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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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 tests[1]. 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.

B5 Terms Related to Plastics

B5.1 Terms defined in ASTM D883, Standard Definitions of Terms Relating to PLASTICS[3] 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

[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.

[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 Series[4] 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 ± 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 ± 0.10 $in.^2$ (45.20 ± 0.65 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 ±0.0070 in. (0.18 mm) for hot molded and ±0.012 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 ± 0.008 in. (3.18 ± 0.20 mm) thick (Surface area, 7.00 ± 0.10 $in.^2$ or 45.20 ± 0.65 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 ± 0.10 $in.^2$ (45.2 ± 0.65 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 ± 0.10 $in.^2$ (45.20 ± 6.5 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 ± 0.10 $in.^2$ (45.20 ± 6.5 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 165-170ºF (74-77ºC), 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.

D5 **Number of Test Specimens**

Two sets (Set M and Set M^1) of eight specimens each and two sets (Set L and Set L^1) of eight specimens each shall be identified and treated as:

Set M and M^1	Set L and L^1	For Tests In:
M:0 M^1-0	L-0: L^1-0	Controls, distilled water
M:1 M^1-1	L-1: L^1-1	Solutions A-B
M:2 M^1-2	L-2: L^1-2	Solutions A-B-H-A-B
M:3 M^1-3	L-3: L^1-3	Solutions A-B-C-H-A-B-C
M:4 M^1-4	L-4: L^1-4	Solutions A-B-D-H-A-B-D
M:5 M^1-5	L-5: L^1-5	Solutions A-B-E-H-A-B-E
M:6 M^1-6	L-6: L^1-6	Solutions A-B-F-H-A-B-F
M:7 M^1-7	L-7: L^1-7	Solutions A-B-G-H-A-B-G

An extra molded test specimen or a piece of the sheet, rod or tube shall be available for the comparisons required in E10.2.1 and F3.2.1.

E PROCEDURE - CLEANABILITY RESPONSE

E1 After conditioning the test specimens according to Section D4 above, all samples are to be weighed (W_1) on an analytical balance to 0.0001 g. Specimens shall be handled with clean tongs or forceps and latex gloves worn when required. After W_1 has been determined treat specimens as follows:

E2 Specimens M-0,M^1-0 and L-0, L^1-0:

(a) Immerse in distilled water, 165-170°F (74-77°C), 60 min.
(b) Rinse, hot water.
(c) Dry, SLA, 20 h.
(d) Re-weigh (W_2).

E3 Specimens M-1,M^1-1 and L-1, L^1-1:

(a) Immerse in Solution A, 165-170°F (74-77°C), 30 min.
(b) Rinse, hot water.
(c) Immerse in Solution B, 165-170°F (74-77°C), 30 min.
(d) Rinse, hot water.
(e) Dry, SLA, 20 h.
(f) Re-weigh (W_2).

E4 Specimens M-2,M^1-2 and L-2, L^1-2:

(a) Immerse in Solution A, 165-170°F (74-77°C), 15 min.
(b) Rinse, hot water.
(c) Immerse in Solution B, 165-170°F (74-77°C), 15 min.
(d) Rinse, hot water.
(e) Immerse in Solution H, SLA, 20 h.
(f) Rinse, hot water.
(g) Immerse in Solution A, 165-170°F (74-77°C), 15 min.
(h) Rinse, hot water.
(i) Immerse in Solution B, 165-170°F (74-77°C), 15 min.
(j) Rinse, hot water.
(k) Dry, SLA, 20 h.
(l) Re-weigh (W_2).

E5 Specimens M-3,M^1-3 and L-3, L^1-3:

(a) Immerse in Solution A, 165-170°F (74-77°C), 15 min.
(b) Rinse, hot water.
(c) Immerse in Solution B, 165-170°F (74-77°C), 15 min.
(d) Rinse, cold water.
(e) Immerse in Solution C, SLA, 60 min.
(f) Rinse, hot water.
(g) Immerse in Solution H, SLA, 20 h.
(h) Rinse, cold water.
(i) Immerse in Solution A, 165-170°F (74-77°C), 15 min.
(j) Rinse, hot water.
(k) Immerse in Solution B, 165-170°F (74-77°C), 15 min.
(l) Rinse, cold water.
(m) Immerse in Solution C, SLA, 60 min.
(n) Rinse, hot water.
(o) Dry, SLA, 20 h.
(p) Re-weigh (W_2).

E6 Specimens M-4,M^1-4 and L-4, L^1-4:
Identical to regimen stated in Section E5 for M-3, M^1-3 and L-3, L^1-3 except: Use Solution D in place of Solution C.

E7 Specimens M-5,M^1-5 and L-5, L^1-5:
Identical to regimen stated in Section E5 for M-3, M^1-3 and L-3, L^1-3 except: Use Solution E in place of Solution C.

E8 Specimens M-6,M^1-6 and L-6, L^1-6:
Identical to regimen stated in Section E5 for M-3, M^1-3 and L-3, L^1-3 except: Use Solution F in place of Solution C.

E9 Specimens M-7,M^1-7 and L-7, L^1-7:
Identical to regimen stated in Section E5 for M-3, M^1-3 and L-3, L^1-3 except: Use Solution G in place of Solution C.

E10 Report the following for each specimen tested (For Report Form, see Appendix, Section M):

E10.1 Calculated % weight loss or gain:

$$\% \text{ Loss} = (W_1 - W_2)/W_1 \times 100$$
$$\% \text{ Gain} = (W_2 - W_1)/W_1 \times 100$$

Note: Averages of specimens are not permitted. A weight gain is not to be used to offset a weight loss.

E10.2 Surface comparisons made visually with the aid of magnification:

E10.2.1 The test specimen is compared with the original as to change in surface smoothness as: NO CHANGE, SLIGHT CHANGE, or MARKED CHANGE.

E10.2.2 The rating as to the smoothness of the test specimen compared to a surface finish equivalent to a 150 grit or better finish as obtained with silicon carbide, properly applied on stainless steel sheets: SMOOTHER, EQUAL, or ROUGHER.

E10.2.3 Report under the "Remarks" column other observable (temporary or permanent) changes to the specimen's surface and appearance, such as surface tack, exudation, surface cracks, color, transparency, surface wettability, delamination, shape distortion, or any other appearance changes. To demonstrate whether changes in color or transparency are temporary, an additional drying step of 20 hours at 50°C may be conducted.

F **PROCEDURE - PRODUCT TREATMENT**

The test specimens which were treated in Section E, "Cleanability Response," are to be further tested as follows:

F1 Immerse Set M and M^1 (Specimens M-0 to M-7 and M^1-0 to M^1-7 inclusive) in Test Solution I at room temperature for a total time of 168 h, renewing the Test Solution I every 24 h. Test specimens shall be rinsed with cold distilled or deionized water to remove old solution prior to re-immersing in renewed solution. At the conclusion of the 168 h immersion, the specimens shall be removed and cleaned, using Test Solution B at 165-170°F (74-77°C), with six repeated 1 min immersions, followed by a thorough hot water rinse, dry at SLA, for 20 h. Re-weigh (W_3).

F2 Immerse Set L and L^1 (Specimens L-0 to L-7 and L^1-0 to L^1-7 inclusive) in Test Solution J at 155-160°F (68-71°C) for a total time of 168 h, renewing the Test Solution J every 24 h. Test specimens shall be rinsed with cold distilled or deionized water to remove old solution prior to re-immersing in renewed solution. At the conclusion of the 168 h immersion, the specimens shall be removed and cleaned, using Test Solution B at 165-170°F (74-77°C), with six repeated 1 min immersions, followed by a thorough hot water rinse, dry at SLA, for 20 h. Re-weigh (W_3).

F3 Report the following for each specimen tested (For Report Form, see Appendix, Section N):

F3.1 Calculated % weight loss or gain:

$$\% \text{ Loss} = (W_2 - W_3)/W_2 \times 100$$
$$\% \text{ Gain} = (W_3 - W_2)/W_2 \times 100$$

Note: Averages of specimens are not permitted. A weight gain is not to be used to offset a weight loss.

F3.2 Surface comparisons made visually with the aid of magnification:

F3.2.1 The test specimen is compared with the original as to change in surface smoothness as: NO CHANGE, SLIGHT CHANGE, or MARKED CHANGE.

F3.2.2 The rating as to the smoothness of the test specimen compared to a surface finish equivalent to a 150 grit or better finish as obtained with silicon carbide, properly applied on stainless steel sheets: SMOOTHER, EQUAL, or ROUGHER.

F3.2.3 Report under the "Remarks" column other observable (temporary or permanent) changes to the specimen's surface and appearance, such as surface tack, exudation, surface cracks, color, transparency, surface wettability, delamination, shape distortion, or any other appearance changes. To demonstrate whether changes in color or transparency are temporary, an additional drying step of 20 hours at 50°C may be conducted.

G PROCEDURE-CLEANABILITY COMPARISON

G1 All of the test specimens, after exposure to the regimens set forth in Sections E and F, are to be immersed in Test Solution H at SLA for 20 h, cleaned using Test Solution B at 165-170°F (74-77°C) with six repeated 1 min immersions, followed by a thorough hot water rinsing and drying at SLA for 20 h.

G2 The 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, or a piece of it approximately 3.00 in. (76.20 mm) in length and 1.00 in. (25.40 mm) in width, is to be cleaned as set forth in D4. This sample of stainless steel is then to be exposed to the regimen set forth in G1.

G3 With the aid of magnification, visually judge the cleanability of the test specimens by comparing them with the sample of AISI 300 Series stainless steel sheet after exposure to the regimen set forth in G1. Rate the cleanability of the test specimens as: BETTER, EQUAL, or POORER. (For Report Form, see Appendix O.)

H STANDARDS FOR ACCEPTABILITY

Acceptable plastic materials shall comply with the following:

H1 Test specimens, after exposure to the regimens set forth in Sections E and F, shall not have a loss in weight greater than 0.05% except as provided in Section H6 concerning data analysis.

H2 Test specimens, after exposure to the regimens set forth in Sections E and F, shall not have a gain in weight greater than that given for the generic class shown in Table 1 except as provided in Section H6 concerning data analysis.

H3 When compared to the original all of the test specimens, after exposure to the regimen set forth in Sections E and F, shall have NO CHANGE in surface smoothness and relatively little change in color, transparency, translucency, shape, flexibility, dimension or other similar functional properties affecting the appearance or surface characteristics of the sample.

H4 All of the test specimens, after exposure to the regimens set forth in Sections E, F and G, shall be at least as smooth and cleanable 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 to stainless steel sheets. To conform to this, all of the test specimens shall be judged to be SMOOTHER or EQUAL in the comparisons made in accordance to E10.2.2 and F3.2.2 and BETTER or EQUAL in the comparisons made in accordance to G3.

H5 Certification of each formulation for compliance with FDA regulations and/or FD&C Act requirements and compliance with the criteria herein are to be maintained by the manufacturer and supplier. Test results and a statement of compliance by the testing laboratory shall be kept by the manufacturer and supplier. This information shall be made available to distributors, users, and regulatory agencies upon request. (See Appendix, Section P for the information required on a certification form).

H6 Data values beyond the permitted maximum weight loss or weight gain limits may be challenged as outlying observations as described in ASTM 178. Physical reasons may be known or discovered which could reject a data value. Procedures or calibrations of equipment, for example, may be causes. Statistical tests may be used to determine of the values are outlying observations. Documented outlying observations may be rejected.

TABLE 1 - Plastics Included in These Standards	Maximum % Weight Gain		
Generic Classes (Code of Federal Regulations Citation[5])	Section E - Cleanability Response	Section F - Product Treatment (Solution I)	Section F - Product Treatment (Solution J)
Acrylics (21 CFR 177.1010)	0.20	0.50	1.50
Acrylonitrile butadiene styrene (21 CFR 177.1020)	0.30	0.45	0.90
Chlorinated polyether (21 CFR 177.2430)	0.05	0.05	0.05
Cross-linked polyester resins (vinyl ester-styrene copolymer) (21 CFR 177.2420)	0.20	0.20	0.20
Epoxy resin as coating (21 CFR 175.300)			
(a) Isopropylidenediphenol Hardener-TETA Triethylenetetramine	0.10	0.15	0.25
(b) Phenol-Formaldehyde Polymer, glycidyl ether (silica filled) Hardener - DETA Adduct	0.15	0.15	2.0
Ethylene-vinyl acetate copolymers (21 CFR 177.1350)	0.25	0.55	0.10
Fluorocarbons (21 CFR 170.39, 177.1380, 177.1550, 177.2510)			
(a) CTFE, PTFE, FEP, PFA, and ETFE types	0.05	0.05	0.05
(b) Vinylidene fluoride types	0.05	0.05	0.15
Nylon (21 CFR 177.1500)			
(a) Nylon Type 66	2.00	3.00	8.00
(b) Nylon Type 610	1.00	2.00	4.00
(c) Nylon Type 6	2.00	3.00	8.00
(d) Nylon Type 12T (PA 12/MACMI)	1.00	1.00	3.00
(e) Nylon Type MACM12 (FCN No. 883)	1.00	1.00	3.00
Nylon 66-Nylon 6-aramid fiber blend (21 CFR 177.1500, 177.1632)	2.00	3.00	8.00
Nylon 66-Nylon 6-aramid fiber-PTFE blend (21 CFR 177.1500, 177.1380, 177.1632)	2.00	3.00	8.00
Plasticized polyvinyl chloride (21 CFR 175.300)			
(a) For contact with high-water, low-fat products (8% milk fat)	0.25	0.55	0.90
(b) For contact with high-fat products (>8% milk fat)	0.10	0.20	0.55
Poly (arylетherketone) resins (21 CFR 177.2415)	0.10	0.20	0.50
Polyarylsulfone resin (21 CFR 177.1560)	0.40	0.80	1.50
Polycarbonates (21 CFR 177.1580)	0.10	0.15	0.25
Polyetherimide (21 CFR 177.1595)	0.20	0.25	0.75
Polyethylene (21 CFR 177.1520)			
(a) ASTM Type O	0.20	0.50	0.20
(b) ASTM Type I	0.20	0.50	0.20
(c) ASTM Type II	0.20	0.20	0.20
(d) ASTM Type III	0.20	0.20	0.20
(e) Ultra-high molecular weight polyethylene (UHMWPE)	0.20	0.50	0.20
Polyethylene phthalate polymers (21 CFR 177.1630)	0.10	0.15	0.65
Polymethylpentene (21 CFR 177.1520)	0.10	0.20	0.20
Polyoxymethylene copolymer (21 CFR 177.2470)	0.25	0.60	1.00
Polyoxymethylene homopolymer (21 CFR 177.2480)	0.40	0.50	1.40
Polyphenylene oxide (21 CFR 177.2460)	0.10	0.15	0.25
Polyphenylene sulfide (21 CFR 177.2490)	0.06	0.08	0.08
Polyphenylene sulfide-PTFE (alloy) (21 CFR 177.2490, 177.1380)	0.06	0.08	0.30
Polyphenylsulfone (repeated use)	0.40	0.80	1.50
Polypropylene - (unmodified and modified for impact resistance) (21 CFR 177.1520)	0.10	0.20	0.20
Polystyrene - Normal (unmodified) Type 3 of ASTM D703-78 (21 CFR 177.1640)	0.10	0.10	0.10
Polystyrene - Modified (impact), Type III, Grade 6, of ASTM D1892-78 (21 CFR 177.1640)	0.10	0.10	0.10
Polysulfone resin (21 CFR 177.1655)	0.3	0.45	0.45
Polysulfone-PTFE (alloy) (21 CFR 177.1655, 177.1380)	0.30	0.45	0.45
Polytetrafluoroethylene (PTFE)- Poly(arylетherketone) blend (21 CFR 177.1550, 177.2415)	0.05	0.06	0.05
Polytetramethylene terephthalate (21 CFR 177.1660)	0.10	0.15	0.65
Polytetramethylene terephalate-PTFE blend (21 CFR 177.1660, 177.1380)	0.10	0.15	0.65
Polyurethane (21 CFR 177.1680)	1.22	1.59	1.29
Propoxylated bisphenol-A fumarate polyester-styrene copolymer (21 CFR 177.2420)	0.20	0.20	0.20
Reinforced epoxy, molded, natural (no color added), and black (21 CFR 175.300)	0.20	0.25	0.35
Styrene-acrylonitrile (21 CFR 177.1040)	0.20	0.50	0.50
Thermoplastic polyether-ester (21 CFR 177.2600)	0.35	1.1	0.50

[5] Citations are by title, part, and section number, thus 21 CFR 177.1010 refers to Title 21, Part 177, Section 1010. CFR references include the basic polymers, optional adjuvants, specifications, and limitations and conditions of use.

APPENDIX

I **Fabrication**

Components and devices manufactured from plastic materials should be designed and fabricated as provided in the appropriate 3-A Sanitary Standards. Good manufacturing practices shall be used in the manufacture of plastic components to assure the utmost in quality and cleanliness.

J **Selected References**

J1 E.6, Definitions of Terms Relating to Methods of Mechanical Testing, *Annual Book of ASTM Standards, Vols. 03.01 and 08.03* (latest edition).

J2 *Dictionary of Scientific and Technical Terms.* McGraw-Hill, Inc., New York, NY, 1975.

J3 *SPI Plastic Engineering Handbook, 4th ed.* Society of Plastic Industry Inc., Book Division, New York, NY 1960.

J4 Whittington, L.R. *Whittington's Dictionary of Plastics, 2nd Ed.* Technomic Publishing Co., Westport, CT, 1978.

J5 *Handbook of Chemistry and Physics.* The Chemical Rubber Publishing Co., Cleveland, OH.

J6 *The Condensed Chemical Dictionary.* Reinhold Publishing Co., New York, NY.

J7 *Modern Plastics Encyclopedia.* McGraw-Hill, Inc. New York, NY. (Published annually in October.)

J8 "Terms Relating to Plastics," ASTM D-883-91. ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

J9 *Code of Federal Regulations*, Title 21, Parts 170-199.

J10 E 178 "Dealing with Outlying Observations," *Annual Book of ASTM Standards, Vol. 14.02.* ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

K **Re-testing of Plastic Materials**

K1 Re-testing (re-qualification) of plastic materials will be mandatory when the formulation of the product has been changed by any one, or any combination of, the following means:

K1.1 A significant change was made to the polymer;

K1.2 Plastic additives or plasticizers were deleted or added, except that:

K1.2.1 Colors may be added provided the colorant(s) comply with the FDA regulations for polymer colorant(s) found in 21 CFR 178.3297 or other appropriate FDA regulations and the maximum total pigment load is ≤ 1.5% (w/w).

K1.3 Two or more listed plastics are alloyed or blended together. Furthermore, a change such as this would necessitate the generation of a new generic class of plastics for which new maximum % weight gain values would have to be assigned to the Cleanability Response and Product Treatment Values found in Table 1 herein. (See Appendix, Section P for Certification Form.)

K1.3.1 **Alloys and Blends of Polymers**

K1.3.1.1 The combining of two or more polymers in a formulation of ≤ 7.0% (w/w) total added polymers is considered as a plastic additive(s), and tested according to 3-A 20- and evaluated against the appropriate weight gain percentages of the identified generic class of the basic plastic.

K1.3.1.2 The combination of two or more polymers in a formulation at > 7.0% (w/w) total load is considered an alloy or blend of polymers. These polymers are considered to be a new generic class of plastic. In order to be covered by 3-A 20-, an amendment is required to provide an accurate name for the blend or alloy, reference FDA regulations that establish suitability for repeated food contact and determine the maximum weight gain percentages.

K2 Certification of Plastic Materials with Multiple Trade Names or Product Names

K2.1 Plastic materials which already meet 3-A criteria may be certified by suppliers under other trade names and/or product designations. A company manufacturing the final plastic product from a plastic material already meeting 3-A criteria may certify its trade name and its type or grade meets the 3-A Sanitary Standards for Multiple-Use Plastic Materials, Number 20- without re-qualification provided:

K2.2 The plastic material was tested according to procedures in, and meets or exceeds, the Standards for Acceptability in the 3-A Sanitary Standards for Multiple-Use Plastic Materials, Number 20- and meets FD&C Act requirements and;

K2.3 The formulation of the final fabricated plastic material was not changed by the addition of additives (See Section K1 herein) and;

K2.4 The manufacturer of the final fabricated plastic material certifies, in writing, K2.2 to K2.3. (See Appendix, Section P for the information required on a certification form).

APPENDIX L: MATERIAL/CHEMICAL LIST FOR TEST SOLUTIONS (SIMULATED REAGENTS)

MATERIAL OR CHEMICAL	CHEMICAL FORMULA	CONCENTRATION OR GRADE	SUGGESTED SUPPLIER
Acetic acid, glacial	CH_3COOH	ACS or reagent	Laboratory supply companies
ACL-60 (dichlorisocyanurate, sodium salt)	------	62% available Cl_2	Monsanto Chemical Co., St. Louis, MO 1-800-325-4330 Ext. 346
Aerosol® O.T. (Dioctyl sodium sulfosuccinate) (anionic detergent)	------	100% dry solid	Sigma Chemical
Benzalkonium chloride (alkyl dimethyl benzyl ammonium chloride)	------	NF	ICM Biochemicals Co., Cleveland, OH 1-800-321-6842
Iodine, crystals	I_2	ACS or reagent	Laboratory supply companies
Lactic acid	$CH_3CHOHCOOH$	85%, ACS or reagent	Laboratory supply companies
Nacconol 40g (granular) or 40f (flake) (sodium dodecylbenzene sulfonate)	------	40%	Stepan Co., Northfield, IL 60093 1-800-457-7673
Non-fat dry milk	------	------	Dairy products store/Food store
Orthophosphoric acid, concentrated	H_3PO_4	ACS or reagent	Laboratory supply companies
Sodium hydroxide, pellets	NaOH	ACS or reagent	Laboratory supply companies
Sodium hypochlorite	NaOCI	4-6% available Cl_2, purified	Laboratory supply companies
Sodium phosphate, monobasic anhydrous	NaH_2PO_4	ACS or reagent	Laboratory supply companies
Sodium phosphate, tripoly	$Na_5P_3O_{10}$	Purified	Laboratory supply companies
Sodium sulfate, anhydrous	Na_2SO_4	ACS or reagent	Laboratory supply companies
Sterox N.J. (Nonyl phenol ethylene oxide condensate) (nonionic wetting agent)	------	9.5-10 mol ethylene oxide	Monsanto Chemical Co., St. Louis, MO 1-800-325-4330 Ext. 346
Sugar (sucrose)	$C_{12}H_{22}O_{11}$	Common table sugar	Food store
Trisodium phosphate (Sodium phosphate, tribasic)	$Na_3PO_412H_2O$	ACS or reagent	Laboratory supply companies
Heavy whipping cream	------	36% milkfat	Dairy products store/Food store

APPENDIX M: CLEANABILITY RESPONSE

SAMPLE NUMBER	WEIGHT		SURFACE COMPARISON TO ORIGINAL SAMPLE (SECTION E10.2.1): No Change, Slight Change, or Marked Change	SURFACE COMPARISON TO STAINLESS WITH 150 GRIT FINISH (SECTION E10.2.2): Smoother, Equal, or Rougher	REMARKS[5]
	% Loss	% Gain			
M-0					
M[1]-0					
M-1					
M[1]-1					
M-2					
M[1]-2					
M-3					
M[1]-3					
M-4					
M[1]-4					
M-5					
M[1]-5					
M-6					
M[1]-6					
M-7					
M[1]-7					
L-0					
L[1]-0					
L-1					
L[1]-1					
L-2					
L[1]-2					
L-3					
L[1]-3					
L-4					
L[1]-4					
L-5					
L[1]-5					
L-6					
L[1]-6					
L-7					
L[1]-7					

APPENDIX N: PRODUCT TREATMENT

SAMPLE NUMBER	WEIGHT		SURFACE COMPARISON TO ORIGINAL SAMPLE (SECTION F3.2.1): No Change, Slight Change, or Marked Change	SURFACE COMPARISON TO STAINLESS WITH 150 GRIT FINISH (SECTION F3.2.2): Smoother, Equal, or Rougher	REMARKS[5]
	% Loss	% Gain			
M-0					
M[1]-0					
M-1					
M[1]-1					
M-2					
M[1]-2					
M-3					
M[1]-3					
M-4					
M[1]-4					
M-5					
M[1]-5					
M-6					
M[1]-6					
M-7					
M[1]-7					
L-0					
L[1]-0					
L-1					
L[1]-1					
L-2					
L[1]-2					
L-3					
L[1]-3					
L-4					
L[1]-4					
L-5					
L[1]-5					
L-6					
L[1]-6					
L-7					
L[1]-7					

APPENDIX O: CLEANABILITY COMPARISON

SAMPLE NUMBER	CLEANABILITY COMPARISON (SECTION G3): Better, Equal, Poorer	REMARKS[6]
M-0		
M^1-0		
M-1		
M^1-1		
M-2		
M^1-2		
M-3		
M^1-3		
M-4		
M^1-4		
M-5		
M^1-5		
M-6		
M^1-6		
M-7		
M^1-7		
L-0		
L^1-0		
L-1		
L^1-1		
L-2		
L^1-2		
L-3		
L^1-3		
L-4		
L^1-4		
L-5		
L^1-5		
L-6		
L^1-6		
L-7		
L^1-7		

[6] The purpose of the "Remarks" in this section is to provide a means to record unusual changes in physical properties of the test specimens after exposure to test regimens in Section E & F. These recorded observations are not to be used as part of the standards for acceptability. It is beyond the scope of these Standards to set limits of acceptable changes in physical properties except surface smoothness. However, plastic materials should retain or return to their original physical properties such as color, transparency, translucency, flexibility, form or shape after test regimens E & F. Users should consider these observations when judging whether a plastic material will maintain essential properties in the intended application.

APPENDIX P: CERTIFICATION FORM EXAMPLE

PART 1: To be completed by all suppliers. Please type all information except signature.

I certify that _____ **{name of plastic, including generic class as listed in Table 1}** has been evaluated under the terms of the test regimen contained in 3-A Sanitary Standards for Multiple-Use Plastic Materials, Number 20- as amended, and complies with the limitations set forth under Section H of those standards as well as the other criteria in the standards. This plastic complies with Part _____ of Title 21, Code of Federal Regulations. Samples of the material were/were not **{choose one}** submitted to testing by the company listed below.

Name _____

Company Name _____

Address _____

_____

_____

Signature _____

Date _____

PART 2: To be completed as provided in K2 if the plastic material being certified was not submitted for testing by the company listed above.

The name of the plastic material originally tested, and currently certified is _____ **{name of plastic, including generic class as listed in Table 1}**. I certify that this plastic is the same formulation as that originally tested and is not alloyed or blended with another polymer. Attached is a copy of the Certification Form and a statement of compliance by the testing laboratory used for the initial certification of this material.

Signature _____

Date _____

PART 3: To be completed by all suppliers.

	% WEIGHT CHANGE ALLOWED[7]	% WEIGHT CHANGE OBSERVED[8]
Section E - Cleanability Response		
Section F - Product Treatment (Solution I)		
Section F - Product Treatment (Solution J)		
Average Weight Loss	0.05%	

PART 4: To be completed by all suppliers.

The surface comparison of the test samples when compared to the original sample and to stainless steel with 150 grit finish when subjected to the cleanability responses and product treatment test regimens showed no change and was at least as smooth as 150 grit stainless steel. **{yes/ no}.**

[7] See Table 1.

[8] Averages.