Designation: D7198 – 05 (Reapproved 2012)

# Standard Specification for Disposable Embalming Gloves for Single-Use Applications[1]

This standard is issued under the fixed designation D7198; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This specification covers certain requirements for natural rubber (Latex), synthetic rubber (Polychloroprene and Nitrile), and vinyl (PVC) disposable gloves for use in conducting single-use embalming procedures.

1.2 This specification covers natural rubber (Latex), synthetic rubber (Polychloroprene and Nitrile), and Vinyl (PVC) disposable gloves that fit either hand, paired gloves, gloves by size, and gloves packed in bulk.

1.3 An assessment to measure the chemical resistance performance of the glove can be made based on the ultimate permeation (breakthrough) of embalming chemicals through the glove material over a specified period of time.

1.4 This specification is similar to the following specifications: D3578, D4679, D5250, D6319, and D6977.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

D3578 Specification for Rubber Examination Gloves

D3767 Practice for Rubber—Measurement of Dimensions

D4679 Specification for Rubber General Purpose, Household or Beautician Gloves

D5151 Test Method for Detection of Holes in Medical Gloves

D5250 Specification for Poly(vinyl chloride) Gloves for Medical Application

D5712 Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method

D6124 Test Method for Residual Powder on Medical Gloves

D6319 Specification for Nitrile Examination Gloves for Medical Application

D6499 Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

D6977 Specification for Polychloroprene Examination Gloves for Medical Application

F739 Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact

2.2 *ISO Standard:*

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes[3]

2.3 *Other Document:*

U.S. Pharmacopeia[4]

## 3. Significance and Use

3.1 This specification is intended to be a specification for evaluating the performance and quality of disposable natural rubber, synthetic rubber, and vinyl (PVC) gloves for single-use embalming applications.

3.2 The safe and proper use of disposable natural rubber, synthetic rubber (polychloroprene and nitrile), and vinyl gloves is beyond the scope of this specification.

3.3 The chemical permeation tests described in this specification are intended to be "Type Tests" for these types of gloves.

3.3.1 The chemical permeation tests are not intended to be testing instructions nor testing protocols to be used for routine lot release.

[1] This specification is under the jurisdiction of ASTM Committee D11 on Rubber and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] *U. S. Pharmacopeia*, latest edition, Mack Publishing Co., Easton, PA 19175.

## 4. Materials and Manufacture

4.1 Any natural rubber, synthetic rubber, and plastic polymer compound may be used that permits the glove to meet the requirements of this specification.

4.2 A lubricant that meets the current requirements of the U.S. Pharmacopoeia for absorbable dusting powder may be applied to the glove. Other lubricants may be used if their safety and efficacy have been previously established.

4.3 The inside and outside surface of the natural rubber, synthetic rubber, and plastic disposable gloves shall be free of talc.

## 5. Sampling

5.1 For referee purposes, gloves shall be sampled from finished product and inspected in accordance with ISO 2859. The inspection levels and acceptable quality levels (AQL) shall conform to those specified in Table 1, or as agreed upon between the purchaser and the seller, if the latter is more comprehensive.

## 6. Performance Requirements

6.1 Gloves shall be sampled in accordance with Section 5.

6.2 Gloves shall meet the referee performance requirements as described in Table 1.

6.2.1 Shall comply with freedom from holes when tested in accordance with 7.2.

6.2.2 Have consistent physical dimensions in accordance with 7.3.

6.2.3 Have acceptable physical property characteristics in accordance with 7.4.

6.2.4 Powder-free gloves shall have a recommended maximum powder residue limit of 2.0 mg per glove in accordance with 7.5 and A2.1.

6.2.5 Powdered gloves shall have a recommended maximum powder limit of 10 mg/dm$^2$ in accordance with 7.6 and A2.2.

**TABLE 1 Quality Performance and Barrier Property Requirements: Natural Rubber (Latex), Synthetic Rubber (Polychloroprene and Nitrile), and Vinyl (PVC)**

| Characteristic | Related Defects | Inspection Level | AQL |
|---|---|---|---|
| Freedom from holes | holes | G-1 | 2.5 |
| Dimensions | width, length, thickness | S-2 | 4.0 |
| Physical properties | before aging, after accelerated aging | S-2 | 4.0 |
| Powder-free residue | exceeds recommended maximum limit per Annex A2.1 | N=5 | N/A |
| Powder amount | exceeds recommended maximum limit per Annex A2.2 | N=2 | N/A |
| Protein content (Latex only) | exceeds recommended maximum limit per Annex A1 | N=3 | N/A |
| Antigenic protein (Latex only) | exceeds recommended maximum limit per Annex A3 | N=1 | N/A |
| Permeation | steady-state is reached maximum rate is reached permeation at increased rate | N=3 | N/A |

6.2.6 Have a recommended aqueous soluble protein content limit of 200 µg/dm$^2$ in accordance with 7.7 and Annex A1 or have a recommended antigenic protein content limit of 10 µg/dm$^2$ in accordance with 7.8 and Annex A3.

## 7. Test Methods

7.1 The following tests shall be conducted to ensure the requirements of Section 8 are met, as prescribed in Table 1.

7.2 *Freedom from Holes*—Testing for freedom from holes shall be conducted in accordance with Test Method D5151.

7.3 *Physical Dimensions Test:*

7.3.1 The gloves shall comply with the dimension requirements prescribed in Tables 2-4.

7.3.2 The length shall be expressed in millimeters as measured from the outside tip of the middle finger to the outside edge of the cuff.

7.3.3 The width of the palm shall be expressed in millimeters as measured at a level between the base of the index finger and the base of the thumb. Values of width per size other than listed shall meet the stated tolerance specified in Tables 2-4.

7.3.4 The minimum finger, palm, and cuff thicknesses shall be expressed in millimeters as specified in Tables 2-4 when using a dial or digital micrometer that meets requirements described in Test Methods D412 and Practice D3767, and in the locations indicated in Fig. 1. For referee tests, cutting the glove is necessary to obtain single-wall thickness measurements. (See Practice D3767 for more information.)

7.4 *Physical Requirements Test:*

7.4.1 Before and after accelerated aging, the gloves shall conform to the physical requirements specified in Tables 5-9. Tests shall be conducted in accordance with Test Methods D412.

7.4.2 *Accelerated Aging*—The gloves shall be aged in accordance with Test Method D573. Test the gloves in accordance with the following methods:

7.4.3 After being subjected to a temperature of 70 ± 2°C for 166 ± 2 h, the tensile strength and ultimate elongation shall not be less than the values specified in Tables 5-9. This method shall be the conditions for referee tests.

7.4.4 Or, after being subjected to a temperature of 100 ± 2°C for 22 ± 0.3 h (if validated by manufacturer), the tensile strength and ultimate elongation shall not be less than the values specified in Tables 5-9.

7.5 *Powder Free Gloves:*

7.5.1 Determine the powder residue for powder-free gloves using Test Method D6124.

7.5.2 The powder residue shall not exceed the recommended average powder mass referenced in A2.1 when tested in accordance with Test Method D6124 for powder-free gloves.

7.6 *Powdered Gloves:*

7.6.1 Determine the powder amount for powdered gloves using Test Method D6124.

7.6.2 The powder amount shall not exceed the recommended average powder mass referenced in A2.2 when tested in accordance with Test Method D6124 for powdered gloves.

7.6.3 Determine the square decimeters for the glove size as described in section 7.7.3 or 7.7.3.1.

**TABLE 2 Dimensions and Tolerances: Natural Rubber (Latex)**

NOTE 1—Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes, for example, small/medium and medium/large.

| Designation | Size | | | | | | | Tolerance, mm |
|---|---|---|---|---|---|---|---|---|
| | 6 | 6½ | 7 | 7½ | 8 | 8½ | 9 | |
| Width by size, mm | 75 | 83 | 89 | 95 | 102 | 108 | 114 | ±6 |
| Width by label, | X-small | small | Unisize | medium | large | X-large | XX-large | |
| mm | 70 | 80 | 85 | 95 | 110 | 120 | 130 | ±10 |
| Length | 240 | 240 | 240 | 240 | 240 | 240 | 240 | Min |
| Thickness, mm | | | | For All Sizes | | | | |
| Finger | | | | 0.08 | | | | Min |
| Palm | | | | 0.08 | | | | Min |
| Cuff | | | | 0.08 | | | | Min |

**TABLE 3 Dimensions and Tolerances: Synthetic Rubber (Polychloroprene and Nitrile)**

NOTE 1—Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes, for example, small/medium and medium/large.

| Designation | Size | | | | | | | Tolerance, mm |
|---|---|---|---|---|---|---|---|---|
| | 6 | 6½ | 7 | 7½ | 8 | 8½ | 9 | |
| Width by size, mm | 75 | 83 | 89 | 95 | 102 | 108 | 114 | ±6 |
| Width by label, | X-small | small | Unisize | medium | large | X-large | XX-large | |
| mm | 70 | 80 | 85 | 95 | 110 | 120 | 130 | ±10 |
| Length | 240 | 240 | 240 | 240 | 240 | 240 | 240 | Min |
| Thickness, mm | | | | For All Sizes | | | | |
| Finger | | | | 0.05 | | | | Min |
| Palm | | | | 0.05 | | | | Min |
| Cuff | | | | 0.05 | | | | Min |

**TABLE 4 Dimensions and Tolerances: Vinyl (PVC)**

NOTE 1—Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes, for example, small/medium and medium/large.

| Designation | Size | | | | | | | Tolerance, mm |
|---|---|---|---|---|---|---|---|---|
| | 6 | 6½ | 7 | 7½ | 8 | 8½ | 9 | |
| Width by size, mm | 75 | 83 | 89 | 95 | 102 | 108 | 114 | ±6 |
| Width by label, | X-small | small | Unisize | medium | large | X-large | XX-large | |
| mm | 70 | 80 | 85 | 95 | 110 | 120 | 130 | ±10 |
| Length | 240 | 240 | 240 | 240 | 240 | 240 | 240 | Min |
| Thickness, mm | | | | For All Sizes | | | | |
| Finger | | | | 0.05 | | | | Min |
| Palm | | | | 0.08 | | | | Min |
| Cuff | | | | 0.05 | | | | Min |

7.7 *Aqueous Extractable Protein Content:*

7.7.1 Determine the aqueous extractable protein (µg/mL) using Test Method D5712 for each glove sample tested.

7.7.2 Determine the total µg of aqueous extractable protein in each glove sample by multiplying the result from 7.7.1 by the total volume of extractable used for that specific glove sample. If the glove sample is less than a whole glove, then adjust the protein results to reflect the amount of protein in the whole glove.

7.7.3 Determine the surface area for each glove sample tested, by size, in square decimeters. To do so, multiply the actual length (mm) and actual width (mm) found on each glove and convert to $dm^2$ using the following equation: $(dm^2/mm^2)$ $(mm^2/10\ 000)$. Four (4) is the factor for all inside and outside surface areas.

7.7.3.1 The applied surface area by glove size shall be determined by taking the average surface areas of the gloves measured by size.

7.7.4 Determine the aqueous extractable protein content of a glove sample by dividing the result from 7.7.2 (total of µg of Protein) by 7.7.3 (total surface area of the glove.)

7.7.5 If the sample is more than one (1) glove, use the average $\mu g/dm^2$ of protein for the number of gloves tested in the sample.

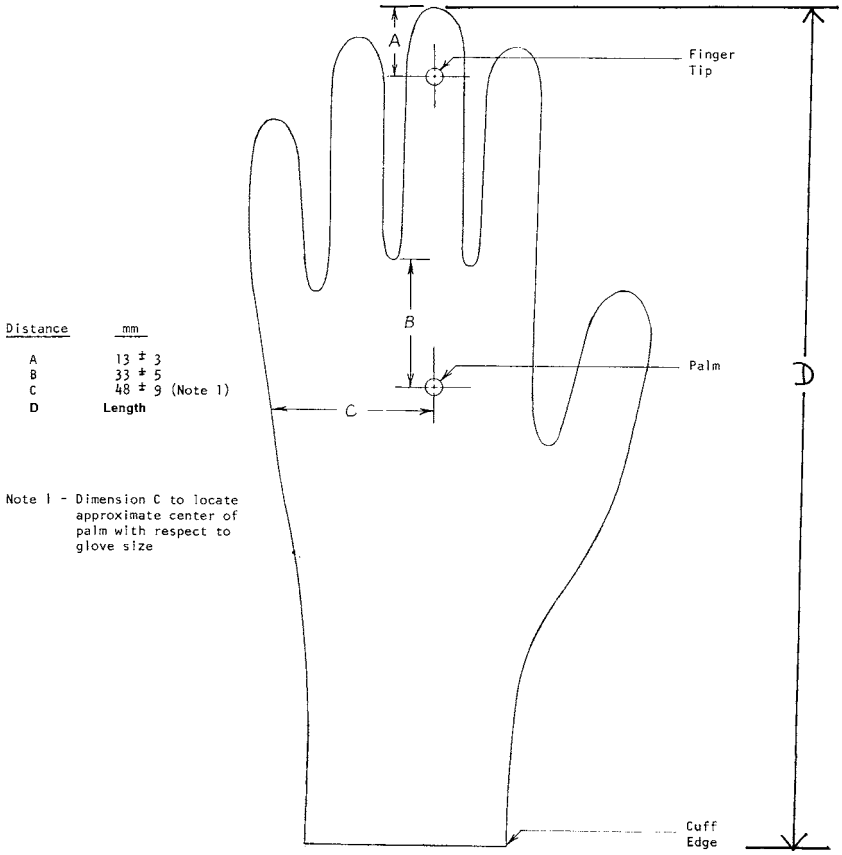


**FIG. 1 Location of Thickness and Length Measurements**

**TABLE 5 Physical Requirements for Natural Rubber (Type I)**

| Before Aging | | After Accelerated Aging | |
|---|---|---|---|
| Tensile Strength | Ultimate Elongation | Tensile Strength | Ultimate Elongation |
| 18 MPa min | 650 % min | 14 MPa min | 500 % min |

**TABLE 6 Physical Requirements for Natural Rubber (Type II)**

| Before Aging | | After Accelerated Aging | |
|---|---|---|---|
| Tensile Strength | Ultimate Elongation | Tensile Strength | Ultimate Elongation |
| 14 MPa min | 650 % min | 14 MPa min | 500 % min |

**TABLE 7 Physical Requirements for Synthetic Rubber (Polychloroprene)**

| Before Aging | | After Accelerated Aging | |
|---|---|---|---|
| Tensile Strength | Ultimate Elongation | Tensile Strength | Ultimate Elongation |
| 14 MPa min | 500 % min | 14 MPa min | 400 % min |

**TABLE 8 Physical Requirements for Synthetic Rubber (Nitrile)**

| Before Aging | | After Accelerated Aging | |
|---|---|---|---|
| Tensile Strength | Ultimate Elongation | Tensile Strength | Ultimate Elongation |
| 14 MPa min | 500 % min | 14 MPa min | 400 % min |

**TABLE 9 Physical Requirements for Vinyl (PVC)**

| Before Aging | | After Accelerated Aging | |
|---|---|---|---|
| Tensile Strength | Ultimate Elongation | Tensile Strength | Ultimate Elongation |
| 9 MPa min | 300 % min | 9 MPa min | 300 % min |

7.8 *Antigenic Protein Content:*

7.8.1 Determine the extractable antigenic protein (mg/mL) using Test Method D6499 for each glove sample tested.

7.8.2 Determine the total microgram of extractable antigenic protein in each glove sample by multiplying the result from 7.8.1 by the total volume of extractant used for that specific glove sample.

7.8.3 Determine the extractable antigenic protein content of a glove sample by dividing the result from 7.8.2 (total microgram of antigenic protein) by 7.7.3 (total surface area of glove).

7.9 *Chemical Permeation:*

7.9.1 *Representative Chemicals to be Tested:*

7.9.1.1 The following list of embalming chemicals represents the minimum chemicals that shall be tested:

Formaldehyde (37 %)
Glutaraldehyde (20 %)
Phenol (30 %)
Methanol (30 %)
Bleach (sodium hypochlorite, 5.25 %)

7.9.2 The embalming chemicals shall be prepared and used for permeation testing as routinely used in practice.

7.9.3 *Specific Test Conditions for Using Test Method F739:*

7.9.3.1 The test shall be conducted in triplicate at 25 ± 2°C.

7.9.3.2 The outer surface of the glove material shall contact the donor solution of the test chemical.

7.9.3.3 The collection medium shall be mixed continuously.

7.9.3.4 Using Test Method F739, the test period shall last for 4 h. If breakthrough is achieved before the 4-h end point, the test shall be stopped and the end time recorded. The following time intervals (at the minimum) shall be used for the analysis of each glove:

5 min
15 min
30 min
45 min
60 min
120 min
180 min
240 min

7.9.4 *Test Termination*—The test shall be continued for the full 4-h test period and the end time point recorded. This is necessary to determine the steady-state permeation rate.

7.9.4.1 The test may be terminated prior to reaching 4 h if one of the following occurs:

Steady-state permeation is reached.
Permeation proceeds at an ever increasing rate.
A maximum rate is reached.

7.9.4.2 The breakthrough time shall be deemed to have occurred when the quantitative analysis detects a permeation rate of 0.1 μg/cm$^2$/min (per Test Method F739).

7.9.5 A full test is complete at 4 h or at any prior breakthrough time.

7.9.6 Each test glove material shall be inspected at the end of the test period for physical changes, such as signs of flaking, swelling, disintegration, embrittlement, discoloration, or other physical changes, and recorded.

## 8. Acceptance

8.1 Gloves will be considered to meet the performance requirements when the test conforms to the requirements prescribed in Table 1.

8.2 The supplier of disposable single-use embalming gloves shall readily have and make available to the end-user test data and reports to support the sale and use of the supplied gloves for embalming applications.

8.3 Retests are permissible under the provisions described in the U.S. Pharmacopeia and ISO 2859.

## 9. Report

9.1 Each test report shall, at a minimum, contain the following information:

9.1.1 Permeation test data for the embalming chemicals identified in this specification.

9.1.2 Record the following information for each chemical tested:

9.1.2.1 Normalized breakthrough time,

9.1.2.2 Permeation rate, and

9.1.2.3 Observations of material degradation.

9.1.3 The concentration of each chemical tested.

9.1.3.1 Such test reports shall be made available to the glove purchaser upon request.

## 10. Packaging and Package Marking

10.1 *Disposable, Single-Use and Bulk Glove Packaging:*

10.1.1 The gloves shall be enclosed in an outer package that has sufficient strength to withstand normal transportation and storage within the cartons or shipping cases, or both.

10.1.2 None of the packaging material shall contain any material likely to impair the quality and use of the gloves.

10.1.3 Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.

10.2 *Package Marking:*

10.2.1 Disposable, single-use, and bulk glove packages shall bear at minimum markings for the contents to include the glove size and manufacturing lot number.

10.2.2 The outermost case shall be labeled minimally with the contents, glove size, and a manufacturing lot number. All levels of packaging shall conform to all appropriate government labeling regulations.

## 11. Keywords

11.1 disposable; embalming; gloves; latex; natural rubber; nitrile; polychloroprene; single-use; synthetic rubber; vinyl

# ANNEXES

**(Mandatory Information)**

## A1. PROTEIN CONTENT

A1.1 The current assay precision is large enough that only a recommended limit can be considered.

A1.2 Consideration should be given to the relative repeatability and reproducibility when reporting test method results.

A1.3 Reasonable allowance should be given for test results in excess of the recommended limit until greater precision of the method can be attained.

## A2. POWDER AMOUNT

A2.1 *Average Powder Mass Limit for Powder-free Gloves (Powder Residue)*—The recommended limit is not more than 2 mg per glove.

A2.2 *Average Powder Mass Limit for Powdered Gloves (Powder Amount)*—The recommended limit is not more than 10 mg per square decimeter.

## A3. ANTIGENIC PROTEIN CONTENT

A3.1 The current assay precision is large enough that only a recommended limit can be considered.

A3.2 Consideration should be given to the relative repeatability and reproducibility when reporting test methods.

A3.3 A pooled sample from three individual NR specimens or products as extracted in accordance with Test Method D5712 is permitted for use as the extraction sample.