

3-A[®] Sanitary Standard for Rupture Disc Assemblies, Number 60-01

Standards Developing Organizations

3-A Sanitary Standards, Inc. (3-A SSI)

In collaboration with

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United States Food and Drug Administration (USFDA)

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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.

3-A SSI, its employees and its volunteer committees/working groups shall not incur any obligation or liability for damages, including consequential damages, arising from or in connection with the development, use, interpretation, or reliance upon this 3-A Sanitary Standard.

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.

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 establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of rupture disc assemblies.

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)/United States Food and Drug Administration (USFDA), 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 This standard covers the sanitary aspects of rupture disc assemblies used as pressure and/or vacuum relief devices on product vessels, processing equipment, and pipelines. When the process conditions are within normal operating temperature and pressure, the rupture disc assembly is closed, and the process is contained on the process side of the rupture disc assembly. Upon a pressure event (over-pressure or vacuum pressure), the rupture disc assembly will open at the specified burst pressure and relieve pressure through the opening of the rupture disc.
- A2 This standard does not apply to multiple-use vacuum breakers.
- A3 For purposes of this standard, the term rupture disc assembly shall include explosion vent assemblies.
- A4 In order to conform to this 3-A Sanitary Standard, rupture disc assemblies shall conform to the following criteria for design, materials of construction, fabrication techniques and installation, as appropriate, and the current revisions or editions of all referenced documents cited herein.

B NORMATIVE REFERENCES

- B1 The following listed 3-A Sanitary Standards, 3-A Accepted Practices and other documents shall be considered as Normative References and the provisions of the referenced documents shall apply to this Standard without further reference in this document unless necessary to describe special considerations.

B2 3-A Sanitary Standards

Doc. No.	Title (3-A Standard for)
18-	Multiple-Use Rubber and Rubber-Like Materials
20-	Multiple-Use Plastic Materials
63-	Sanitary Fittings

B3 Other references and standards**Ref. No. Title**

1. Sanitizing or Sanitization related normative references:

- a. The Code of Federal Regulations (CFR), Title 21, Part 110.3 (o), Current good manufacturing practice in manufacturing, packaging, or holding human food, definitions. (FDA's definition of sanitize from the GMP regulations).
- b. The Code of Federal Regulations (CFR), Title 40, Part 152.500, Pesticide registration and classification procedures, requirements for devices.
- c. The Code of Federal Regulations (CFR), Title 40, Part 161.640, Data requirements for registration, product performance data.
- d. The Code of Federal Regulations (CFR), Title 40, Part 180.940, Tolerances and exemptions from tolerances for pesticide chemicals in food, tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).

Above items for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.

- e. www.fda.gov reference to ultrasonic cleaning under, "Ultrasound In The Food, Drug, And Device Industries"

2. *AIST Stainless Steels: A Steel Products Manual*, Association for Iron & Steel Technology, 186 Thorn Hill Road, Warrendale, PA 15086, Phone: (724) 814 3000, Internet: www.aist.org
3. *Steel Casting Handbook, Supplement #2*, 1999. Available from Steel Founders Society of America, 780 McArdle Dr., Unit G, Crystal Lake, IL 60014, Phone: (815) 455-8240, Fax: (815) 455-8241, Internet: www.sfsa.org.
4. The Code of Federal Regulations (CFR), Title 21, Parts 175 – Indirect Food Additives: Adhesives and Components of Coatings. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.
5. ASTM E 498 Standard Test Methods for Leaks Using the Mass Spectrometer Leak Detector or Residual Gas Analyzer in the Tracer Probe Mode
6. EHEDG Guideline 2, A Method for Assessing the In-Place Cleanability of Food Processing Equipment. European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org.
7. EHEDG Guideline 8, Hygienic Equipment Design Criteria. European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org.

C. DEFINITIONS

- C1 *Bond*: The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.
- C2 *Burr*: A thin ridge or sharp area remaining after cutting, drilling, or punching a material.
- C3 **Cleaning**
- C3.1 *Clean-in-Place (CIP) Cleaning*: The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Rupture disc assemblies which are not designed to be cleaned in place, are removed to be COP or manually cleaned. Product contact surfaces to be CIP cleaned shall be inspectable, when dismantled. Inspection in place is not physically practical for most rupture disc assembly installations.
- C3.2 *Clean-Out-of-Place (COP)*: Removal of soil when the rupture disc assembly is partially or totally disassembled. Soil removal is effected by circulating chemical solutions and water rinses in a wash tank, which may be fitted with circulating pump(s).
- C3.3 *Manual Cleaning*: Removal of soil when the rupture disc assembly 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, and high or low pressure hoses, with cleaning aids manipulated by hand.
- C3.4 *Sterilization*: “Commercial sterility” of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. Ref 21 CFR Ch. 1 (4-1-01 Ed.) Sec. 113.3 (2).
- C3.5 *Sanitizing or Sanitization*: A process to adequately treat a clean product contact surface that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or safety for the consumer. Any process used must be acceptable to the regulatory agency. (Refer to B3, Reference No. 1.)
- C3.6 *Ultrasonic Cleaning*: Ultrasonic aided cleaning with a proper cleaning solution is considered effective for removing contaminants. Ultrasonic cleaning is achieved by vigorously agitating the solution with Ultrasonic energy. Energy is transmitted through the use of an ultrasonic frequency generator and a transducer physically

fixed to the cleaning solution container or reservoir. When ultrasonic energy is transmitted to a solution, it produces cavitation - a rapid buildup and collapse of numerous tiny bubbles. Cavitation causes a scrubbing action on the surface of the work being cleaned. This scrubbing action, combined with the nontoxic chemical action of the solvent, results in cleaning. To remove gross contaminants precleaning cycles often precede ultrasonic cleaning. (Refer to B3, Reference No. 1.e.)

- C4 *Continuous Weld*: The uninterrupted joining of metals by welding.
- C5 *Inspectable*: Designed, fabricated and installed to make product contact surfaces available for close visual observation.
- C6 *Non-Continuous Weld*: The joining of metals by welding such that a continuous seal is not achieved. For example, an intermittent (strip or spot) weld.
- C7 *Nontoxic Materials*: Substances, which under the conditions of their use, are in compliance with applicable requirements of the FDA.
- C8 *One Time Installation*: A rupture disc assembly designated for One Time Installation is designed to be easily cleaned by CIP and not intended for removal and reinstallation.
- C9 *Product*: Milk, milk products or other related products.
- C10 *Readily Removable*: Designed, fabricated, and installed to be quickly separated from the equipment with or without the use of simple hand tools.
- C11 *Rupture Disc Assembly*: A non-reclosing pressure and/or vacuum relief device. If the differential pressure changes to a predetermined level, the rupture disc opens, providing instantaneous relief and thus preventing a specific pressure and/or vacuum condition. The rupture disc assembly primarily consists of a rupture disc which by interaction with other components of the assembly will open within a predetermined pressure range at the selected coincident temperature. (The word “disc” may also be understood as the word “disk”.)
- A rupture disc assembly may optionally consist of any or all of the following: a top section, slot cover, rupture disc, a buckle member, a support ring, alarm indicator and means for opening the disc, as shown in Illustrations 3 thru 8.
- C11.1 *Alarm Indicator*: An optional device which may be integrated into the rupture disc assembly to provide an indication to monitoring equipment of a pressure relief event.
- C11.2 *Buckle Member*: A rupture disc assembly component designed to collapse or buckle within a predetermined pressure range.
- C11.3 *Differential Pressure*: The resulting pressure acting on the rupture disc assembly which is the combination of internal pressure or vacuum and external pressure, including back pressure.
- C11.4 *Explosion Vent Assembly*: An explosion vent assembly is functionally equivalent to a rupture disc assembly by definition, as a non-reclosing pressure and/or vacuum relief device. Explosion vent assemblies and corresponding explosion vent components may be circular, square or rectangular. See Appendix, Section 4, Illustration 8.
- C11.5 *Knife Blade*: An optional part of the rupture disc holder or rupture disc assembly that is used as a means for opening the disc when the burst pressure is reached.
- C11.6 *Rupture Disc*: A pressure and/or vacuum retaining membrane and is a component of the rupture disc assembly. The rupture disc may be designed to open within a predetermined pressure range, or the rupture disc may interact with components of the rupture disc assembly which determines the burst pressure to open the rupture disc.
- C11.7 *Rupture Disc Holder*: May consist of a custom inlet and outlet, or may be a pair of sanitary fittings, which then effectively “hold” the rupture disc assembly.

- C11.8 *Rupture Membrane:* The name for the rupture disc when used in an explosion vent assembly. The rupture membrane is equivalent to the rupture disc, except that it may be square or rectangular.
- C11.9 *Sanitary Ferrule Inlet:* A bottom optional component used in combination with the outlet to provide seating geometry for the rupture disc assembly.
- C11.10 *Sanitary Ferrule Outlet:* A top optional component used in combination with the inlet to provide seating geometry for the rupture disc assembly.
- C11.11 *Score Line:* A line of weakness on the rupture disc which provides a means for opening the rupture disc. In certain rupture disc assemblies, the score line may contribute to control of the burst pressure.
- C11.12 *Slot Cover:* A thin plastic film-type, non-pressure bearing, barrier used to protect the film rupture disc material from being pulled into or cut by slots or holes in adjacent supporting members such as the top section when pressure is applied to the rupture disc assembly. It is used in combination with plastic film-type rupture discs.
- C11.13 *Support Ring:* An optional; devise attached to the inlet or outlet side of the rupture disc to provide a rigid support. The support ring may have a hub, which is a feature to aid control of fragmentation on the downstream side of the rupture disc.
- C11.14 *Top Section:* Can be used to control the burst pressure by breaking within a predetermined pressure range. Refer to Illustration 4 & 5.
- C12 *Sealed:* Closed to the penetration of fluids by the application of one or more of the following: continuous welds, coatings, overlays, encapsulations, adhesives, rubber, rubber-like or plastic gasket under compression, mechanical force seals, and/or press fits or shrink-fits.
- C13 *Simple Hand Tools:* A screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.
- C14 *Soil:* Unwanted organic residue or inorganic matter.
- C15 **Surfaces**
- C15.1 *Product Contact Surfaces:* All surfaces which are exposed to the product and surfaces from which splashed product, liquids or material may drain, drop, or be drawn into the product or onto product contact surfaces when the rupture disc assembly is closed.
- C15.2 *Nonproduct Contact Surfaces:* All exposed surfaces from which splashed product, liquids, or other materials cannot drain, drop or be drawn into or onto the product or product contact surfaces when the rupture disc is closed.