NC membrane filter was carbonized. The burning time for the measuring distance of 52 mm was 189 seconds, resulting in a burning rate of 0.28 mm/s.

BAM evaluation of UN test N.1 for sample 1:

The sample “NC membrane filter UniSart® CN 140 backed (19501)” on rolls is not a flammable solid because the combustion did not propagate along the 198 mm or 65 mm measuring distance, respectively, the burning rate is less than 2.2 mm/s.

For the sample 2 “NC membrane filter UniSart® CN 140 unbacked (11301)” on rolls also an UN test N.1 with an ignition with a gas flame from one side was performed.

BAM evaluation of UN tests N.1 for sample 2:

The sample “NC membrane filter UniSart® CN 140 unbacked (11301)” on rolls is not a flammable solid because the combustion did not propagate along the 160 mm or 65 mm measuring distance, respectively, the burning rate is less than 2.2 mm/s.