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# Standard Terminology Relating to Primary Barrier Packaging[1]

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## 1. Scope

1.1 This terminology covers the principal terms relating to primary barrier packaging and its materials. This terminology contains related definitions and descriptions of terms used or likely to be used in primary barrier packaging standards. The purpose of terminology is to promote clear understanding and interpretation of the standards in which they are used.

1.2 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

D883 Terminology Relating to Plastics

D1129 Terminology Relating to Water

F1349 Test Method for Nonvolatile Ultraviolet (UV) Absorbing Extractables from Microwave Susceptors

F1980 Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices



## 3. Terminology

**accelerated aging—**a technique to simulate the effects of time on a package by subjecting the product/package system to elevated temperatures in a controlled environment representative of controlled environment storage conditions. The equivalent time is generally estimated by assuming the degradation of packaging materials follows the kinetics described by the Arrhenius reaction rate function, more discussion of which is available in Guide F1980.

**accumulative pump,** *n*—a mechanical pump dispenser that accumulates internal pressure by means of a valving-system that maintains a high velocity flow of the product no matter what the actuation velocity that results in a consistent fine mist spray.

**acid foods—**foods that have a natural pH of 4.6 or below.

**adhesive transfer—**a condition occurring when an adhesive-coated material is peeled away from an opposing material to which it has been sealed and shows visible evidence of the adhesive being left on the opposing material. This evidence is in the form of an adhesive layer that remains with the opposing material, the adhesive having separated either adhesively from the coated web or cohesively within the adhesive itself.

**aseptic—**as applied to aseptic packaging, synonymous with commercially sterile.

**aseptic packaging—**filling of a commercially sterilized product into presterilized containers, followed by hermetic sealing in a commercially sterile atmosphere.

**aseptic presentation—**introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination.

**atomization,** *n*—the separation process of liquid into small particles.

**barrier—**any material limiting passage through itself of solids, liquids, semisolids, gases, vapors, or forms of energy such as ultraviolet light.

**barrier materials—**specialized porous or nonporous packaging materials that provide environmental protection to the package contents as well as protection to the environment from the package contents: (*1*) gas, vapor, humidity, liquid, microbial, or light resistant materials that control or eliminate the amount of those environmental constituents that pass into or out of a package; (*2*) a porous material preventing the passage of microorganisms that might contaminate the contents of the package.

**biological evaluation test (biotest)—**a test which involves exposure of sealed packages to biological indicators and is designed to determine the microbiological integrity of a package under the specific conditions of the test.

[1] This terminology is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of F02.50 on Package Design and Development.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

**burst strength—**a measure of the internal pressure necessary to rupture a package or seal.

**channel—**any unimpaired pathway across the entire width of the intended seal.

**clogging,** *v*—the restriction of normal product flow. Most commonly due to product drying in a product flow passage area of the mechanical break-up system.

**coextrusion—***in flexible barrier materials*, (*1*) a process whereby two or more plastic streams are forced simultaneously through one or more shaping orifices to become one continuously-formed multilayered structure. (*2*) Also, the product resulting from such a process.

**commercial sterility—** *of thermally processed food*, the condition achieved by application of heat, alone or in combination with other appropriate treatments, to render the food free of microorganisms capable of growing in the food at normal nonrefrigerated conditions at which the food is likely to be held during distribution and storage.

**conditioning—**the exposure of a material to the influence of a prescribed atmosphere for a stipulated period of time or until a stipulated relation is reached between material and atmosphere.

**cross direction (CD)—**the direction perpendicular to a material's flow through the machine on which the material is being produced or processed. Material orientation perpendicular to the flow direction through a machine may have different properties than *machine direction*. Also known as *transverse direction (TD)*.

**delamination—**the separation of layers in a multilayered structure.

**dispersion coating—***in flexible barrier materials*, (*1*) a process of applying a material, suspended or dispersed in a vehicle, to a surface in such a way that a continuous, coalesced, adherent layer results when the vehicle liquid (usually water) is evaporated. (*2*) Also, the product resulting from such a process.

**dual ovenable—**terms describing a food packaging container used to prepare food in either a conventional oven or a microwave oven.

**environmentally challenging—**the process of subjecting a package to extremes of temperature and/or humidity and/or other environmental conditions, with the goal of determining sensitivities of the package to environmental stresses. In contrast to accelerated aging, environmental challenging often includes conditions, or transitions, or both, of temperature and humidity that equal or exceed those that can be encountered in a package life cycle.

**exit orifice,** *n*—the final passage found in the insert that the liquid flows through before exiting the dispensing system where the size of the orifice diameter can determine the size of the spray particles and spray pattern.

**extrusion coating—***in flexible barrier materials*, (*1*) a process of extrusion whereby a molten extrudate adheres to the surface of another (solid) material, forming a continuous layer upon cooling. (*2*) Also, the product resulting from such a process.

**fine mist pump,** *n*—a mechanical pump dispenser that atomizes liquid into a fine mist. An accumulative pump is the most common type of fine mist pump.

**flexible—**easily hand-folded, flexed, twisted, and bent.

DISCUSSION—"Flexible" may be a characteristic of thin barrier materials, especially when thinner than 125 to 255 µm (5 to 10 mils), that are composed of materials that are otherwise classified as "rigid" or "semi-rigid" under the definitions concerning rigidity based on modulus of elasticity (see Terminology D883). Modulus of elasticity is an inherent property of a material which in conjunction with thickness determines flexibility.

**flexible package—**any package with at least one flexible component that can be bent back or folded back upon itself.

**fluoroptic temperature measurement—**temperature measurement based on the variation in total luminescence of a fluoroptic phosphor which has been previously calibrated versus a known temperature standard.

**food simulant—**a well-characterized substance used in place of food for investigative studies.

**force to actuate (FTA),** *n*—the peak force that corresponds to the pressure on the finger that a consumer feels upon fully actuating the mechanical pump dispenser.

**functional barrier—***in food packaging,* a material that effectively restricts passage of solids, liquids, semi-solids, vapors, or forms of energy such as ultraviolet light through itself, across its borders, or interface with another material or substance.

**functional compatibility,** *n*—effect of physical or chemical interaction between a consumer product and a specific pump mechanism where problems typically include deformation and degradation of components that result in a lower performance of the mechanical pump dispenser.

**fusion seal—**a bond formed by combining two or more materials through melting or other means so that the joining layers become indistinguishable at the interface.

**heat seal—**the result of bonding surfaces by controlled application of heat, pressure, and dwell time.

**hermetically sealed aseptic container—**a container that is designed and intended to be secure against the entry of microorganisms and thereby to maintain the commercial sterility of its contents.

**hot spot,** *n*—the area of a spray where the product concentration is high which can be visibly seen on a spray pattern as a concentrated stain on the alcohol-sensitive paper.

**hot tack—**the property of a heat seal to hold together when stressed while it is still hot from the sealing operation.

**laminate—**a product made by bonding together two or more layers of material or materials. (See also **multilayered structure**)

**lamination—***in flexible barrier materials*, the process of preparing a laminate which consists of two or more flexible barriers bonded together (see also **laminate**).

**leak—**a hole, void, or defect in the package material or mated components of a package capable of passing particulate, aerosols, liquid, or gas from one side (inside or outside) of the package to the other side contrary to intention.

**load (water load)—**an amount of water used to moderate the microwave radiation absorbed by a susceptor during simulated microwave heating tests.

**low-acid food—**any food, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity ($a_w$) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

**machine direction (MD)—**the direction parallel to a material's flow through the machine on which the material is being produced or processed. Flow direction through a machine may impart directional properties to a material. Also called *longitudinal direction (LD)*.

**major package defect—**a defect that is likely to result in failure or reduce significantly the usability of the package for its intended use.

**mechanical break-up unit (MBU),** *n*— a design structure found in the insert that forces product to flow in a swirling method for producing specific spray characteristics.

**mechanical pump dispenser,** *n*—a small, finger- or hand-actuated, mechanical device used to dispense (spray, stream, or flow) product from a container that may be, generally, held in one's hand.

**medical device—**any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other related article, intended by the manufacturer to be used, alone or in combination, for one of more of the specific purpose(s) of (*1*) diagnosis, prevention, monitoring, treatment, or alleviation of a disease; (*2*) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; (*3*) investigation, replacement, modification or support of the anatomy or of a physiological process—supporting or sustaining life; (*4*) control of conception; (*5*) disinfection of medical devices; and (*6*) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

**microbial barrier—**property of the sterile barrier system that prevents the ingress and/or egress of microorganisms under specified conditions.

**microbiological contamination (of packaged products)—**the entry of viable microorganisms into a finished package due to lack of or loss of package integrity.

**microbiological package integrity—**the physical condition of a finished package, including, but not limited to, the security of package seals, which ensures the maintenance of the package contents in a commercially sterile condition.

**microwave extraction cell—**a polytetrafluoroethylene cell used for evaluating microwave active materials. Refer to Test Method F1349 for schematics of cell construction.

**microwave only food package—**a container used to heat foods only in a microwave oven.

**microwave susceptor—**packaging material that, when placed in a microwave field, is designed to interact with the field and provide substantial heat to the package contents.

**minor package defect—**a defect that does not significantly reduce the usability of the package for its intended purpose, or that is a departure from established standards having little or no bearing on the effective use of the package.

**multilayered structure—***in flexible barrier materials*, a structure that consists of two or more continuous layers or plies of material.

DISCUSSION—Processes such as lamination, coextrusion, extrusion coating, and solution or dispersion coating can be used to make multilayered structures. (See also **laminate**).

**nonporous packaging material—**material which does not have pores or minute openings to allow volumetric air flow.

**nonvolatile extractables—** *(1) for purposes of the ASTM tests for volatile extractables and nonvolatile extractables,* nonvolatiles shall be defined as those compounds that give more than 50 % recovery in studies using the applicable nonvolatile extractables method; (*2*) *in microwave packaging*, those chemical species that are released from microwave food packaging under simulated use conditions and are detected using an applicable nonvolatile extracables method.

**output per stroke (OPS),** *n*—the amount of product dispensed with one complete actuation when measured in terms of weight (grams) or volume (microliter, milliliters, or cc's).

**package—**a container providing protection to a product during distribution, storage, retailing, and use.

**package integrity—**the physical capability of a given package to protect its contents with the desired level of protection over a defined period of service; for example, as a barrier to physical, microbiological, or chemical challenges.

**package performance—**the ability of the packaging system, including the primary package or sterile barrier system and protective packaging, to withstand the hazards of handling, distribution, and storage.

**packaging system—**combination of the sterile barrier system and protective packaging.

**peelable seal—**the opening characteristic of forcibly separating two package substrates, which have been joined together by a sealing process, without tearing, film fracturing, delamination, or fiber tear of the substrates.

**permeation—**the transfer of a gas or vapor through a nonporous material.

**pinhole—**a small opening of non-specific shape or dimension that passes linearly and completely through all layers of a packaging material.

DISCUSSION—In a foil laminate structure a void, commonly called a pinhole or foil pinhole, may only be in the foil layer without an opening through all laminate layers.

**porous packaging material—**a material used in medical packaging which is intended to provide an environmental and biological barrier, while allowing sufficient air flow to be used in gaseous sterilization methods (for example, EtO, steam, gas plasma).

**preformed sterile barrier system—**sterile barrier system that is supplied partially assembled for filling and final closure or sealing (for example, pouches, bags, and open reusable containers).

**primary packaging,** *n*—the first wrap or containment of the contents.

**primary barrier packaging,** *n*—the first level of packaging that provides environmental protection to the package contents as well as protection to the environment from the package contents: *(1)* gas, vapor, humidity, liquid, microbial, or light resistant packaging that controls or eliminates the amount of those environmental constituents that pass into or out of a package; *(2)* a porous package preventing the passage of microorganisms that might contaminate the contents of the package.

**priming,** *v*—the initial process of evacuating air from the mechanical pump dispenser and replacing it with product so that the dispensing process may begin.

**protective packaging—**(*1*) configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use; (*2*) any package or configuration of materials that eliminates external factors that may adversely affect the form, function, use, or appearance of the product through its intended packaging life cycle.

**retention of prime,** *n*—ability of a pump to retain its prime and dispense a full dose without re-priming after a period of non-use.

**retortable—**capable of withstanding specified thermal processing in a closed retort at temperatures above 100°C.

**seal—**the result of joining surfaces together to form a continuous bond without skips or breaks in the pattern, over the contact surface. For example, surfaces can be joined together by the use of adhesives or thermal fusion.

**seal contamination—**foreign matter in the seal area such as, but not limited to, water, grease, or food.

**seal creep—**the reduction in width of a seal due to a force being exerted on it, such as a bulky product, pouch distortion, or internal air pressure.

**seal creep resistance—**a measure of the ability of a sealed package or seal to remain intact when subjected to a constant force.

**seal integrity—**(*1*) characteristics of the seal that ensures that it maintains label claim(s), acceptable quality, and adequately contains the product; (*2*) characteristics of the seal, which ensures that it prevents the ingress of microorganisms under specified conditions.

**seal strength—**mechanical capacity of the seal to withstand force.

DISCUSSION—The measured seal strength will be impacted by the mechanical properties of the sealed material(s) (for example. the bending force of the sealed material(s), elongation of the material(s), and/or breaking or tearing of the material(s)) and will vary depending on the peeling tail angle.

**seam—**a noncontinuous joint of two or more surfaces of sheet material such as made by stitching, spot adhesions, or intermittent fusion.

**solution coating—***in flexible barrier materials*, (*1*) a process in which a substrate is covered with a homogeneous solution containing the coating material, followed by removal of the (usually organic) solvent(s). (*2*) Also, the product resulting from such a process.

**spitting,** *v*—dispensing of a low dose of product when both product and air are dispensed resulting in the pump generating a distinctive spitting noise.

**spray particles/droplets,** *n*—the spherically-shaped liquid objects that are the result of the atomization process created by a dispensing system with the size of these particles or droplets usually expressed in microns.

**spray pattern,** *n*—pattern, preferably round, dispensed onto a flat surface when this surface is positioned so that it will intercept a spray at a 90 degree angle at a specific distance.

**standard sprayer,** *n*—generally, a finger-actuated, higher-output (greater than 500 µL) pump that delivers a coarser spray than a fine mist sprayer.

**sterilant—**an agent used to achieve commercial sterility.

**sterile—**free of any viable microorganisms, either active or dormant (Terminology D1129, D19).

**sterile barrier system—**minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

**sterilization compatibility—**attributes of the packaging material and/or system that allow it to both withstand the sterilization process and attain the required conditions for sterilization within the packaging system.

**streaming,** *v*—dispensing of a product in the form of a jet or a stream.

**stroke length,** *n*—the total distance of travel for the mechanical pump dispenser from where the mechanism of a pump sits at rest to where it is fully depressed.