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**Plasticized poly(vinyl chloride) compounds for
transfusion (infusion) equipment**

输血（液）器具用聚氯乙烯塑料

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Plasticized poly(vinyl chloride) compounds for transfusion (infusion) equipment

1 Scope

This standard specifies the requirements, test methods, markings, packaging, transportation, storage of plasticized poly(vinyl chloride) compounds for transfusion (infusion) equipment.

This standard applies to the PVC plastics for disposable transfusion (infusion) bags, transfusion (infusion) catheters, accessories, which are made through blending and modifying the main material of polyvinyl chloride resin, by adding other necessary additives such as bis(2-ethylhexyl) phthalate (DEHP) plasticizer, epoxy soybean oil and/or epoxy linseed oil.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this standard.

GB/T 1040.2-2006 Plastics - Determination of tensile properties - Part 2: Test conditions for molding and extrusion plastics

GB/T 2411-2008 Plastics and ebonite - Determination of indentation hardness by means of a durometer (shore hardness)

GB/T 2917.1 Determination of compounds and products based on vinyl chloride homopolymers and copolymers to evolve hydrogen chloride and any other acidic products at elevated temperatures - Congo red method

GB/T 4615 Poly (vinyl chloride) - Determination of residual vinyl chloride monomer content - Gas chromatographic method

GB/T 5470-2008 Plastics - Determination of the brittleness temperature by impact

GB/T 9345.5-2010 Plastics - Determination of ash - Part 5: Poly (vinyl chloride)

GB 14232.1-2020 Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers

GB/T 14233.1-2008 Test methods for infusion transfusion injection equipments for medical use - Part 1: Chemical analysis methods

GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

3 Requirements

3.1 Material requirements

It shall control the raw materials used in production. It shall not artificially add the substances, that have been prohibited in the relevant regulations and instructions AND have not been toxicologically evaluated. Any changes in the material formula shall be approved by the user AND subject to related verification.

Note: The recognition that bis(2-ethylhexyl) phthalate (DEHP) plasticizers have reproductive toxicity risks is widely accepted. The application of non-DEHP plasticized PVC plastics has become a trend. Pellets manufacturers and medical device manufacturers should conduct risk assessments, on the safety of materials and devices, based on their end use. For information about non-phthalic plasticizers and non-phthalic PVC plastics, see Appendix A.

3.2 Appearance

It is in natural transparent or natural translucent particles, in uniform color, without charred particles, foreign impurities. For special colors, it can be determined, through negotiation between the user and the manufacturer.

3.3 Performance

3.3.1 Physical properties

The physical properties of PVC plastics shall meet the requirements of Table 1.

4.4 Chemical properties

4.4.1 Determination of the chemical properties of PVC plastic water-soluble matter

4.4.1.1 Preparation of test solution for PVC plastic water-soluble matter

Take the uniform part of sheet specimen, which has a total surface area (including the two surfaces of the plastic sheet) of 600 cm² [when the sample is PVC plastic for blood bags, the total surface area is 1200 cm²], AND a thickness of (0.45 ± 0.05) mm. Use soapy water, tap water, laboratory grade 2 water to wash it clean. Dry it naturally. Cut into pieces of 1 cm². Then according to the ratio of 2:1 between specimen (cm²) and water (mL) [for the PVC plastic for blood bags, the ratio between specimen (cm²) and water (mL) is 6:1], immerse in a 500 mL glass container. Use an appropriate method to seal it. Place it in a pressure steam sterilizer. Extract for 20 minutes under saturated steam at (121 ± 2) °C (for the PVC plastic sample for blood bags, extract for 30 min). After heating, separate the sample from the liquid. Cool it to room temperature, as the test solution. The water used for the preparation of the test solution shall be laboratory grade 2 water.

4.4.1.2 Preparation of blank control solution

Use the same batch of laboratory grade 2 water, without adding the test piece, to operate at the same time, to prepare a blank control solution.

4.4.1.3 Determination of reducing substances

It is performed according to the requirements for indirect titration of 5.2.2 in GB/T 14233.1-2008.

4.4.1.4 Determination of pH

It is performed according to the requirements of 5.4.1 in GB/T 14233.1-2008.

4.4.1.5 Determination of color

Take 50 mL each of the test solution and the blank control solution. Respectively place them in a Nessler colorimetric tube. Use a white object as a background. Under a fluorescent lamp, use normal or corrected vision, to make comparison observation with the blank control solution.

4.4.1.6 Determination of UV absorption

According to 5.7 of GB/T 14233.1-2008, within 5 h, use a 1 cm absorption cell, to measure the peak value of the ultraviolet light absorption peak, in the

wavelength range of 230 nm ~ 360 nm.

4.4.1.7 Determination of evaporation residue

It is performed according to the requirements of 5.5 in GB/T 14233.1-2008. The difference, between the mass of the residue of the extract and the blank control solution, is expressed in milligrams.

4.4.1.8 Determination of zinc

It is performed according to the requirements of 5.9.2.1 in GB/T 14233.1-2008.

4.4.1.9 Determination of metals

4.4.1.9.1 Determination of barium (Ba), chromium (Cr), copper (Cu), lead (Pb), tin (Sn), cadmium (Cd), aluminum (Al)

It is performed according to the requirements of 5.9.1 in GB/T 14233.1-2008.

4.4.1.9.2 Determination of mercury (Hg)

It is performed according to the requirements of 5.9.3 in GB/T 14233.1-2008.

4.4.1.10 Determination of the total amount of heavy metals (in Pb)

It is performed according to the requirements of Method 2 in 5.6 of GB/T 14233.1-2008. The chemical detection method of total heavy metal can be used to replace atomic absorption spectroscopy.

4.4.2 Determination of ethanol extract (DEHP)

The specimen uses a 250 mL empty bag. It is performed according to the requirements of A.4.10 in GB 14232.1-2020.

4.4.3 Determination of the chemical properties of PVC plastics

4.4.3.1 Determination of ash

Accurately weigh 2 g of sample, accurate to 0.1 mg. Make determination according to the provisions of method B in GB/T 9345.5-2010.

4.4.3.2 Determination of vinyl chloride monomer

It is performed according to the requirements of GB/T 4615.

Appendix C

(Normative)

Test method of water absorption

C.1 Test sample

There are 10 specimens of 25 mm × 70 mm with straight edges, wherein 5 specimens are the test group, the other 5 specimens are the blank control group.

C.2 Test instrument

C.2.1 Analytical balance, which has an accuracy of 0.0001 g.

C.2.2 Constant temperature water bath, which has an accuracy of 0.5 °C.

C.2.3 Drying box, which has an accuracy of 1 °C.

C.2.4 Drying tank.

C.3 Test procedure

C.3.1 Cut 10 pieces of 25 mm × 70 mm specimens, with straight edges, wherein 5 specimens are the test group, the other 5 specimens are the blank control group.

C.3.2 Wash the pieces with soapy water, normal water, laboratory grade 2 water one by one. Use clean degreasing gauze and silk cloth to wipe off the surface moisture and fibers.

C.3.3 Accurately weigh the total mass of the test group (A) and the blank control group (B), accurate to 0.1 mg.

C.3.4 Use spiral stainless steel wire, to separate each specimen of the test group, at an appropriate distance. Immerse the specimen in a constant temperature water tank, which has reached the constant temperature of (50 ± 0.5) °C. Soak it for $2\text{ h} \pm 20\text{ s}$.

C.3.5 After taking out the specimen from the constant temperature water tank, immediately put it into water at room temperature. Take it out after 5 min. Wipe off the water. Accurately weigh it within $2\text{ min} \pm 20\text{ s}$ (C), accurate to 0.1 mg.

C.3.6 Respectively spread the test group specimens and the blank control group specimens, in a porcelain plate. Put it into a drying oven, which has reached constant temperature of (80 ± 1) °C. Dry it for $2\text{ h} \pm 20\text{ s}$. Then take it out. Cool it in a drying tank for 30 min. Accurately weigh the total mass of the

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