

3-A[®] Sanitary Standards for Multiple-Use Plastic Materials, Number 20-27

*Standards Developing Organizations
3-A Sanitary Standards, Inc. (3-A SSI)
In Collaboration With
United States Public Health Service (USPHS)/
United States Food and Drug Administration (USFDA)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)*

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Note: The highlighted text denotes changes to the previous document.

Disclaimers

3-A Sanitary Standards and 3-A Accepted Practices are developed through the efforts of experts, working on a volunteer basis, using science-based information and their professional experiences to reach consensus decisions on the sanitary (hygienic) criteria in these 3-A documents.

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3-A Sanitary Standards and 3-A Accepted Practices do not include provisions for mechanical, electrical, or personnel safety. Such safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

Drawings and illustrations contained herein are examples to assist in understanding the criteria in this 3-A Sanitary Standard. Appendix drawings and illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Appendix drawings and illustrations are non-normative.

Foreword

This 3-A Sanitary Standard is to establish minimum sanitary (hygienic) requirements for Plastic Materials.

This 3-A Sanitary Standard is for use on a voluntary basis by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by other SDOs to assure adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses these documents as its source of sanitary criteria for 3-A Symbol authorization.

This 3-A Sanitary Standard was developed jointly by 3-A SSI, the United States Public Health Service (USPHS), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our intent to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome at any time for consideration by 3-A SSI. Please forward comments to the 3-A Secretary, 6888 Elm Street, Suite 2D; McLean, VA 22101-3829, USA or by fax: 703-761-6284, or by e-mail to: 3-ainfo@3-a.org.

A SCOPE

A1 These sanitary standards cover the material requirements of plastics for multiple-use as product contact and/or cleaning solution contact surfaces in equipment for production, processing, and handling of milk and milk product(s). Test criteria are provided for plastics as a means of determining their acceptance as to their ability to be cleaned and to receive effective bactericidal treatment and to maintain their essential functional properties and surface finish in accelerated use-simulating tests¹. These standards do not apply to plastics for single service application nor plastics which are of rubber or rubber-like origin resulting from chemical or thermal vulcanization or curing. These standards are also not meant to cover design and fabrication criteria for individual plastic components, because such criteria are provided for in other 3-A Sanitary Standards and 3-A Accepted Practices.

A2 In order to conform to these 3-A Sanitary Standards, multiple-use plastics shall comply with the following material, fabrication of test specimens as described in Section D3 herein, and cleanability standards.²

B DEFINITIONS

B1 *Product*: Shall mean milk and milk products.

B2 *Product Contact Surfaces*: Shall mean all surfaces that are exposed to the product, and surfaces from which liquids may drain, drop or be drawn into the product or into the container, and surfaces that touch product contact surfaces of the container.

B3 *Cleaning Solution Contact Surfaces*: Shall mean the interior surfaces which are used exclusively for supply and recirculation of cleaning and/or sanitizing solutions, except those surfaces used to supply concentrated cleaning and/or sanitizing materials to the point of use.

B4 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

¹ Procedures in Sections F and G are not normal cleaning and bactericidal treatment tests but are accelerated use-simulating tests.

² Use current revisions or editions of all referenced documents cited herein.

B5 Terms Related to Plastics

B5.1 Terms defined in ASTM D883, Standard Definitions of Terms Relating to PLASTICS³ shall be the following, except those materials included in the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces on Dairy Equipment, Number 18-.

B5.1.1 *Plastic(s)*, *n*.

B5.1.2 *Polymer*, *n*.

B5.1.3 *Thermoplastic*, *n*.

B5.1.4 *Thermoplastic*, *adj*.

B5.1.5 *Thermoset*, *n*.

B5.1.6 *Thermoset*, *adj*.

B5.1.7 *Thermosetting*, *adj*.

B5.1.8 *Plasticizer*, *n*.

B5.1.9 *Elastomer*, *n*.

B5.2 Other terms defined by 3-A Committees:

B5.2.1 *Plastic Additive*, *n*: Any material that is added to a plastic or polymer to enhance or modify the original physical and/or chemical properties.

B5.2.2 *Plastic*, *adj.*: The adjective “plastic” indicates that the noun is made of, consists of or pertains to plastic.

B6 Definitions of Terms Relating to Testing

B6.1 *Standard Laboratory Atmosphere (SLA)*: A relative humidity of 50 ± 5% at a temperature of 23 ± 1°C or 73.4 ± 1.8°F as defined in ASTM E 41-86 - Definitions of Terms Relating to Conditioning.

B6.2 *Hot Water*: From 100-115°F (38-46°C).

B6.3 *Cold Water*: From 45-65°F (7-18°C).

B6.4 *Rinse*: Shall mean to totally immerse in 2 L of water to remove all residue of cleaning and/or test solution. The water temperature shall be

³ Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

determined by referring to B6.2 for hot water or B6.3 for cold water. Immersion time shall be determined by the instructions for carrying out the applicable procedure, or if no time is given, rinse by six repeated 1 min immersions. All water used shall be deionized or distilled.

- B6.5 *Dry or Dried:* Shall mean to allow the samples to reach an equilibrium moisture content in a Standard Laboratory Atmosphere (SLA), utilizing the times specified in the procedure to be followed. Specimens should be suspended or placed on edge on a screen to facilitate draining and drying.

C MATERIALS

Plastic materials used as product contact and/or cleaning solution contact surfaces shall be nontoxic, shall comply with FDA regulations of the Food, Drug and Cosmetic Act and shall comply with Section H - Standards for Acceptability. Plastic materials complying with Section H shall be considered to be relatively unaffected when subjected to normal cleaning and bactericidal treatment. Only virgin, unadulterated or clean in-process and/or properly stored re-grind plastic materials shall be used. Plasticizers, and plastic additives, if used, shall be used at the minimum levels required for the desired functionality and also be used in accordance with the conditions prescribed by current federal regulations or the FD&C Act as amended.

D PREPARATION FOR CLEANABILITY RESPONSE, PRODUCT TREATMENT AND CLEANABILITY COMPARISONS PROCEDURES

D1 Apparatus

Appropriate glassware, oven, hot plate, analytical balance, wide field microscope or magnifying lens of 7 to 10 power, sample of AISI 300 Series⁴ stainless having a surface finish equivalent to 150 grit or better finish as obtained with silicon carbide properly applied on stainless steel sheets. (Also see Section G2).

- D2 **Test Solutions** (Simulated Reagents): (See Appendix, Section L for suggested material/chemical supplier list.)

- D2.1 **Test Solution A (Acid Cleaner):**
Acid Solution: 2% Orthophosphoric Acid (20.18 g Acid/L solution) 28.1 mL of 85% orthophosphoric acid volumetrically diluted to 2 L with distilled water.
- D2.2 **Test Solution B (Alkaline Cleaner equivalent to 63% sodium oxide):**
Sodium tripolyphosphate, 3.85 g
Sodium hydroxide, 20.51 g
Trisodium phosphate, 0.77 g
Synthetic detergent, anionic type (Aerosol® O.T.), 0.51 g
Dilute volumetrically to 1 L with distilled water to produce a 25% solution by weight.
- D2.3 **Test Solution C (Alkaline Chlorine Sanitizer)**
Hypochlorite solution: 10.00 mL of a 4-6% sodium hypochlorite solution is made up to 1 L with distilled water in a volumetric flask to yield 400 ppm available chlorine in water, adjusted to pH 8.0 $\pm$ 0.5 with sodium bicarbonate.
- D2.4 **Test Solution D (Acid Chlorine Sanitizer):**
Dichloroisocyanurate, sodium salt (ACL 60 Monsanto), 15.00 g
Monosodium phosphate, anhydrous, 29.00 g
Sodium sulfate, anhydrous, 25.00 g
Dissolve in distilled water up to 1 L in a volumetric flask.
Dilute 44.74 mL of above solution with distilled water to 1 L in a volumetric flask to give a test solution containing 400 ppm of available chlorine.
- D2.5 **Test Solution E (Quaternary Ammonium Sanitizer):**
Alkyl dimethylbenzyl ammonium chloride, 400 ppm in water (0.40 g/L).
- D2.6 **Test Solution F (Iodophor Sanitizer):**
Nonylphenol ethylene oxide condensate, 9.5-10 mol
Ethylene oxide, 15.00 g
Iodine to provide 1.75% available iodine, 2.45 g
Orthophosphoric acid-100% basis, 17.60 g (12.26 mL of 85% acid)
Water, 64.95 g
Dilute 2.86 g of above solution with distilled water up to 1 L in a volumetric flask to give a test solution of 50 ppm of available iodine.

⁴ The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086.

- D2.7 Test Solution G (Acid Anionic Sanitizer):
Orthophosphoric acid - 100% basis, 24.70 g (17.20 mL of 85% acid)
Dodecylbenzene sulfonic acid, sodium salt, 2.75 g
Nonionic wetting agent, 1.00 g
Water, 71.55 g
Dilute 14.80 g of above solution with distilled water up to 1 L in a volumetric flask to give a test solution of 400 ppm of active anionic.
- D2.8 Test Solution H (Simulated Dairy-Soil Solution):
Cream (36% milkfat), 583.30 g
Nonfat dry milk, 140.00 g
Sucrose, 210.00 g
Water, 466.70 g
To give a composition of:
15.0% Fat
12.0% Milk-solids-not-fat
15.0% Sucrose
58.0% Water
- D2.9 Test Solution I (Dairy Product, High Fat Medium):
Pasteurized heavy cream, minimum 36.0% milkfat.
- D2.10 Test Solution J (Dairy Product, Acid Medium):
Lactic acid, 3.0% in aqueous solution (70.60 g or 59.00 mL of 85% lactic acid or 60.00 g of anhydrous lactic acid) diluted with distilled water to 2 L in a volumetric flask.
- D3 **Test Specimens**
- D3.1 Test specimens, when prepared for testing shall have a surface at least as smooth as a sample of AISI 300 Series stainless steel having a surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets and shall have a total exposed surface area of $7.00 \pm 0.10 \text{ in.}^2$ ($45.20 \pm 0.65 \text{ cm}^2$) for each test specimen. Test specimens shall have one of the following configurations.
- D3.1.1 Molded test specimens shall be in the form of a disk 2.00 in. (50.80 mm) in diameter and 1/8 in. (3.20 mm) in thickness. Permissible variations in thickness are $\pm 0.0070 \text{ in.}$ (0.18 mm) for hot molded and $\pm 0.012 \text{ in.}$ (0.30 mm) for cold molded or cast materials. The disk mold prescribed in Section 3 of ASTM D 647-88a - Recommended Practice for Design of Molds for Test Specimens of Plastic Molding Materials - is suitable for molding disk specimens of thermosetting materials, and Section 5 of ASTM D 647-88a is suitable for injection of molding of thermoplastic materials.
- D3.1.2 Sheet test specimens shall be in the form of a bar 3.00 in. (76.20 mm) in length and 1.00 in. (25.40 mm) in width, which for comparison, shall be $1/8 \pm 0.008 \text{ in.}$ ($3.18 \pm 0.20 \text{ mm}$) thick (Surface area, $7.00 \pm 0.10 \text{ in.}^2$ or $45.20 \pm 0.65 \text{ cm}^2$).
- D3.1.3 Rod test specimens shall be of normal diameter as received, and cut to proper length to produce the required surface area of $7.00 \pm 0.10 \text{ in.}^2$ ($45.2 \pm 0.65 \text{ cm}^2$). The diameter of the specimen shall be the diameter of the rod.
- D3.1.4 Tube test specimens of less than 3.00 in. (76.20 mm) in diameter shall be the full section of the tube cut to proper length to produce the required surface area of $7.00 \pm 0.10 \text{ in.}^2$ ($45.20 \pm 6.5 \text{ mm}^2$) including as the exposed surface area the outside, inside, and ends of the tube. For a tube having an inside diameter of 3.00 in. (76.20 mm) or more, a rectangular specimen shall be cut 3.00 in. (76.20 mm) in length laterally to the tube or cut to proper length and width to produce the required surface area of $7.00 \pm 0.10 \text{ in.}^2$ ($45.20 \pm 6.5 \text{ mm}^2$) including as the exposed area the outside, inside, and ends of the cut section.
- D3.2 Test specimens from sheets, rods and tubes shall be machined, punched, sawed or sheared from the sample and so treated on such surfaces as to have edges free from cracks, rough surfaces and loose material. All test specimens shall be free of grease, dirt or other extraneous material.
- D3.3 Additional guidelines for the handling of specimens, suspension of specimens in reagents, stirring of reagents, etc. can be found in ASTM Test Methods D 543-87 and D 471-79 (Re-approved 1991).
- D4 **Conditioning of Test Specimens**
All test specimens pre-conditioned to equilibrium for water content in a Standard Laboratory Atmosphere (see B6.1), shall be cleaned using Test Solution B (Alkaline Solution) at 165-170°F (74-77°C), with six repeated 1 min immersions, followed by six repeated 1 min immersions in 2 L of cold distilled or deionized water to thoroughly rinse and then dry at Standard Laboratory Atmosphere for 24 h.