

3-A® Sanitary Standards for Diaphragm Pumps, Number 44-03

Formulated by
International Association of Food Industry Suppliers (IAFIS)
International Association for Food Protection (IAFP)
United States Public Health Service (USPHS)
The Dairy Industry Committee (DIC)
United States Department of Agriculture – Dairy Programs (USDA)

It is the purpose of the IAFIS, IAFP, USPHS, DIC, and USDA in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Diaphragm pump specifications 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, DIC, and USDA 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. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

A SCOPE

A1 These standards cover the sanitary aspects of air, hydraulically, or mechanically driven diaphragm pumps for milk and milk products.

A2 In order to conform to these 3-A Sanitary Standards, diaphragm pumps shall comply with the following design, material, and fabrication criteria¹.

B DEFINITIONS

B1 *Product*: Shall mean milk, milk products, and other comestibles.

B2 Surfaces

B2.1 *Product Contact Surfaces*: Shall mean all surfaces which are exposed to the product and surfaces from which liquids may drain, drop, diffuse, or be drawn into the product.

B2.2 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

B3 *Mechanical Cleaning or Mechanically Cleaned*: Shall denote cleaning, solely by circulation and/or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned, by mechanical means.

B4 *Air Driven-Type Pumps*: Shall mean those that apply compressed air directly to the nonproduct side of the diaphragm for the purpose of driving the pump.

B5 *Hydraulically Driven-Type Pumps*: Shall mean those that apply hydraulic fluid directly to the nonproduct side of the diaphragm for the purpose of driving the pump.

B6 *Mechanically Driven-Type Pumps*: Shall mean those that have the nonproduct side of the diaphragm open to the atmosphere at all times and use a mechanical shaft directly connected to the diaphragm for the purpose of driving the pump.

C MATERIALS

C1 All product contact surfaces shall be of stainless steel of the AISI 300 Series² or corresponding ACI types³ (See Appendix, Section E), or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, except that:

C1.1 Rubber and rubber-like materials may be used for O-

²The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, Table 2-1. Available from the American Iron and Steel Society, 186 Thorn Hill Road, Warrendale, PA 15086 (724) 776-1535.

³Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160.

¹ Use current revisions or editions of all referenced documents cited herein.

rings, seals, diaphragms, valve seats, check valve balls and flaps, and parts having the same functional purposes.

C1.2 Rubber and rubber-like materials, when used for specified applications, shall comply with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

C1.3 Plastic materials may be used for O-rings, seals, diaphragms, valve seats, check valve balls and flaps, and parts having the same functional purposes.

C1.4 Plastic materials, when used for specified applications, shall comply with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

C1.5 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformation characteristics when exposed to conditions encountered in the environment of intended use and in cleaning and bactericidal treatment, or sterilization.

C1.6 The final bond and residual adhesive, if used, of bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic⁴.

C1.7 Check valve balls may also be of hard rubber (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) that is nontoxic and relatively resistant to abrasion, will maintain its original characteristics, such as form, shape, and dimensions, and will not affect the product and shall, when subjected to the test regimen set forth in the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-, (a) comply with the criteria in Section I (1) and Section I (3), (b) have maximum weight gains as set forth in Section I (2) of 0.30 and in the Cleanability Response, 0.30 in Product Treatment with Solution I and 0.30 in Product Treatment with Solution J.

⁴Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 783-3238.

C1.8 Where materials having certain inherent functional purposes are required for specific applications, such as check valve balls, solid ceramic materials may be used. Ceramic materials shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

C2 Nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. Nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

C3 In hydraulically driven diaphragm pumps, the hydraulic fluid used shall be food grade white oil as provided for in 21 CFR Parts 172.878 and 178.3620A.

C3 Sterilizability

C3.1 In a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher, all materials having product contact surface(s) used in the construction of diaphragm pumps and nonmetallic component parts shall be such that they can be (1) sterilized by saturated steam or water under pressure (at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) and (2) operated at the temperature required for processing.

D FABRICATION

D1 All product contact surfaces shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds, and crevices in the final fabricated form. (See Appendix, Section F.)

D2 All permanent joints in metallic product contact surfaces shall be continuously welded. Welded areas on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds, and crevices in the final fabricated form.

D3 Rubber or rubber-like materials, hard (vulcanized) rubber, and plastic materials having product contact surfaces that are a coating or covering shall be bonded