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Dentistry — Chairside denture base relining materials —

Part 1: Hard type materials

Médecine bucco-dentaire — Matériaux de rebasage pour base de prothèses dentaires —

Partie 1: Matériaux durs

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 2, *Prosthodontic materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 23401 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The purpose of denture base relining materials is to improve the fit of dentures to the oral mucosa. The materials can reline the denture the same day. Thus, they can be a useful material for the general denture patients and especially for bedridden patients who may have no access to dental surgery.

Requirements and test methods for the soft type materials are defined in detail by ISO 10139-1 and ISO 10139-2, but it is extremely difficult to incorporate the hard type materials in these International Standards of soft lining materials because of the differences in the main components, curing mechanisms and physical properties.

Also, chairside denture base relining materials and denture base materials covered by ISO 20795-1 and ISO 20795-2 differ in terms of polymerization method and required properties. As chairside denture base relining materials are partially or even mainly handled intraorally, properties such as consistency and exothermicity during intra-oral polymerization are quite important.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

Dentistry — Chairside denture base relining materials —

Part 1:
Hard type materials

1 Scope

This document specifies the requirements for acrylic hard type materials used as chairside denture base relining materials and the test methods to determine compliance with these requirements. This document also specifies requirements for packaging and marking the products and for the instructions for use to be supplied by the manufacturer.

Dentures which are relined by chairside denture base relining materials specified by this document are limited to those of acrylic.

This document is not applicable to either denture base relining materials that are for laboratory use or soft lining materials.

NOTE 1 Acrylic hard type materials contain acrylic and methacrylic monomers such as acrylic acid esters and substituted (meth)acrylic acid esters and their polymers.

NOTE 2 Acrylic dentures are made of polymers such as poly (acrylic acid esters), poly (substituted acrylic acid esters) and rubber-modified poly (methacrylic acid esters).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 4545-1, *Metallic materials — Knoop hardness test — Part 1: Test method*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 20795-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
chairside denture base relining
denture base relining where the relining material is moulded and partially or completely polymerized intraorally

3.2
peak temperature
maximum temperature during polymerization

4 Classification

4.1 Types

The chairside denture base relining materials are classified into the following types in accordance with their methods of polymerization.

— Type 1: materials whose setting is affected by mixing initiator(s) and activator(s) ("self-curing" materials);

— Type 2: materials whose setting is affected by the application of light from an external source ("light-curing" materials);

— Type 3: materials whose setting is affected by mixing initiator(s) and activator(s) and also by the application of light from an external source ("dual-curing" materials).

4.2 Classes

The chairside denture base relining materials are classified into the following classes in accordance with material form.

— Class 1: powder and liquid;

— Class 2: paste;

— Class 3: sheet.

5 Requirements

5.1 Appearance

5.1.1 Liquid

The liquid shall be homogeneous when tested in accordance with 6.4.1. The liquid shall be free of deposits or sediment.

5.1.2 Powder, paste and sheet

The powder, paste and sheet shall not contain extraneous materials when tested in accordance with 6.4.1. Separation of liquid (e.g. monomer) shall not be observed in the paste or sheet when tested in accordance with 6.4.

5.2 Consistency

The diameter of the compressed mixture of Class 1 or Class 2 materials shall be from 30 mm to 60 mm when tested in accordance with 6.5.

5.3 Peak temperature

The peak temperature of the Type 1 and Type 3 materials shall not be more than 60 °C when tested in accordance with 6.6.

5.4 Porosity and defects

The cured chairside denture base relining materials shall not have porosities or defects that can be easily identified when tested in accordance with 6.4.2.

5.5 Surface finish

The cured chairside denture base relining materials shall have a glossy surface when tested in accordance with 6.4.3.

5.6 Water sorption

The water sorption shall not be more than 32 µg/mm^3 when the cured chairside denture base relining material is tested in accordance with 6.7.

5.7 Water solubility

The water solubility shall not be more than 8,0 µg/mm^3 when the cured chairside denture base relining material is tested in accordance with 6.7.

5.8 Knoop hardness

The Knoop hardness of the cured chairside denture base relining materials shall not be less than 7 HK 0,1 /20 (load / dwell time) when tested in accordance with 6.8.

6 Test methods

6.1 Sampling

The test sample shall consist of a retail package, or packages, from the same batch and enough amount of the material to carry out the specified tests with an allowance for any repeat tests (approximately 60 ml).

6.2 Preparation of test specimens

Prepare the test specimens in accordance with the manufacturer's instructions for use. For Class 1 materials, vibration may be applied for 15 s or less to remove porosity immediately after mixing, if necessary.

6.3 Conditions for testing

Unless specified otherwise by the manufacturer or in this document, prepare and test all specimens at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 20) %. Leave the chairside denture base relining material and test apparatus at a temperature of (23 ± 2) °C for 2 h or longer before testing, unless specified otherwise.

Leave the accessories used for fabrication of the test specimens under the same conditions for 30 min or longer before use.

6.4 Visual inspection

6.4.1 Appearance

Visually inspect the test sample of the liquid, powder, paste or sheet without magnification to determine compliance with the requirements (5.1.1 and 5.1.2).

6.4.2 Porosity and defects

Visually inspect the test specimen prepared in accordance with 6.7.3 without magnification to determine compliance with the requirements (5.4).

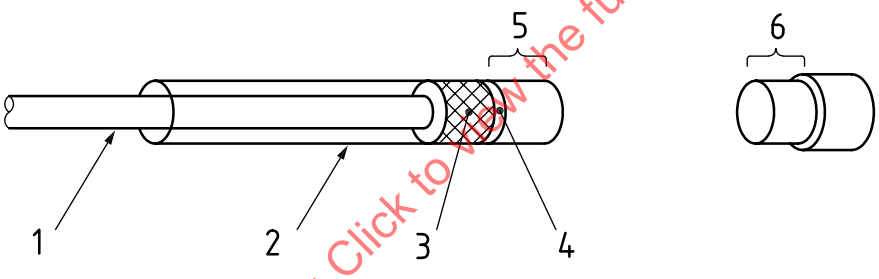
6.4.3 Surface finish

Visually inspect the test specimen prepared in accordance with 6.8.2 to determine compliance with the requirements (5.5).

6.5 Consistency

6.5.1 Apparatus

6.5.1.1 Sampling instrument, capable of measuring and collecting 0,5 ml of uncured material in a mixture of an appropriate amount (e.g. Figure 1).



Key

1 plunger
2 plastic (polyethylene or polypropylene) or glass tube
3 rubber plug
4 plastic (polyethylene or polypropylene) film
5 (0,5 ± 0,05) ml volume
6 plug gauge of (0,5 ± 0,05) ml volume

Figure 1 — Apparatus for measuring consistency

6.5.1.2 Unplasticized sheets (polyester, polyethylene, or polypropylene), having a thickness of (50 ± 25) µm.

6.5.1.3 Glass plate, with dimensions of approximately 70 mm × 70 mm and a thickness of 1 mm.

6.5.1.4 Plate for pressure, with dimensions of approximately 70 mm × 70 mm and made of glass or metal.

6.5.1.5 Weight, with a mass of 750 g including the plate for pressure.

6.5.2 Procedure

Prepare enough amount of material using the method specified by the manufacturer, collect (0,5 ± 0,05) ml using the sampling instrument (6.5.1.1) and place it on the central part of the lower glass plate (6.5.1.3) covered with an unplasticized sheet (6.5.1.2).

After 2 min from the start of mixing, gently place another unplasticized sheet and the plate for pressure (6.5.1.4) on top of the sample, then place the weight (6.5.1.5) centrally on the plate for a total mass of 750 g and apply for 5 min.

After removing the weight, measure the diameter values of the obtained disc-like sample in four directions at intervals of approximately 45° and calculate the mean of these values and make it the sample diameter.

Perform this test three times. When the consistency of at least two specimens fulfil the requirement (5.2), the material complies.

6.6 Peak temperature

6.6.1 Apparatus

6.6.1.1 Unplasticized sheet (polyester, polyethylene, or polypropylene), having a thickness of (50 ± 25) µm.

6.6.1.2 Two glass plates, with dimensions of approximately 100 mm × 80 mm × 6 mm.

6.6.1.3 Temperature measuring equipment, using a calibrated thermocouple and potentiometer for monitoring the temperature.

6.6.1.4 Circular stainless steel ring, with a notch in which a thermocouple can be placed, with an inner diameter of (60 ± 0,1) mm, an outer diameter of (67 ± 0,1) mm, a height of (2 ± 0,1) mm, and a notch depth of (1 ± 0,1) mm.

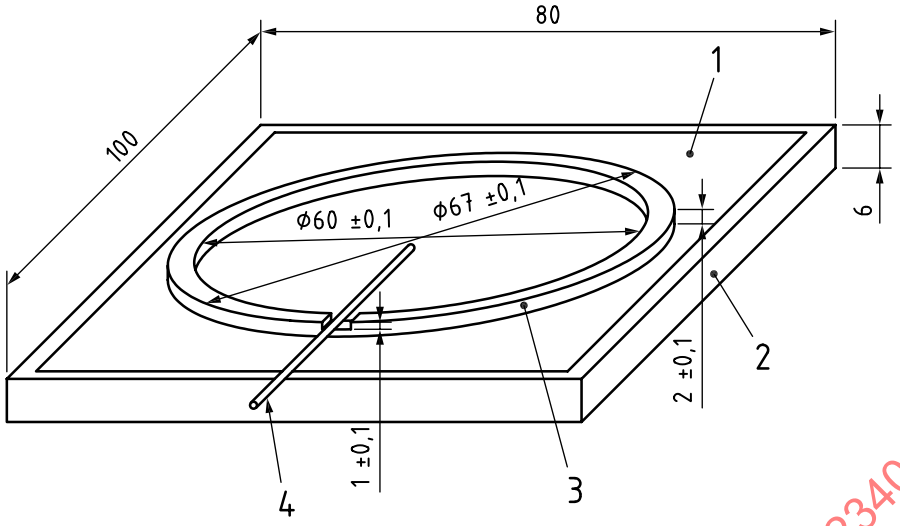
6.6.1.5 Thermocouple, consist of wires 0,1 mm to 1,0 mm in diameter, made of a material (e.g. copper/copper-nickel alloy) capable of registering temperature changes in a specimen of setting material to an accuracy of 0,1 °C.

6.6.2 Procedure

Place one of the glass plates (6.6.1.2) in an oven at (37 ± 2) °C at least 2 h before the start of testing.

Place the unplasticized sheet (6.6.1.1) on the first glass plate (6.6.1.2) that has been kept at (23 ± 2) °C and place the ring (6.6.1.4) in the centre of it. Place the thermocouple (6.6.1.3) so that it is positioned in the centre of the ring (see Figure 2).

Dimensions in millimetres



Key

1 unplasticized sheet
2 glass plate
3 circular stainless steel ring
4 thermocouple

Figure 2 — Apparatus for measuring the peak temperature

Prepare the material using the method specified by the manufacturer and place the material into the ring at a temperature of (23 ± 2) °C, while applying vibration as necessary. Cover the ring with the unplasticized sheet and the second glass plate that has been kept at (37 ± 2) °C. Remove excess resin that has overflowed outside the ring.

NOTE The mixing time of Class 1 material is the middle time recommended by the manufacturer.

Insert and maintain this assembly (material, glass plates, unplasticized sheets, ring and thermocouple) at a temperature of (37 ± 2) °C within 1 min to 1,5 min after the start of mixing the material. Thereafter measure the temperature from 2 min after the start of mixing the material, until 2 min after the peak temperature is reached, and record the peak temperature to an accuracy of 0,5 °C.

The process of insertion of the assembly into the oven should be done within 10 s, and temperature in the open oven should be at least 30 °C.

Perform this test three times. When the peak temperature in at least two measurements fulfil the requirement (5.3), the material complies.

6.7 Water sorption and solubility

6.7.1 Materials

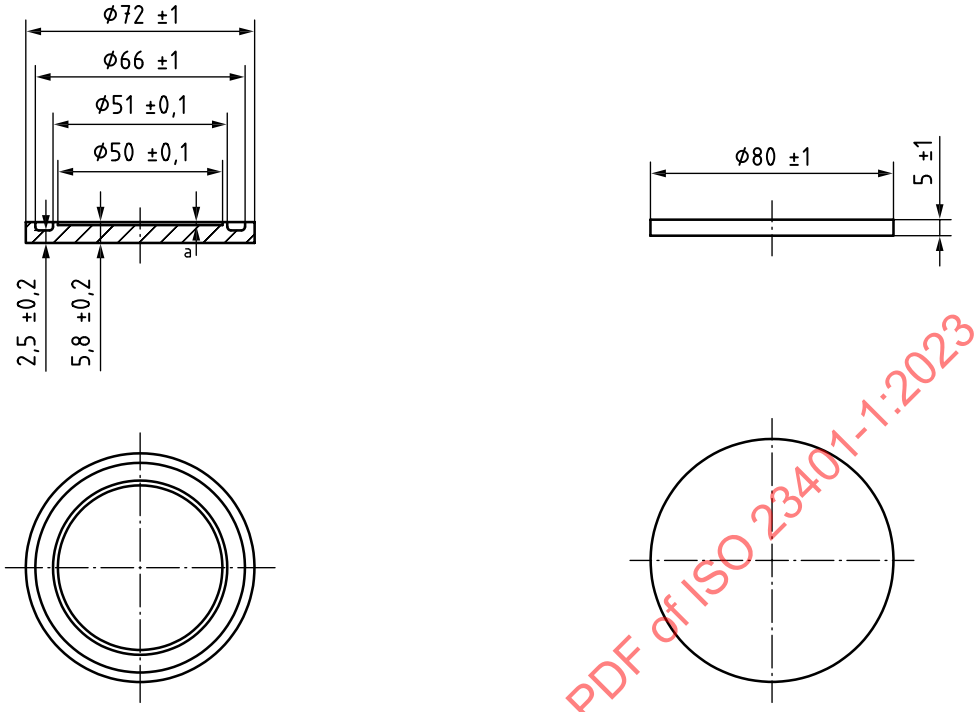
6.7.1.1 Silica gel, freshly dried in accordance with manufacturer's instructions for use or for (300 ± 10) min at (130 ± 5) °C.

6.7.1.2 Water, complying with grade 2 of ISO 3696:1987.

6.7.2 Apparatus

6.7.2.1 Circular stainless steel mould and cover, having the dimensions shown in Figure 3.

Dimensions in millimetres



a) Mould **b) Cover**

[a] Mould depth (0,5 ± 0,1) mm to form specimen.

Figure 3 — Stainless steel mould and cover for specimen preparation for water sorption and solubility

6.7.2.2 Circular stainless steel ring, with an inner diameter of (50 ± 0,1) mm and thickness of (0,5 ± 0,1) mm, and glass plates (6.6.1.2).

6.7.2.3 Unplasticized sheet (polyester, polyethylene, or polypropylene), having a thickness of (50 ± 25) µm.

6.7.2.4 Micrometer or dial caliper, accurate to 0,01 mm and fitted with parallel anvils.

6.7.2.5 Rack, to keep the specimens parallel and separated.

6.7.2.6 Two desiccators.

6.7.2.7 Oven, maintained at (37 ± 1) °C.

6.7.2.8 Polymer-coated tweezers.

6.7.2.9 Towel, clean and dry.

6.7.2.10 Analytical balance, accurate to 0,1 mg.

6.7.3 Preparation of test specimens

Prepare the material in accordance with the instructions for use specified by the manufacturer. Use either the mould and cover (6.7.2.1) or the steel ring (6.7.2.2) to prepare the specimen. Place the material immediately into the mould (6.7.2.1) or ring (6.7.2.2) with the unplasticized sheets (6.7.2.3) and glass plate to a slight excess, avoiding air inclusions. Place an unplasticized sheet onto the material in the mould or ring and cover this with cover or glass plate. Retain the unplasticized sheets during the processing cycle.

— For Type 1 materials: Polymerize the Type 1 material at (37 ± 2) °C for the curing time specified by the manufacturer.

— For Type 2 and Type 3 materials: Polymerize the Type 2 or Type 3 material by the method specified by the manufacturer and the instructions for use regarding the use of the external energy source(s).

Check with a micrometer or dial caliper (6.7.2.4) to ensure that each specimen has a diameter of (50 ± 1) mm and a thickness of (0,5 ± 0,1) mm and that the top and bottom surfaces are flat.

Make five specimens.

6.7.4 Procedure

6.7.4.1 Conditioned specimens

Place the specimens in the rack (6.7.2.5) inside one of the desiccators (6.7.2.6) containing freshly dried silica gel (6.7.1.1). Store the desiccator in the oven (6.7.2.7) at (37 ± 1) °C for (23 ± 1) h and then remove the desiccator from the oven.

Transfer the specimens kept in the rack directly to the second desiccator which has been supplied with freshly dried silica gel. Keep the second desiccator at (23 ± 2) °C. After (60 ± 10) min in the second desiccator, the specimens are ready for weighing.

Use an analytical balance (6.7.2.10) to weigh the specimen to an accuracy of 0,1 mg. Keep the desiccators sealed except for the shortest possible period required for removing and replacing specimens. After all the specimens have been weighed, replace the silica gel in the first desiccator with freshly dried gel and place the first desiccator with the rack with the specimens in the oven.

Repeat the cycle described until a constant mass, m_1, to be called the "conditioned mass", is reached, i.e. until the loss in mass of each specimen is not more than 0,2 mg between successive weighing.

After final drying, take three measurements of the diameter with micrometer or dial caliper (6.7.2.4), at the angle of 120° to each other, to an accuracy of 0,01 mm and calculate the mean diameter. Measure the thickness of the specimen with a micrometer or dial caliper (6.7.2.4) to an accuracy of 0,01 mm at the centre of the specimen and at four equally spaced points on the circumference. Calculate the area, in square millimetres, from the mean diameter and then, using the mean thickness, calculate the volume, V, in cubic millimetres.

6.7.4.2 Wet specimens

Immerse the conditioned specimen in 100 ml water (6.7.1.2) at (37 ± 1) °C for 7 d. After this time, remove the discs from the water with polymer-coated tweezers (6.7.2.8), wipe with a clean, dry towel (6.7.2.9) until free from visible moisture, wave in the air for (15 ± 1) s and weigh (60 ± 10) s after removal from the water to an accuracy of 0,1 mg. Record the mass as m_2.

6.7.4.3 Reconditioned specimens

After this weighing, recondition the specimens to constant mass in the desiccator as described in 6.7.4.1. Record the mass of the "reconditioned" specimens as m_3.

It is essential that the same conditions be applied as for the first drying process, using the same number of specimens and the freshly dried silica gel in the desiccators.

6.7.5 Calculation and expression of results

6.7.5.1 Water sorption

Calculate the value for the water sorption, W_{sp}, for each of the five specimens, expressed in micrograms per cubic millimetre (µg/mm^3), using the Formula (1):

$$W_{sp} = (m_2 - m_3) / V \quad (1)$$

where

m_2 is the mass of the specimen, in micrograms (µg), after immersion in water;

m_3 is the reconditioned mass of the specimen, in micrograms (µg);

V is the volume of the specimen, in cubic millimetres (mm^3).

Round off the values calculated for water sorption to the nearest micrograms per cubic millimetre (µg/mm^3).

6.7.5.2 Water solubility

Calculate the value for the water solubility, W_{sl}, for each of the five specimens, expressed in micrograms per cubic millimetre (µg/mm^3), using the Formula (2):

$$W_{sl} = (m_1 - m_3) / V \quad (2)$$

where

m_1 is the conditioned mass of the specimen, in micrograms (µg);

m_3 is the reconditioned mass of the specimen, in micrograms (µg);

V is the volume of the specimen, in cubic millimetres (mm^3).

Round off the values calculated for water sorption to the nearest 0,1 µg/mm^3.

6.7.5.3 Conformity evaluation

Calculate the water sorption and the water solubility for five specimens respectively.

When the water sorption or the water solubility of at least four specimens fulfil the requirement (5.6 or 5.7), the material complies.

6.8 Knoop hardness

6.8.1 Apparatus

6.8.1.1 Circular stainless steel ring, with an inner diameter of (30 ± 2) mm and thickness of (1,5 ± 0,2) mm.

6.8.1.2 Abrasive paper, P600 in accordance with ISO 6344-3.

6.8.1.3 Abrasive paper, between P1200 and P1500 in accordance with ISO 6344-3.

6.8.2 Preparation of test specimens

Prepare three test specimens using the ring (6.8.1.1) and the procedure of 6.7.3. Polish the surfaces of the test specimens with the abrasive paper (P600) (6.8.1.2) and then with abrasive paper (between P1200 and P1500) (6.8.1.3), and then, smooth the surface using 0,3 µm alumina powder. Store the specimens dark at room temperature.

6.8.3 Procedure

Perform the test (24 ± 3) h after the preparation of the test specimens. Measure the Knoop hardness at 10 points for each test specimen using 0,1 kg load and 20 s dwell time in accordance with ISO 4545-1. Calculate the mean value for the 10 measurement values for each of three test specimens.

The indention points should be equally spread out on the test surface and should not be close to the circumference of the specimen.

Test three specimens.

When the Knoop hardness of at least two specimens fulfil the requirement (5.8), the material complies.

7 Requirement for packaging, marking and instructions supplied by the manufacturer

7.1 Packaging

The components shall be supplied in sealed containers made of materials that shall neither contaminate, nor permit contamination of the contents. The immediate containers shall be packaged so as to prevent damage or leakage during transit and storage.

An outer package may be used to present the containers as a single unit.

7.2 Marking and manufacturer's instructions for use

The outer packages and the immediate containers or wrappings of the components shall be clearly marked with the information given in Table 1.

If the size of the immediate container or package is too small to fit the required information, reference shall be made on the outer package to a leaflet inside where the additional information shall be provided.

Instructions for use shall accompany each package and, shall at a minimum include the information given in Table 1.

Table 1 — Requirements for marking and manufacturer's instruction

	Requirement	Outer package and immediate containers	Manufacturer's instruction
1	The trade name of the product	M	M
2	The manufacturer's name or trademark and address, or those of the agent in the country of sale	M	M
3	The Type and Class of material, as determined in accordance with 4.1 and 4.2	M	M
4	The colour of the material (if the material has multiple colours)	M	M
Key			
M : mandatory			
/ : no relevance for this combination of container/marking/instructions or that requirement would be impracticable or impossible or that the information can be informative but optional			