

3-A Sanitary Standard for Formers, Fillers, and Sealers of Containers for Fluid Products, Number 17-12

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)

3-A SSI Effective Date: March 10, 2018

TABLE OF CONTENTS

TITLE	1
TABLE OF CONTENTS	2
DISCLAIMERS	5
FOREWORD	5
A SCOPE	6
B NORMATIVE REFERENCES	6
C DEFINITIONS	8
C1 Container	8
C2 Controlled Environment	8
C3 Filling Head	8
C4 Perforated Screens	8
C5 Product	8
C6 Dry Product Contact Surfaces	8
C7 Dry Non-Product Contact Surfaces	8
C8 Supplementary Fitment or Device	8
C9 Powdered Metal	9
C10 Surfaces	9
C10.1 Sterilant and Sanitizer Contact Surfaces	9
C10.2 Splash Contact Surfaces	9
C11 Unitized	9
C12 Woven Wire	9
C13 Slip-On Connectors	9
C14 Product Tank	9
D MATERIALS	9
D1 Product and Solution Contact Surfaces	9
D1.1 Metals	9
D1.2 Non-Metals	10
D2 Non-Product Contact Surfaces	10
E FABRICATION OF PRODUCT AND SOLUTION CONTACT SURFACES	
E1 Surface Texture	11
E2 Joints	11
E2.1 Permanent Joints	11
E2.2 Non-Permanent Joints	11
E3 Coatings	11
E4 Cleaning and Inspectability	11
E5 Draining	12
E6 Dead Ends	12
E7 Gaskets, Gasket Retaining Grooves, O-rings and Seals	12

E8	Radii	12
E9	Threads	12
E10	Perforated Surfaces	12
E11	Coil Springs	12
E12	Shafts	13
E13	Bearings	13
E14	Openings and Covers	13
E15	Hose Assemblies	13
E16	Flexible Tubing	13
E17	Product Tanks	13
E18	Shields and Guards	13
E19	Fill Valves Entering the Package (Bottom-Up Fill)	14
E20	Solution Pumps	14
F	FABRICATION OF NON-PRODUCT CONTACT SURFACES	
F1	Surfaces	15
F2	Joints	15
F3	Coatings	15
F4	Cleaning and Inspectability	15
F5	Draining	15
F6	Threads	15
F7	Service Piping and Lines	15
F8	Panels, Doors, or Access Ports	15
F9	Guards and Other Safety Devices	15
F10	Supports	15
F11	Name and/or Information Plates (Nameplates)	15
F12	Sterilizing Chambers	16
F13	Bearings	16
F14	Casters	16
F15	Recirculated Liquid Cooling and/or Heating Media	16
G	SPECIAL CONSIDERATIONS	16
APPENDIX		
1	STAINLESS STEEL AND EQUIVALENT MATERIALS	19
2	PRODUCT CONTACT SURFACE FINISH	19
3	AIR VENTING	19
4	CIP CLEANING	19
5	ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE ...	19

6 **INSTRUCTION HANDBOOK FOR INSTALLATION,
MAINTENANCE, AND CLEANING**.....19

7 **ELECTROLESS NICKEL ALLOY** 19

8 **HARMONIZATION**.....19

9 **HANDLING OF COLLECTED MILK**.....20

10 **RECOMMENDED REPLACEMENT OF SINGLE USE NOZZLE
SCREENS** 20

11 **RECOMMENDED CLEANING AND SANITIZING OF
MULTIPLE USE NOZZLE SCREENS** 20

12 **INFORMATION PLATE** 20

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 Sanitary Standards Inc. (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.

Drawings and illustrations contained herein are examples to assist in understanding the criteria in this 3-A Sanitary Standard. Illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Illustrations are non-normative.

Metric conversions are provided for convenience and are not intended to be mandatory.

The Appendix is an advisory or informative section unless specifically cited in the Materials or Fabrication Section as requiring conformance.

Foreword

This 3-A Sanitary Standard establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of Formers, Fillers, and Sealers of Containers for Fluid Products equipment and/or system(s).

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, and regulatory agencies, and by other SDOs to assure that adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses this document as its primary 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 (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: 3-A SSI, 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 3-A Sanitary Standard applies to the sanitary aspects of the unitized equipment for forming, filling, and sealing containers for fluid products. The equipment shall perform one or more of the following functions:

1. Forming the container
2. Dispensing a preformed container
3. Opening the container
4. Rinsing the container
5. Sanitizing or disinfecting the container
6. Filling the container
7. Closing the container
8. Sealing the container
9. Capping the container
10. Applying and sealing a supplementary fitment or device

The equipment shall start at the points where the product, utilities (air, water, steam, cleaning chemicals, etc.), container, container blank, or container material first enters the unitized equipment. The equipment shall end where the formed, filled, and/or sealed container and utilities exit the equipment.

A2 This standard does not pertain to the container, to free-standing container forming equipment or to other equipment such as labelers, printers, daters, applicators of supplementary fitments or devices or wrappers not furnished as part of the unitized equipment, nor does it apply to fillers of viscous products.

A3 To conform to this 3-A Sanitary Standard, formers, fillers and sealers of containers shall conform to the following criteria for design, materials of construction, fabrication techniques and installation, as applicable, 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 Sanitary Standard for):**

- | | |
|-----|---------------------------------------|
| 00- | General Requirement |
| 01- | Insulated Tanks |
| 02- | Centrifugal and Positive Rotary Pumps |
| 04- | Homogenizers and Reciprocating Pumps |