

Organizations/Agencies and their Standards:

3-A Dairy

3-A was founded in 1920's by three dairy related associations in the interest of creating sanitary standards and practices for equipment and systems used to process milk and milk products, and other perishable foods. Today, the 3-A Sanitary Standards Committees are composed of representatives from many government agencies and industry alike.

Standard Number 20-17, 3-A Sanitary Standards for multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment has been developed to "...cover the material requirements of plastics for multiple-use as product contact and/or cleaning solution contact surfaces in equipment for production, processing and handling of milk and milk product(s). Test criteria are provided for plastics as a means of determining their acceptance as to their ability to be cleansed and to receive effective bactericidal treatment and to maintain their essential functional properties and surface finish in accelerated use-simulating test..." Samples are subjected to chemicals representative of dairy cleaning compounds and measured for weight change and changes in surface appearance.

Historically, 3-A has maintained a published list of plastic materials, which comply with Standard Number 20-17. The 3-A Steering Committee has chosen to terminate maintenance of this list. Suppliers achieve compliance with this standard through independent evaluation and self-certification.

For further information regarding 3-A Sanitary Standards, contact 3-A Sanitary Standards Committees, 6245 Executive Blvd., Rockville, MD 29852-3938. By phone; (703) 761-2600.

ASTM

The American Society for Testing and Materials (ASTM) is a not-for-profit organization, which provides a forum for producer, users, and consumers to establish standards for materials, products, systems, and services. ASTM standards are developed voluntarily and used voluntarily. Standards become legally binding only when a government body references them in regulations, or when they are cited in a contract. ASTM standards referenced in this Guide pertain to characteristics of plastic resins prepared for property testing via injection molding. Property values listed in these Standards are not always representative of extruded shapes.

For further information on ASTM Standards, contact ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. By phone; (610) 832-9500.

FDA

The food and drug Administration (FDA) is a regulatory agency of the U.S. government, responsible for determining how materials may be used in contact with food products. The FDA participates in publication of The Federal Register, which contains The Code of Federal Regulations (CFR), a codification of the general rules established by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles, which represent a broad subject matter.

Title 21- *Food and Drugs* is composed on nine volumes, which are subdivided into Parts. Part 177 – *Indirect Food Additives: Polymers*, lists standards for polymers acceptable for use in components of single and repeat use food contact surfaces. Part 178 – *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers* include standards for certain polymer additives. Parts are divided into Sections identified by chemical family, which indicate physical, chemical, and compositional requirements, as well as acceptable service conditions for food contact. Regulations generally limit the extractable substance when exposed to selected solvents.

For further information on FDA regulations, contact U.S. Food & Drug Association, Office of Premarket Approval HFS-216, 200 C. Street SW, Washington, DC 20204. By phone; (202) 418-3080.

Health Canada/Agriculture Agrifood Canada

Health Canada and Agriculture Canada are Canadian Government Agencies analogous to the FDA and USDA, respectively, in the United States. These Canadian counterparts both conduct evaluations on material formulations, issuing “no objection letter(s)” on an application specific basis. Unlike current FDA and USDA policies, materials cannot be self-certified by manufacturers without prior Agency review and approval.

For further information on Health Canada regulations, contact Health Canada, Health Protection Branch, Bureau of Chemical Safety, First Floor East, Sir Frederick Banting Building, Tunney’s Pasture, Postal Locator 2201D, Ottawa, Ontario K1A 0L2. By phone; (613) 952-8000.

For further information on Agriculture & Agrifood Canada regulations, contact Agriculture and Agrifood Canada, Food Production & Inspection Branch, meat & Poultry Products Division, Plant & Equipment Evaluation, 59 Camelot Dr., Nepean, Ontario, K1A 0Y9. By phone; (613) 952-8000.

NSF

NSF International, formally known as The National Sanitation Foundation, is an independent, not-for-profit, neutral agency, serving government, industry, and consumers in achieving solutions to problems relating to public health and the environment. NSF Standards for equipment, products and services are developed with the active participation of public health and other regulatory officials, users, and industry. NSF publishes Listing Books which identify equipment, products, components, materials, ingredients or services that have demonstrated conformance with NSF requirements and are authorized for Certification.

Materials used for NSF approved devices must often comply with NSF material standards. Three commonly referenced NSF Standards for plastics materials are 14, 61, and 51. *NSF Standard 14: Plastics Piping Components and Related Materials* applies to thermoplastic and thermoset plastics piping system components in contact with potable water and primarily addresses physical properties of plastic components in piping and plumbing systems. *ANSI/NSF Standard 61: Drinking Water System Components – Health Effects* covers indirect drinking water additives. This standard addresses health and toxicity effects of plastic resins. *NSF Standard 51: Plastic Materials and Components Used in Food Equipment* defines the material requirements for food protection, considering extractables using FDA guidelines.

For further information on NSF Standards, contact NSF International, 3475 Plymouth Road, P.O. Box 1301140, Ann Arbor, MI 4811300140. By phone; (313) 769-8010.

Underwriters Laboratories (UL)

Underwriters Laboratories (UL) is an independent not-for-profit organization chartered “to establish, maintain, and operate laboratories for the investigation of devices, systems, and materials with respect to hazards affecting life and property.” “Listing”, the most widely recognized of UL’s services, means that samples of a product have been evaluated, and they comply with UL Standards. Products tested and recognized by UL are listed in a *Component Directory*.

Plastic Materials can be evaluated per the following UL Test Methods: *UL746A Polymeric Materials - Short Term Property Evaluations*; *UL 746B Polymeric Materials – Long Term Property Evaluations*; *UL746C Polymeric Materials – Use in Electrical Equipment Evaluations*; *UL94 Test for Flammability of Plastic Materials*. These tests are described in detail in *Plastics Recognized Component Directory – Polymeric Materials, Processes and Systems*, available from UL.

For further information, contact Underwriters Laboratories, 333 Pfingsten Road, Northbrook, IL 60062-2096. By phone; (800) 704-4050.

USP

The United States Pharmacopoeia (USP) is a voluntary, not-for-profit organization that promotes the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and other health care technologies by health professionals, patients, and consumers.

USP is responsible for establishing legally recognized product standards for drugs and other health related articles in the United States. In the 1960's, methodology and requirements were established for plastic materials used for pharmaceutical containers and closures, and were subsequently adopted by medical device manufacturers. USP tests measure biological reactivity of plastics in contact with mammalian cell cultures (in-vitro) and via implantation and injection of extractables into laboratory animals (in-vivo). Plastics are classified into one of six classes, each requiring different levels of testing. Class VI requires the most extensive testing.

USP does not regulate compliance or certification of plastics tested according to their published methods. The FDA has adopted some the tests specified by USP for regulation of medical devices.

For further information on USP test methods, contact USP at the United States Pharmacopoeia, 12601 Twinbrook Parkway, Rockville, MD 20852. By phone; (301) 881-0666. Reference USP 23 – NF 18, Chapters 87 – 88.

USDA

The United States Department of Agriculture (USDA) Food and Safety and Inspection Service regulates manufacturing, packaging and handling practices in the agricultural food industry. Historically, the USDA reviewed material composition and issued "letters of no objection" for materials deemed to be chemically acceptable for their intended application. This protocol is no longer practiced. Current policies for assuring the chemical acceptability of materials used for components of food processing equipment is outline in *Accepted Meat & Poultry Equipment Publication* (MPI-2, 3818 Directive 11220.0) November, 1193. This policy states that components used in direct food contact must be documented as to their compliance with the Federal Food, Drug and Cosmetic Act ("FDA compliance") by a written letter of guaranty from the manufacturer to ensure that they are formulated in compliance with appropriate regulations. Therefore, USDA requirements for material approval are satisfied by a certification of FDA compliance.

For further information on USDA regulations, contact U.S. Department of Agriculture, Compounds and Packaging Branch, Product Assessment Division, Building 306 BARC-East, Beltsville, MD 20705. By phone; (301) 504-8566.

We believe this information is the best currently available on the subject. It is subject to revision as additional knowledge and experience is gained. Plastics International makes no guarantee of results and assumes no obligation of liability whatsoever in connection with this information. Anyone intending to use recommendations contained in this publication should first satisfy himself that the recommendations are suitable for his use and meet all appropriate safety and health standards. This publication is not a license to operate under, or intended to suggest infringement of any existing patents. References to products not of A. L. Hyde manufacture do not indicate endorsement of named products or unsuitability of other similar products.

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