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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 15593-2020

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

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1 Scope

GB/T 15593-2020 is the Chinese national standard on plasticized poly(vinyl chloride) compounds for transfusion (infusion) equipment, in the field of rubber and plastic industries. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 19 November 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 October 2021. Classification: ICS 83.080.20, CCS G32. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

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.

4.4.1 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.

4.4.3.1 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 x 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