

3-A[®] Sanitary Standards for Inline Rotor-Stator Mixers Number 36-01

*Standards Developing Organizations
3-A Sanitary Standards, Inc. (3-A SSI)
in collaboration with
United States Public Health Service (USPHS)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)*

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Drawings and illustrations contained herein are to assist in understanding the criteria in this 3-A Standard. Drawings and illustrations are not intended to show all variations of the equipment or system nor are they (it) to exclude alternate methods meeting this standard. Drawings and illustrations are non-normative.

Foreword

This 3-A Standard is to establish minimum sanitary (hygienic) requirements for Inline Rotor-Stator Mixers. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Standard is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A Sanitary Standards, Inc. to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Standard was developed jointly by 3-A Sanitary Standards, Inc. (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 purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to the 3-A SSI, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-4334. By e-mail to: trugh@3-a.org.

A SCOPE

A1 These standards cover the sanitary aspects of inline devices which use a combination of a rotor and a stator to effect mixing and size reductions for liquids, slurries, and liquid-gas mixtures.

A1.1 The rotor-stator mixer begins at the infeed pipe connection(s) and ends at the exit pipe fitting and includes all equipment in between.

A2 In order to conform to the 3-A Sanitary Standards, rotor-stator inline mixers, (Referred hereinafter as “inline mixers”) shall conform to the following design, material and fabrication criteria and the applicable documents referenced herein.¹

A3 Normative References

3-A Sanitary Standard for:

- 18- Multiple-Use Rubber and Rubber-Like Materials
- 20- Multiple-Use Plastic Materials
- 63- Sanitary Fittings
- 74- Sensors and Sensor Fittings and Connections Used on Equipment

B DEFINITIONS

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

B2 *Inline mixers*: As defined in A Scope, describes equipment commonly known as colloid mills, shear pumps, inline mixers and shear blenders, used for producing suspensions, emulsions, dispersions, particle reduction, or intimate mixtures.

B3 Surfaces

B3.1 *Product Contact Surfaces*: Shall mean all surfaces that are exposed to the product and surfaces from which liquids and/or solids may drain, drop, diffuse, or be drawn into the product.

B3.2 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

B4 Cleaning

B4.1 *Mechanical Cleaning or Mechanically Cleaned*: Shall mean soil removal by impingement, circulation, or flowing chemical detergent solutions

and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.

B4.2 *Manual (COP) Cleaning*: Shall mean soil removal when the equipment is partially or totally disassembled. Soil removal is effected with chemical solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s), and with all cleaning aids manipulated by hand.

B5 Surface Modification²

B5.1 *Surface Treatments*: Shall mean a process whereby chemical compositions or mechanical properties of the existing surface are altered. There is no appreciable, typically less than 1 µm, build-up of new material; or removal of existing material.

B5.1.1 Surface treatments include:

1. Mechanical (shot peening³, polishing)
2. Electropolishing

B5.2 *Coatings*: Shall mean the results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 1 µm, build-up of new material. The coating material does not alter the physical properties of the substrate.

B5.2.1 Coating processes include:

1. Chemical (conversion coatings)
2. Engineering Plating,⁴
3. Thermal spraying, when appropriately sealed, (e.g., flame, plasma, arc spray)
4. Physical Vapor Deposition
5. Chemical Vapor Deposition
6. Overlays and Encapsulation

² Additional information on surface modification is contained in *Advanced Materials and Processes*, Volume 137(1), “Coatings and Coating Practices” by H. Herman; “Surface Modification” by F. A. Smidt. ASM International, Materials Park, OH 44073.

³ AMS-S-13165, *Shot Peening of Metal Parts*. Available from Society of Automotive Engineers, Inc. (SAE), 400 Commonwealth Drive, Warrendale, PA.

⁴ SAE-AMS-QQ-C-320, “Chromium Plating (Electrodeposited)” and SAE-AMS-QQ-N-290, “Nickel Plating (Electrodeposited).” Available from Society of Automotive Engineers, Inc. (SAE), 400 Commonwealth Drive, Warrendale, PA.

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

- B6 *Soil*: Shall mean the presence of unwanted organic residue or inorganic matter, with or without microorganisms, including food residue, in or on the equipment.
- B7 *Sanitizing or Sanitization*: Shall mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 log₁₀ reductions (99.999%) to 7 log₁₀ reductions (99.99999%) by applying accumulated hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.
- B8 *Sterilization*: Shall mean a process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores.
- B9 *Easily or Readily Removable*: Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.
- B10 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by personnel from the floor, platform, or other permanent work area.
- B11 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.
- B12 *Simple Hand Tools*: Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, or mallet.
- B13 *Nontoxic Materials*: Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food and Drug Administration.
- B14 *Corrosion Resistant*: Shall mean the surface has the property to maintain its original surface characteristics for its predicted service period when exposed to the conditions encountered in the environment of intended use, including expected contact with product and cleaning, sanitizing treatment, or sterilization compounds or solutions.

C MATERIALS

C1 For Product Contact Surfaces

C1.1 Metals

C1.1.1. Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series⁵, (except 301 and 302) or corresponding Alloy Cast Institute (ACI) types⁶ 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. (See Appendix, Section E.)

C1.1.2 Product contact surfaces made of the materials provided for in C1.1.1 may have their surfaces coated.

C1.2 Solder, when used, shall be gold or silver containing solder and shall be corrosion resistant, free of cadmium, lead and antimony, nonabsorbent, and shall not impart any toxic substance to the product when exposed to the conditions encountered in the environment of intended use and in cleaning, sanitizing treatment or sterilization.

C1.3 Nonmetals

C1.3.1 Rubber and rubber-like materials may be used for gaskets, seals, and parts having the same functional purposes.

C1.3.1.1 Rubber and rubber-like materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 18-.

C1.3.2 Plastic materials may be used for gaskets, seals, and parts having the same functional purposes.

C1.3.2.1 Plastic materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 20-.

⁵ The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steel*, Table 2-1. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086.

⁶ Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016.