

# 3-A<sup>®</sup> Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-03

*Formulated by*  
*International Association of Food Industry Suppliers (IAFIS)*  
*International Association for Food Protection (IAFP)*  
*United States Public Health Service (USPHS)*  
*The European Hygienic Equipment Design Group (EHEDG)*  
*The Dairy Industry Committee (DIC)*

It is the purpose of the IAFIS, IAFP, USPHS, EHEDG, and DIC in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Multiple-use rubber and rubber-like materials heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAFIS, IAFP, USPHS, EHEDG, and DIC at any time. The 3-A Sanitary Standards and 3-A Accepted Practices provide hygienic criteria applicable to equipment and systems used to produce, process, and package milk, milk products, and other perishable foods or comestible products. NOTE: Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

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|----|---|---|
| A  | <b>SCOPE</b>  | properties and serviceability requirements <sup>3</sup> .   |
| A1 | These sanitary standards cover the material and serviceability requirements <sup>1</sup> of rubber and rubber-like materials intended for multiple-use as product contact surfaces or solution contact surfaces in the production, processing and handling of milk or milk products. Test procedures and criteria are also provided for rubber and rubber-like materials as a means of determining their acceptance as to their ability to be cleaned and to receive effective bactericidal treatment or steam sterilization and to maintain their essential properties in these accelerated use-simulating conditions <sup>2</sup> . These standards are not meant to cover design and fabrication criteria for individual rubber or rubber-like components because such criteria are provided for in other 3-A Sanitary Standards and 3-A Accepted Practices, nor are these standards intended to cover RTV silicone adhesives or sealants. | <b>B DEFINITIONS</b><br><br><b>B1 Rubber Materials</b><br><br>B1.1 <i>Rubber:</i> See ASTM D1566 - Terminology Relating to RUBBER <sup>4</sup> . (Except for hard rubber as defined in B1.3.)<br><br>B1.2 <i>Rubber-Like:</i> See ASTM D1566 - Terminology Relating to RUBBER <sup>4</sup> . (Except for hard rubber as defined in B1.3.)<br><br>B1.3 <i>Hard Rubber:</i> Shall mean a vulcanized rubber having a ratio of combined sulfur to rubber hydrocarbon in excess of 15% and a Shore A Durometer value in excess of 90.<br><br>B1.4 <i>Low-fat Tolerance Rubber and Rubber-Like Materials:</i> Shall mean rubber and rubber-like materials designed to meet the requirements of this standard only when used in contact with products containing 8.0% fat or less. |
| A2 | In order to conform with these 3-A Standards, multiple-use rubber and rubber-like materials shall comply with the following material, original physical   | <b>B2 Temperature of Exposure:</b> Shall mean temperatures to   |

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<sup>1</sup>Procedures in Section C are serviceability requirements performed to evaluate the original physical properties of rubber or rubber-like materials.

<sup>2</sup>Procedures in Section D are not normal cleaning and bactericidal treatment tests but are accelerated use tests.

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<sup>3</sup>Use current revisions or editions of all referenced documents cited herein.

<sup>4</sup>Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. Phone: (610) 832-9500.

which rubber material is subjected when in contact with the product and/or cleaning and bactericidal treatment or steam sterilization.

B3 **Classifications** (See Appendix, Section F for examples.)

B3.1 **Class I:** Shall mean rubber materials suitable for temperature of exposure to product or sterilization up to 300°F (149°C), and temperature of exposure to chemical solution used in cleaning and bactericidal treatment up to 180°F (82°C).

B3.2 **Class II:** Shall mean rubber materials suitable for temperature of exposure to product or sterilization up to 250°F (121°C), and temperature of exposure to chemical solution used in cleaning and bactericidal treatment up to 180°F (82°C).

B3.3 **Class III:** Shall mean rubber materials suitable for temperature of exposure to product up to 120°F (49°C), and temperature of exposure to chemical solution used in cleaning and bactericidal treatment up to 180°F (82°C).

B3.4 **Class IV:** Shall mean rubber materials suitable for temperature of exposure to product up to 100°F (38°C), and temperature of exposure to chemical solution used in cleaning and bactericidal treatment up to 180°F (82°C).

B4 **Product Definitions**

B4.1 **Product:** Shall mean milk and milk products.

B5 **Surfaces**

B5.1 **Product Contact Surfaces:** Shall mean all surfaces which are exposed to the product or from which liquids may drain, drop, diffuse or be drawn into the product.

B5.2 **Solution Contact Surfaces:** Shall mean the interior surfaces of the equipment or system which are used exclusively for supply and recirculation of cleaning and/or sanitizing solutions, except those used to supply concentrated cleaning and/or sanitizing materials to the point of use.

B5.3 **Nonproduct Contact Surfaces:** Shall mean all other exposed surfaces.

## C MATERIALS

C1 Rubber and rubber-like materials used as product contact and/or solution contact surfaces shall be nontoxic, shall not adversely affect the product and shall comply with the Food, Drug and Cosmetic Act, The Code of Federal Regulations, Title 21, Part 177.2600<sup>5</sup> and shall comply with these materials criteria and be compatible with cleaning and sanitizing agents as defined by the procedures in Section D herein.

C2 The allowable physical properties of rubber and rubber-like materials, as determined by the testing procedures specified, are the following (for suggested report form, see Appendix, Section K):

C2.1 Low-fat tolerance rubber and rubber-like materials used for contact with products with a maximum of 8.0% milk fat shall be exempt from the test criteria and acceptable maximum changes in Section C2.2.1 but shall meet the test criteria in Sections C2.1.1, C2.2.2, C2.2.3 and C3.1.

### C2.1.1 TABLE-Low Fat Tolerance Absorption<sup>a & b</sup>

Class	Acceptable Maximum Changes		
	Hardness Shore A Points	Weight %	Volume %
I	± 6	± 5	± 5
II	± 15	± 25	± 25
III	± 20	± 25	± 25
IV	± 20	± 60	± 75

<sup>a</sup> ASTM D471 - Standard Test Method for Rubber Property - Effect of Liquids<sup>4</sup>. Immersion 22 ± 1/4 h at 158°F (70°C).

<sup>b</sup> The high fat media shall be butter oil or anhydrous milk fat meeting the composition specifications found in the General Specifications for USDA-Approved Dairy Plants, paragraphs 58.305 (b), 58.305 (c) and 58.347. Federal Register, Volume 40, No. 198 - Friday, October 10, 1975<sup>5</sup>.

<sup>5</sup>For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 512-1800.

## C2.2 Absorption and Aging

C2.2.1 TABLE - Milk Fat Absorption<sup>a & b</sup>

Class	Acceptable Maximum Changes		
	Hardness	Weight	Volume
	Shore A Points	%	%
I	± 5	± 5	± 5
II	± 5	± 10	± 10
III	± 10	± 25	± 25
IV	± 10	± 40	± 60

<sup>a</sup> ASTM D471 - Standard Test Method for Rubber Property - Effect of Liquids<sup>4</sup>. Immersion 22 ± 1/4 h at 158°F (70°C).

<sup>b</sup> The high fat media shall be butter oil or anhydrous milk fat meeting the composition specifications found in the General Specifications for USDA-Approved Dairy Plants, paragraphs 58.305 (b), 58.305 (c) and 58.347. Federal Register, Volume 40, No. 198 - Friday, October 10, 1975<sup>4</sup>.

C2.2.2 TABLE - Distilled Water Absorption<sup>a</sup>

Class	Acceptable Maximum Changes		
	Hardness	Weight	Volume
	Shore A Points	%	%
I	± 5	± 5	± 5
II	± 5	± 10	± 10
III	± 10	± 15	± 15
IV	± 10	± 20	± 25

<sup>a</sup> ASTM D471 - Standard Test Method for Rubber Property - Effect of Liquids<sup>4</sup>. Immersion 22 ± 1/4 h at 158°F (70°C).

C2.2.3 TABLE - Air Aging Stability<sup>a</sup>

Class	Acceptable Maximum	
	Test	Hardness Changes
	Temperature	Shore A Points
I	212°F (100°C)	± 10
II	212°F (100°C)	± 10
III	158°F (70°C)	± 10
IV	158°F (70°C)	± 10

<sup>a</sup> ASTM D573 - Standard Test Method for Rubber Deterioration in an Air Oven<sup>4</sup>. (166 ± 1/2 h).

C3 The minimum original physical properties of rubber and rubber-like materials, except hard rubber as determined by the test procedures specified, are the following:

C3.1 TABLE -Original Physical Properties<sup>a</sup>

Class	Acceptable Minimums	
	Tensile Strength	Elongation
	PSI	%
I	1200	100
II	1100	100
III	1000	100
IV	500	75

<sup>a</sup> ASTM D412 - Standard Test Methods for Rubber Properties in Tension<sup>4</sup>.

## D COMPATIBILITY WITH CLEANING AND SANITIZING AGENTS

## D1 References

ASTM D471 - Standard Test Method for Rubber Properties - Effect of Liquids<sup>4</sup>. ASTM D2240 - Standard Test Method for Rubber Property - Durometer Hardness<sup>4</sup>.

## D2 Apparatus

Appropriate glassware, temperature controlled oven or water bath, analytical balance, and hardness measuring device for type Shore A Durometer points (ref: ASTM D2240).

D3 **Test Solution** (Accelerated Use Test Reagents): (See Appendix, Section J.)

## D3.1 Acid Cleaner Test Solutions

D3.1.1 **Nitric Acid:** For testing Class I and Class II rubber and rubber-like materials:

0.50% Nitric acid (5.00g acid/L of solution) is prepared by volumetrically diluting 5.0 mL of 70.0% nitric acid (Sp. Gr. 1.41) to 1 L with distilled water.

D3.1.2 **Phosphoric Acid:** For testing Class III and Class IV rubber and rubber-like materials:

1.0% orthophosphoric acid (10.00g acid/L of solution) is prepared by volumetrically diluting 7.00 ml of 85.0% orthophosphoric acid (Sp. Gr. 1.69) or 8.5 mL of 75.0% orthophosphoric acid (Sp. Gr. 1.58) to 1 L with distilled water.

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D3.2 **Alkaline Cleaner Test Solution:** For all classes of rubber and rubber-like materials:

1.0% sodium hydroxide (caustic) is prepared by dissolving 1.92g sodium tripolyphosphate, 10.20g sodium hydroxide, 0.36g trisodium phosphate, 0.26g anionic-type detergent (Aerosol O.T.<sup>R</sup>) to 1 L with distilled water.

D3.3 **Chlorine Sanitizer Test Solution:** For all classes of rubber and rubber-like materials:

Sodium hypochlorite solution - 200 ppm available chlorine - prepared daily. Dilute a 4.0 to 6.0% sodium hypochlorite solution with distilled water in a volumetric flask to yield 200 ppm of available chlorine. Approximate dilution of sodium hypochlorite per liter with water to yield 200 ppm available chlorine percentage active chlorine.

4.0%	5.0 mL
5.0%	4.0 mL
6.0%	3.4 mL

Adjust pH of solution to  $8.0 \pm 0.5$  with sodium bicarbonate.

D4 **Test Procedures and Acceptable Results**

D4.1 Sample preparation - see ASTM D471, 8. "Test Specimens - Change in Mass or Volume" for preparation of test samples.

D4.2 Submerge test specimens completely in loosely closed test tubes, see ASTM D471, 7. "Nonvolatile Liquids".

D4.3 "Procedure for Change in Mass", see ASTM D471, 9.

D4.4 "Procedure for Change in Volume - Water Displacement Method for Water Insoluble Liquids and Mixed Liquids", see ASTM D471, 10.

D4.5 Visual changes in the rubber material's product surface finish shall be examined by comparing test samples to a control.

D4.6 **TABLE- Nitric Acid-Class I and II** <sup>a, b & c</sup>

Class	Acceptable Maximum Changes		
	Hardness Shore A Points	Weight %	Volume %
I	$\pm 5$	$\pm 5$	$\pm 5$
II	$\pm 10$	$\pm 15$	$\pm 15$

<sup>a</sup> ASTM D471, 7., 8., 9. and 10<sup>4</sup>. Immersion  $22 \pm 1/4$  h at  $180^\circ \pm 2^\circ$  F ( $82^\circ \pm 1^\circ$  C).

<sup>b</sup> Test solution D3.1.1.

<sup>c</sup> The surface smoothness of the tested specimens shall be equal to that of the control.

D4.7 **TABLE-Phosphoric Acid-Class III and IV** <sup>a b&c</sup>

Class	Acceptable Maximum Changes		
	Hardness Shore A Points	Weight %	Volume %
III	$\pm 10$	$\pm 15$	$\pm 15$
IV	$\pm 10$	$\pm 20$	$\pm 25$

<sup>a</sup> ASTM D471, 7., 8., 9. and 10<sup>4</sup>. Immersion  $22 \pm 1/4$  h at  $180^\circ \pm 2$  F ( $82^\circ \pm 1$  C).

<sup>b</sup> Test solution D3.1.2.

<sup>c</sup> The surface smoothness of the tested specimens shall be equal to that of the control.

D4.8 **TABLE-Alkaline Cleaner-All Classes** <sup>a, b & c</sup>

Class	Acceptable Maximum Changes		
	Hardness Shore A Points	Weight %	Volume %
I	$\pm 5$	$\pm 5$	$\pm 5$
II	$\pm 10$	$\pm 10$	$\pm 10$
III	$\pm 10$	$\pm 15$	$\pm 15$
IV	$\pm 10$	$\pm 20$	$\pm 25$

<sup>a</sup> ASTM D471, 7., 8., 9. and 10.<sup>5</sup> Immersion  $22 \pm 1/4$  h at  $180^\circ \pm 2^\circ$  F ( $82^\circ \pm 1^\circ$  C).

<sup>b</sup> Test solution D3.2.

<sup>c</sup> The surface smoothness of the tested specimens shall be equal to that of the control.

D4.9 TABLE-Chlorine Sanitizer-All Classes<sup>a, b & c</sup>

Class	Acceptable Maximum Changes		
	Hardness Shore A Points	Weight %	Volume %
I	± 5	± 5	± 5
II	± 5	± 10	± 10
III	± 10	± 15	± 15
IV	± 10	± 20	± 25

<sup>a</sup> ASTM D471, 7., 8., 9. and 10<sup>4</sup>. Immersion 22 ± 1/4 h at 70° ± 2 F (21° ± 1 C).

<sup>b</sup> Test solution D3.3.

<sup>c</sup> The surface smoothness of the tested specimens shall be equal to that of the control.

## D5 Testing and Compliance

- D5.1 Test samples of rubber and rubber-like materials for each formulation shall be tested and certified to be in compliance with the criteria herein. (See Appendix, Section G.) Test results and a statement of compliance issued by the testing laboratory shall be kept by the manufacturer. These results shall be made available to distributors, users and regulatory agents upon request. In addition, rubber and rubber-like materials shall be certified to be in compliance with the Food and Drug Administration's regulations<sup>4</sup> and FD&C Act of 1938, as amended, requirements.<sup>4</sup>

## APPENDIX

### E FABRICATION

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

### F RUBBER CLASSES AND SELECTION

**Class I:** Some heat exchanger gaskets, O-rings, CIP gaskets, flange gaskets, rotary seals and hoses.

**Class II:** Plate heat exchanger gaskets, homogenizer seals, static seals and hoses.

**Class III:** Cold applications such as milk and milk products and air tubing, manhole and door gaskets, seals and hoses.

### Class IV: Inflations and hoses.

For satisfactory service, it is important that the right kind of rubber materials be selected for specific dairy applications. These sanitary standards cover a large variety of rubber and rubber-like materials which have a wide range of chemical and physical characteristics. These characteristics may be measured by established ASTM tests, such as hardness, resilience, elongation, compression set, adhesion to various substrates, vapor transmission and many more tests. In order to select a suitable rubber material, it is also important to know the intended conditions of dairy use, such as composition of the dairy product, temperature of the process, pressure or vacuum conditions, and the kinds and strengths of cleaners and sanitizers. As in the selection of metal or plastic materials for construction of dairy equipment, there is no single best rubber material for all functions.

### G VERIFICATION TESTING

Independent verification testing of these physical requirements herein, although not mandatory, should be sought by the manufacturer of a part made from rubber or rubber-like materials.

### H EXPECTED SERVICE PERIOD

The service period of rubber and rubber-like materials is dependent on their formulation and the environment of use which in turn is influenced by the product, process temperature, cleaning and bactericidal compounds, and time of exposure. Users should frequently monitor the physical condition of the rubber material product contact surfaces. Such observations are necessary to determine the actual sanitary service period of rubber materials. It is further recommended that rubber products be replaced before surface imperfections or sloughing occurs. Routine replacement schedules should be established and followed.

### I COLOR

The color of rubber materials will vary depending on the ingredients and formulation. The color of the final product is not of sanitary significance, provided the components used are in compliance with the applicable provisions of the FD&C Act and the Code of Federal Regulations<sup>5</sup>.

**J MATERIAL/CHEMICAL LIST FOR TEST SOLUTIONS (Simulated Reagents)**

Material or Chemical	Formula	Concentrations or Grade
Aerosol O.T. <sup>R (a)</sup> (Dioctyl sodium sulfosuccinate) (anionic detergent)	N/A	100% dry solid
Nitric Acid 42 <sup>o</sup> Be	HNO <sub>3</sub>	ACS or reagent
Orthophosphoric acid, concentrated	H <sub>3</sub> PO <sub>4</sub>	ACS or reagent
Sodium hydroxide, pellets	NaOH	ACS or reagent
Sodium hypochlorite	NaOCl	4-6% available Cl <sub>2</sub> , purified
Sodium phosphate, tripoly	Na <sub>5</sub> P <sub>3</sub> O <sub>10</sub>	Purified
Trisodium phosphate (Sodium phosphate, tribasic)	Na <sub>3</sub> PO <sub>4</sub> ·12H <sub>2</sub> O	ACS or reagent
Sodium Bicarbonate	NaHCO <sub>3</sub>	ACS or reagent
Butter Oil	N/A	min99.6% fat, max 0.15% water
Anhydrous Milk Fat	N/A	min 99.8% fat, max 0.15% water

<sup>a</sup> Available from American Cyanamide Company, Mt. Prosped, IL 60056 (708) 827-8871 and Sigma Chemical Company, St. Louis, MO 63118 (800) 325-3010.

K TEST RESULT FORM

**TEST RESULT FORM**

<b>COMPANY:</b>	
<b>CUSTOMER:</b>	
<b>PART NUMBER:</b>	<b>PART NAME:</b>
<b>COMPOUND NUMBER</b>	<b>PRODUCT CLASS:</b>
<b>COMMENTS:</b>	

PROPERTIES	UNIT	SPECIFICATION	MEASURED
Tensile Strength	PSI	MIN	
Elongation at Break	%	MIN	
Hardness Shore A Durmeter	PTS	+/-	

CHANGE IN PROPERTIES AFTER AGING FOR			HOURS AT
Change in Tensile Strength	%	MAX	
Change in Elongation	%	MAX	
Change in Hardness	PTS	MAX	
Visual Change		Observation:	

CHANGE IN PROPERTIES AFTER IMMERSION FOR			HOURS AT
Immersion Material:			
Change in Volume	%	MAX	
Change in Mass	%	MAX	
Change in Hardness	PTS	MAX	
Visual Change		Observation:	

CHANGE IN PROPERTIES AFTER IMMERSION FOR			HOURS AT
Immersion Material:			
Change in Volume	%	MAX	
Change in Mass	%	MAX	
Change in Hardness	PTS	MAX	
Visual Change		Observation:	

**TEST RESULT FORM**  
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<b>CHANGE IN PROPERTIES AFTER IMMERSION FOR</b>	<b>HOURS AT</b>
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Immersion Material:			
Change in Volume	%	MAX	
Change in Mass	%	MAX	
Change in Hardness	PTS	MAX	
Visual Change		Observation:	

<b>CHANGE IN PROPERTIES AFTER IMMERSION FOR</b>	<b>HOURS AT</b>
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Immersion Material:			
Change in Volume	%	MAX	
Change in Mass	%	MAX	
Change in Hardness	PTS	MAX	
Visual Change		Observation:	

<b>CHANGE IN PROPERTIES AFTER IMMERSION FOR</b>	<b>HOURS AT</b>
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Immersion Material:			
Change in Volume	%	MAX	
Change in Mass	%	MAX	
Change in Hardness	PTS	MAX	
Visual Change		Observation:	

<b>CHANGE IN PROPERTIES AFTER IMMERSION FOR</b>	<b>HOURS AT</b>
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Immersion Material:			
Change in Volume	%	MAX	
Change in Mass	%	MAX	
Change in Hardness	PTS	MAX	
Visual Change		Observation:	

<b>TESTED BY:</b>	<b>DATE:</b>
<b>APPROVED BY:</b>	<b>DATE:</b>



# EXAMPLE OF A RUBBER CERTIFICATION FORM

Please type all information except signature:

**Company Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Rubber Compound:** \_\_\_\_\_

**Compound # or Grade:** \_\_\_\_\_

**Part Name:** \_\_\_\_\_

**Rubber Class:** \_\_\_\_\_

The rubber or rubber-like materials listed above have been evaluated according to the test procedures contained in the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-. These materials are (this material is) covered by the Scope and applicable definitions in these Standards. These materials comply (this material complies) with The Code of Federal Regulations, Title 21, Part 177.2600, and complies with the applicable material and compatibility criteria found in Sections C and D. (See attached Test Results Form.)

**Company Representative:**

**Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

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These amended standards are effective August 21, 1999, at which time the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-02 are rescinded and become null and void.