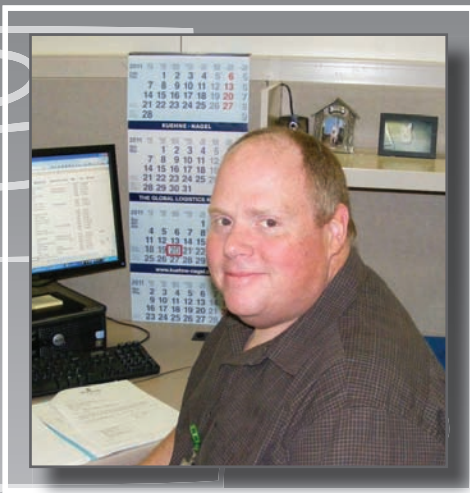


132 Years of Legacy

400



Bill Dempsey, Technical Service Representative

415



Steve Smith, Technical Service Manager

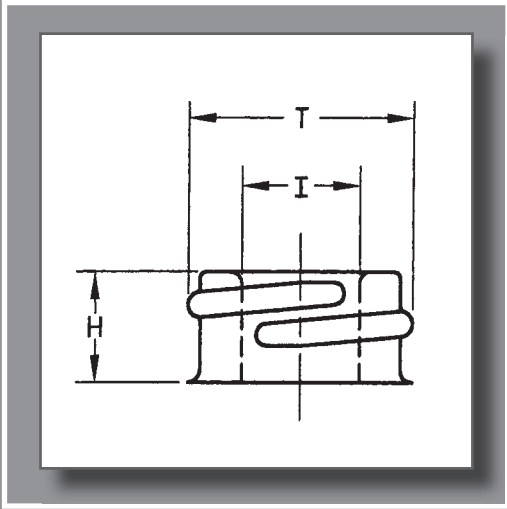
Technical Assistance

Give us a call if you need technical assistance

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Business Hours: 8:00 AM to 5:00 PM EST in U.S.A.

Technical Data



Section Highlights

- Closures
- Glass Facts
- Plastic Facts
- Terminal Sterilization
- Common Acronyms
- Common Conversion Factors
- Chemical Compatibility Chart
- Pipettes
- Plug Styles

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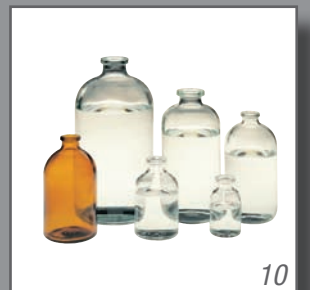
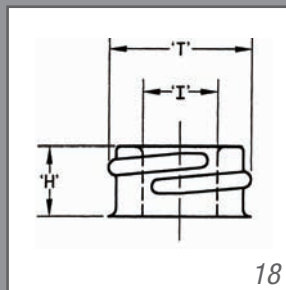
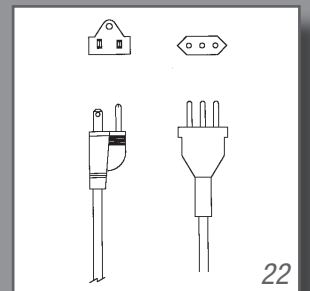
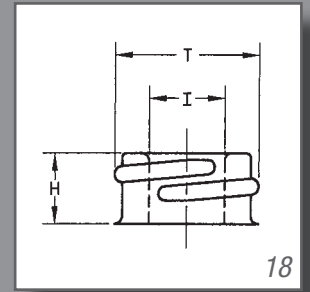
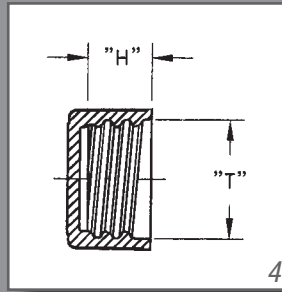
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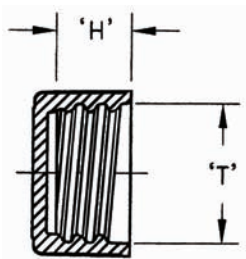
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Closure Size & Thread Style Guide



The screw closure industry has not standardized dimensions to the extent that the container industry has, thus it is advantageous to buy both container and screw closure from the same supplier when possible. Similar to the container industry, when a closure finish is designated as 33-400, it means that the nominal diameter measured across the inside of the closure at the opening is approximately 33mm. (See 'T' dimension on illustration.) The 400 ('H' dimension) designates a specific style of thread. The thread finish of the closure and container must be the same. A container with a 33-400 thread finish should be used with a closure that has a 33-400 thread finish.

Determining Closure Size ('T' Dimension)

To determine closure size, measure the closure opening from one side of the inner wall to the opposite side of the inner wall. Compare this number to the numbers found in the 'T' dimension columns in Table 1. Once this number is found in the table, follow the row to the far left to find the "Nominal Diameter" of the closure (33 in the above example).

Determining Thread Style ('H' Dimension)

To determine the specific thread style, measure the depth of the screw closure from the liner surface to the outside edge of the closure. Compare this number to the numbers found in the 'H' dimension columns in Table 1 that appear in the same row as the Nominal Diameter of the closure. Once this number is found in the table, follow the column to the top to find the specific style number (400 in the above example). The dimensions in the table are approximate and will probably be slightly different from what is measured (especially the 'H' dimension due to variations in liner thickness), but should be close enough to allow for the proper determination of the closure size.

Table 1. Closure Thread Finish Dimensions (Dimensions are in millimeters)

Nominal Dia (mm)	400		410		415		425		430	
	'T'	'H'	'T'	'H'	'T'	'H'	'T'	'H'	'T'	'H'
8	—	—	—	—	—	—	9.14	6.22	—	—
10	—	—	—	—	—	—	10.54	6.48	—	—
13	—	—	—	—	13.21	10.92	13.21	7.11	—	—
15	—	—	—	—	14.86	13.59	14.86	7.11	—	—
18	18.03	9.14	18.03	12.70	18.03	15.11	—	—	18.03	15.37
20	20.07	9.14	20.07	13.46	20.07	18.29	—	—	20.07	15.37
22	22.10	9.14	22.10	14.22	22.10	20.70	—	—	22.10	15.37
24	24.00	9.91	24.00	15.75	24.00	23.75	—	—	24.00	16.51
28	27.81	9.91	27.81	17.40	27.81	26.92	—	—	27.81	18.42
30	28.70	9.91	—	—	—	—	—	—	28.70	19.30
33	32.26	9.91	—	—	—	—	—	—	32.26	19.69
35	34.80	9.91	—	—	—	—	—	—	—	—
38	37.59	9.91	—	—	—	—	—	—	37.59	23.88
40	40.39	9.91	—	—	—	—	—	—	—	—
43	42.16	9.91	—	—	—	—	—	—	—	—
45	44.45	9.91	—	—	—	—	—	—	—	—
48	47.63	9.91	—	—	—	—	—	—	—	—
51	50.16	9.91	—	—	—	—	—	—	—	—
53	52.71	9.91	—	—	—	—	—	—	—	—
58	56.64	9.91	—	—	—	—	—	—	—	—
60	59.69	9.91	—	—	—	—	—	—	—	—
63	62.74	9.91	—	—	—	—	—	—	—	—
66	65.53	9.91	—	—	—	—	—	—	—	—
70	69.72	9.91	—	—	—	—	—	—	—	—
75	74.17	9.91	—	—	—	—	—	—	—	—
77	77.22	11.94	—	—	—	—	—	—	—	—
83	83.19	11.94	—	—	—	—	—	—	—	—
89	89.41	13.08	—	—	—	—	—	—	—	—
100	100.20	14.73	—	—	—	—	—	—	—	—
110	110.23	14.73	—	—	—	—	—	—	—	—
120	120.27	17.14	—	—	—	—	—	—	—	—

Closure Liner Guide

Usually the smallest component part of the package and usually overlooked is the selection of the closure liner. The liner must not alter or be altered by the product. It must withstand repeated applications and removals against the container surface while maintaining the integrity of the sealing surface. Below is some information that may help in choosing the right liner from the WHEATON product offering.

Pulp/Poly-Vinyl	One mil poly-vinyl film bonded to one mil HDPE on a #30 white pulp paper backing. Superior to plain pulp paper because it provides an excellent moisture barrier.	General purpose: Suitable for wide range of applications. Chemical resistance: Good for mild acids, alkalis, solvents, alcohols, oils and aqueous products. Poor for active hydrocarbons and bleaches.
PTFE Faced Foamed Polyethylene (PTFE/PE Foam)	PTFE faced foamed polyethylene liner offers the excellent chemical resistance of PTFE with the compressibility and sealing properties of polyethylene foam.	Typical applications: analytical lab samples, high purity chemicals, strong acids, solvents. Excellent for environmental samples, pharmaceuticals and diagnostic reagents.
Polyethylene Cone (PE Cone)	Manufactured from polyethylene (LDPE). The unique cone design provides a wedge type seal that not only seals across the top but also across the inside diameter.	Unique problem solving type of liner. This liner is stress crack resistant and offers superior torque retention and excellent sealing characteristics. It is recommended that this liner be tested prior to use for leak seal.
Styrene-Butadiene Rubber (14B)	The 14B white rubber lining material consists of homogeneous sulfur cured styrene-butadiene rubber. FDA Status complies with 21CFR 177.26, "Rubber articles intended for repeated use."	Excellent properties of resilience, resistant to moisture vapor. Satisfactory for most moderate chemicals. Not good for oils, strong acids and hydrocarbons. Autoclavable.
Styrene-Butadiene Rubber /0.005 PTFE (PTFE/Styrene-Butadiene)	The white rubber/0.005" PTFE liner consists of virgin PTFE bonded to the white sulfur cured styrene-butadiene rubber. Complies with the FDA 21CFR 177.1550.	Designed for the ultimate in product safety. PTFE provides a totally inert inner seal and surface facing the sample or product. Autoclavable.
Foamed Polyethylene (PE Foam)	A one piece, three ply coextruded liner consisting of both foamed and solid LDPE. The foam core is sandwiched with solid clear PE.	General Purpose: Broad applications base. Chemical resistance-good for acids, alkalis, solvents, alcohols, oils, household cosmetics and aqueous products. Poor for hydrocarbon solvents. Liner provides tight seal.
PTFE Faced Silicone Rubber (PTFE/Silicon)	The liner consists of 0.005" thick PTFE bonded to 0.055" thick silicone rubber.	Ideal for low temperature storage applications. PTFE facing provides excellent chemical barrier. Autoclavable
Pulp/Metal Foil (Foil)	Aluminum foil bonded to pulp board.	Good barrier properties, good resistance to hydrocarbons, oils, ketones and alcohols. Not good for acids or alkalis.
Low Density Polyethylene (LDPE)	Manufactured from polyethylene.	Good for distilled water, analytical standards and reagents.

Note: Closures and liners are designed for a variety of applications. Product performance can vary depending on conditions. It is recommended that proper tests be performed to determine the best liner for the application.

Torque for Screw Closures

The integrity of the closure-to-container seal is dependent upon a number of variables, such as the materials of the closure, liner, and container, the sealing surface of the container, and the application torque applied to the closure. The most important of these is the application torque. If the closure is applied too loosely, the contents could leak, especially during shipping. If the closure is applied too tightly, it may be too difficult to remove, or the container could break during application.

Table 2 offers some suggested torques that should provide an adequate seal for most applications. It is recommended that proper tests be performed to determine the optimum torque for the application. The most practical way to check the tightness is to measure the removal torque after the closure has been on the container for about 5 minutes. The removal torque should closely approximate the application torque. The minimum removal torque noted in the table should be maintained after a 24 hour period.

Table 2. Suggested Torques for Closures (in-lb)

Closure mm	Phenolic/Urea Closure on Glass Container		Phenolic/Urea Closure on Plastic Container		PP/PE Closure on Glass Container		PP/PE Closure on Plastic Container	
	Application Torque	Min Removal Torque	Application Torque	Min Removal Torque	Application Torque	Min Removal Torque	Application Torque	Min Removal Torque
15	8	4	6	3	12	7	8	4
18	9	5	7	4	13	8	9	5
20	10	5	8	4	15	9	10	5
22	11	6	9	5	17	10	11	5
24	12	6	10	5	18	11	12	6
28	14	7	12	6	21	12	14	7
33	18	9	15	7	24	14	17	8
38	20	10	17	7	29	17	19	9
43	22	11	18	9	33	20	22	11
48	24	12	20	10	36	22	24	12
58	28	14	24	12	44	26	29	14
70	35	18	28	14	52	32	35	17
89	45	22	36	18	65	40	45	22
100	50	25	40	20	75	38	50	25

Although the information in this chart was acquired from reputable sources, it should only be used as a guide in determining the proper application torque. WHEATON accepts no responsibility for the accuracy of this data or for any consequences resulting from its use.



2-Leg Lyophilization Stoppers



Straight Plug Style



3-Leg Lyophilization Stopper

Rubber Stopper Formulation Descriptions

Listed below are the primary stopper formulations with general descriptions that are supplied by WHEATON.

Gray Bromobutyl/39 with Complete Coat

Pros: low gas and vapor permeability, good for multiple piercing applications, compatible with most cephalosporin's, resistant to animal, vegetable, and mineral oils, good resistance to aliphatic, aromatic and chlorinated solvents. Cons: not recommended for use with ketones. Can be autoclaved and irradiated.

Gray Bromobutyl/46

Pros: low gas and vapor permeability, good for multiple piercing applications, excellent moisture absorption and desorption properties following autoclave and lyophilization drying cycles. Cons: poor resistance to mineral oil, aliphatic, aromatic, and chlorinated solvents. Can be autoclaved and irradiated.

Gray Bromobutyl/47

Pros: low gas and vapor permeability, great for multiple piercing applications after gamma irradiation, ultra low extractable compound, compatible with most cephalosporin's, very good moisture absorption and desorption properties following autoclave and lyophilization drying cycles, compatible with WFI applications. Cons: poor resistance to mineral oil, aliphatic, aromatic, and chlorinated solvents. Can be autoclaved and irradiated.

Gray Bromobutyl/50

Pros: low gas and vapor permeability, very good properties regarding ozone, animal and vegetable oil. Cons: not good for multiple piercing applications, poor resistance to mineral oil, aliphatic, aromatic, and chlorinated solvents. Can be autoclaved.

Gray Chlorobutyl/45

Pros: low gas and vapor permeability, good for multiple piercing applications, resistant to animal and vegetable oils. Cons: poor resistance to mineral oil, aliphatic, aromatic, and chlorinated solvents. Can be autoclaved and irradiated.

Gray Chlorobutyl/46

Pros: low gas and vapor permeability, good for multiple piercing applications, resistant to animal and vegetable oils, good for lyophilization applications. Cons: poor resistance to mineral oil, aliphatic, aromatic, and chlorinated solvents. Can be autoclaved and irradiated.

Gray Chlorobutyl/50

Pros: low gas and vapor permeability, resistant to animal and vegetable oil, good for lyophilization applications. Cons: poor resistance to mineral oil, aliphatic, aromatic, and chlorinated solvents. Can be autoclaved and irradiated.

Gray Chlorobutyl/55

Pros: low gas and vapor permeability, resistant to animal and vegetable oil, good for lyophilization applications. Cons: not good for multiple piercing applications, poor resistance to mineral oil, aliphatic, aromatic, and chlorinated solvents. Can be autoclaved and irradiated

Gray Chlorobutyl/Isoprene Blend/40 with PTFE Facing

Pros: barrier properties of PTFE, good coring characteristics, fair resistance to gas and moisture transmission compared to red isoprene. Cons: contains dry natural rubber. Can be autoclaved.

Gray Chlorobutyl/Isoprene Blend/50

Pros: good coring and reseal characteristics, fair resistance to gas and moisture transmission compared to red isoprene, good for lyophilization applications. Cons: contains dry natural rubber. Can be autoclaved.

Black Halobutyl/60

Pros: good resistance to gas and vapor transmission, good for lyophilization applications. Cons: poor coring and reseal characteristics, not good for use with acidic products. Can be autoclaved.

Red Natural/40

Pros: good coring and reseal characteristics. Cons: contains dry natural rubber, poor gas and vapor transmission compared to butyl, not appropriate for products that require an inert gas blanket, not good for use with acidic products or solvents. Can be autoclaved and irradiated.

Natural Silicone/55

Pros: Good for high heat applications, can withstand multiple steam autoclaves. Cons: very poor barrier to gas and vapor transmission, not appropriate for products that require an inert gas blanket. Can be autoclaved and irradiated.

Black Viton®/55

Pros: low gas and vapor permeability, resistant to animal, vegetable and mineral oil, aliphatic, aromatic, and chlorinated solvents, good for high heat applications. Cons: not recommended for ketones. Can be autoclaved.

Black EPDM

Pros: Excellent water and chemical resistance, good resistance to gas permeation, good for high heat applications. Cons: Poor oil resistance, poor resistance to solvents.

Rubber Stopper Formulation Characteristics

	Gray Bromobutyl/39 w/ Complete Safety Coat	Gray Bromobutyl/46	Gray Bromobutyl/47	Gray Bromobutyl/50	Gray Chlorobutyl/45	Gray Chlorobutyl/46	Gray Chlorobutyl/50	Gray Chlorobutyl/55
Typical Properties:								
Base Polymer	Bromobutyl	Bromobutyl	Bromobutyl	Bromobutyl	Chlorobutyl	Chlorobutyl	Chlorobutyl	Chlorobutyl
Durometer (shore A +/- 5)	39	46	47	50	45	46	50	55
Specific Gravity	1.19	1.35	1.26	1.35	1.24	1.32	1.30	1.38
Ash %	31	48	41	44.9	38.4	45.5	42.7	47.9

Typical Extraction Data, USP:

Distilled Water

pH Change	- 0.3	- 0.12	0.00	+ 0.22	- 0.20	- 0.37	- 0.23	- 0.30
Reducing Agents, mL, .01N I ₂	0.00	0.00	0.01	0.04	0.00	0.00	0.00	0.00
Turbidity, NTU	0.01	0.70	0.03	1.40	1.00	0.40	0.05	1.00
Total Solids, mg/100mL	0.8	0.70	0.30	1.30	0.00	0.30	0.40	1.0
Zinc, ppm	—	—	—	1.31	1.20	—	0.20	0.30
Lead, ppm	—	—	—	< 0.50	< 0.50	—	< 0.50	< 0.50

Toxicity Data:

Acute Systemic	Passes	—	—	—	Passes	—	Passes	Passes
Intracutaneous Reactivity	Passes	—	—	—	Passes	—	Passes	Passes
Cytotoxicity	Passes	Passes	Passes	Passes	Passes	Passes	Passes	Passes

	Gray Chlorobutyl Isoprene Blend/40	Gray Chlorobutyl Isoprene Blend/50	Black Halobutyl/60	Red Natural/40	Natural Silicone	Black Viton/55
Typical Properties:						
Base Polymer	Chlor/Iso Blend	Chlor/Iso Blend	Halobutyl	Natural	Silicone	Viton
Durometer (shore A +/- 5)	40	50	60	40	55	55
Specific Gravity	1.15	1.46	1.43	1.25	1.14	1.87
Ash %	29.50	55.70	51.20	38.90	N/A	N/A

Typical Extraction Data, USP:

Distilled Water

pH Change	- 0.6	- 0.8	- 0.3	+ 0.1	- 0.30	0.38
Reducing Agents, mL, .01N I ₂	0.0	0.0	0.0	0.0	0.10	0.06
Turbidity, NTU	0.7	2.6	5.0	29.0	1.00	0.00
Total Solids, mg/100mL	0.0	0.0	0.5	1.4	0.00	0.4
Zinc, ppm	1.0	1.6	0.5	0.2	—	0.05
Lead, ppm	0.0	—	0.0	0.0	< 0.50	0.50

Toxicity Data:

Acute Systemic	Passes	Passes	Passes	Passes	Passes	—
Intracutaneous Reactivity	Passes	Passes	Passes	Passes	Passes	—
Cytotoxicity	Passes	Passes	Passes	—	Passes	Passes

All stopper formulation data presented above is general information. Specific laboratory results are available upon request. It is recommended that all stoppers be thoroughly tested by the customer for compatibility.



Glass Manufacturing Terminology

Annealing Point

The temperature at which internal stresses in glass are significantly reduced. In the annealing operation, glass is gradually cooled from above the annealing point temperature to below the strain point temperature. This slow cooling relieves residual thermal stresses that would develop if the glass were allowed to cool in an uncontrolled manner.

Batch

The mixed raw materials used in manufacturing glass that have been blended and proportionally mixed for delivery to the glass furnace.

Blank

Usually refers to a glass parison that is formed during the first step of glass molding. The piece is then transferred to a lamp worker or glass blower for final shape configuration.

Blister

A gaseous inclusion or bubble in the glass.

Blow Mold

Usually a metal mold used to form a piece of glass from a hot gob.

Borosilicate Glass

A high silicate glass that has at least 5% boron oxide.

Contraction Coefficient

The fractional change in length of a piece of glass per degree change in temperature on cooling from the annealing point to ambient temperature.

Cullet

Waste or broken glass. Clean cullet is always used in the batch.

Density

Mass per unit volume measured in grams per cubic centimeter.

Distribution

The wall thickness or the evenness of the glass distribution throughout the container.

Etch

To attack the glass surface with a strong chemical agent, usually hydro-fluoric acid. Usually used in decorating glass.

Finish

The part of a bottle which holds the stopper or closure. The area that has the threads (generally a shortened term for thread finish). The first part made on an automatic machine, but the last part (or finish) to be made when bottles were hand blown. On labware, may refer to an interchangeable ground joint.

Forming

The shaping of hot glass.

Glassblowing

The shaping of glass using air pressure.

Gob

A portion of hot glass that is delivered from the furnace for forming.

Hard Glass

A glass with a high softening point or high viscosity (usually borosilicate).

Hot End

A manufacturing term for the area of a glass manufacturing plant where molten glass is processed.

Lampworking

Flame re-working of a blank or tubing cane, typically on a lathe.

Lehr

A long belt-fed, tunnel-shaped oven used to heat glass to the annealing point and then slowly cool it to room temperature to remove any residual thermal stresses in the glass. Can also be a large oven where glass is manually loaded and unloaded (batch lehr).

Linear Coefficient of Expansion

The fractional change in length of a piece of glass per degree change in temperature. The coefficient of expansion generally indicates the thermal endurance of the glass. Glasses with a low linear coefficient of expansion can be subjected to greater rapid temperature changes with less chance of fracture than glasses with a high coefficient of expansion. (Generally, Type I glass has a lower COE than Type III).

Melt

The amount of glass that is melted at one time.

Mold Mark

The mark in the bottom of the container that denotes the manufacturer.

Pressed Glass

Glassware that is formed by pressing a gob between a mold and a plunger.

Soda-Lime (or Soft) Glass

A glass with a substantial portion of lime in the formula.

Softening Point

Temperature at which a thread or rod of glass rapidly deforms under its own weight.

Strain Point

The temperature at which thermal residual stresses become permanent upon cooling. Temperatures above the strain point will introduce permanent stresses that can cause or contribute to fracture. At temperatures below the strain point, the glass can be temporarily heated and cooled without introducing permanent stress. The strain point can be considered the maximum service temperature.

Tank

The furnace that melts the raw materials into molten glass. Temperatures in the tank vary depending on the glass type being melted, but are typically in excess of 1200°C.

Temper

The degree of residual stress in annealed glass as measured using polarized light techniques.

Weathering

The attack on glass surface by atmospheric elements.

Glass Types

The glass products in this catalog are made from many different glass formulations. Following are brief definitions of these glass types and descriptions of their characteristics. USP refers to the United States Pharmacopeia or U.S. Pharmacopeia, which is the official public standards setting authority for pharmaceutical and healthcare related products in the U.S. The standards set by the USP are recognized in more than 130 countries worldwide.

180 Glass: An exceptionally clear borosilicate glass of high chemical durability, which has been especially formulated for the lowest background count. Great care has been taken to select only those ingredients for the batch that would not cause unwanted background count or color. Potassium as a separate element has been excluded from the batch to minimize K40. Special controls assure high quality and batch to batch uniformity. This glass is only available as a tubing vial.

200 Glass: Also referred to as 33 expansion low extractable borosilicate glass, this is a clear glass with exceptional thermal endurance. This glass conforms to USP Type I, ASTM E438 Type I Class A requirements and meets all sterilization requirements.

300 Glass: A chemically resistant clear borosilicate glass that meets all the requirements for Type I glass as specified in the current revision of the U.S. Pharmacopeia.

320 Glass: A similar composition to 300 Glass except amber color for light sensitive applications. Meets UV light protection limits as specified in the current revision of the U.S. Pharmacopeia.

400 Glass: A clear borosilicate glass that falls well within the limits for USP, Type I chemically resistant borosilicate glass, as specified in the current revision of the U.S. Pharmacopeia.

500 Glass: Similar to the 400 Glass formulation except amber color for light sensitive applications. Meets UV light protection limits as specified in the current revision of the U.S. Pharmacopeia.

800 Glass: A superior soda-lime clear glass that meets requirements for Type III soda lime glass as specified in the current revision of the U.S. Pharmacopeia

900 Glass: Similar in formulation to 800 Glass except amber color for light sensitive applications. Meets UV light protection limits as specified in the current revision of the U.S. Pharmacopeia.

Table 3. Typical Properties of WHEATON Glass

	Glass Type							
	"180"	"200"	"300"	"320"	"400"	"500"	"800"	"900"
Strain Point °C	510	505	525	510	520	505	510	496
Annealing Point °C	560	560	570	560	560	540	548	536
Softening Point °C	821	820	785	770	735	730	729	713
Linear Coefficient of Expansion								
(0-300°C)x10 ⁻⁷	33	33	55	55	63	62	88	91
Density g/cm ³	2.23	2.22	2.33	2.42	2.44	2.46	2.48	2.50
ASTM Glass Type & Class	I A	I A	I B	— —	— —	— —	— —	— —
USP Glass Type	I	I	I	I	I	I	III,NP	III,NP
Light Protection					Yes		Yes	Yes
NP= Non-parenteral			USP= U.S. Pharmacopeia					

Table 4. Typical Composition (%) of Some Glass Containers

Forming Process	"180"	"200"	"300"	"320"	"400"	"500"	"800"	"900"
	Tubing Vial	Tubing Vial	Tubing Vial	Tubing Vial	Molded Container	Molded Container	Molded Container	Molded Container
SiO ₂	81	81	72	70	69	65.5	73	73
Al ₂ O ₃	2	2	7	6	5.5	6	2	2
Na ₂ O+K ₂ O	4	4	9	8	10	9	14	14.2
CaO+MgO	<0.2	<0.2	1	0.5	1.5	0.5	10.5	10
B ₂ O ₃	13	13	12	7	11	9		0.5
Fe ₂ O ₃	<0.1	<0.1	<0.1	1.5	<0.1	1	<0.05	0.3
BaO			<0.1	2	2.5	1.5		
ZnO					0.5	0.5		
MnO ₂						7		
TiO ₂				5				
SO ₃							0.2	

Table 5. Typical Elemental Extraction Data of Some Glass Types (ppm)

USP Glass Type	Si	Al	Na	K	Ca	Mg	Fe	Ba	Zn	Ti
Type I Clear - Molded	1.3	<0.006	0.26	0.05	<0.02	<0.02	<0.015	<0.008	0.14	<0.005
Type III Clear - Molded	26	0.17	9.1	0.18	3.6	0.20	<0.015	<0.008	0.07	<0.005
Type I Amber - Molded	2.4	0.06	0.71	0.1	<0.02	<0.02	<0.015	<0.008	0.21	<0.005
Type III Amber - Molded	22	0.16	9.3	<0.03	3.4	0.23	0.016	<0.008	0.03	<0.005
Type I Clear - Tubular	4.8	<0.01	1.1	<0.03	0.13	0.07	<0.012	<0.008	<0.01	<0.005
Type I Amber - Tubular	7.4	0.17	1.8	0.45	<0.02	<0.02	<0.015	<0.008	0.23	<0.005
Blank- PE	<0.05	<0.006	<0.01	0.048	<0.02	<0.02	<0.015	<0.08	<0.006	<0.005

Results after autoclave at 121°C for 60 minutes - high purity water in 20mL containers



Tubular Sample Vials



Serum Vials



Tubular V Vials

Factors for Selecting a Glass Container

Chemical Durability

The U.S. Pharmacopeia classifies pharmaceutical glass containers according to their chemical durability, which is their resistance to water attack. Different types of glass react differently when exposed to solutions and vapors. Reactive substances will leach constituents from the glass surface into the contained product. This reaction can occur with ordinary aqueous, saline and alcohol based solutions. The primary ion removed from the glass surface is sodium; however all elements are subject to leaching. It is not uncommon to experience an increase in product pH as sodium is extracted from the container. Corrosion of the glass occurs over time and is accelerated by moist heat-treating processes like autoclaving.

Containers are classified by the USP as Type I, Type II, and Type III. Type I is the most chemically durable glass and Type NP is the least durable. Test methods and specification limits are determined by the USP in Chapter <660> Containers. USP Type can be used as a general guide for container selection but should not be the only criteria in the decision making process. A set of criteria has been developed over the years to assist with the selection of glass containers. These guidelines were established to narrow the selection of possible containers. It is the product manufacturers responsibility to do testing to ensure that the glass container is suitable for the application and contained product.



USP Type I

USP Type I classification is a borosilicate glass with superior chemical resistance. This class of glass represents the least reactive glass containers available. Typically, this glass can be used for most applications, including packaging for parenteral and non-parenteral products. Type I glass may be used to package acidic, neutral and alkaline products. Water for injection, unbuffered products, chemicals, sensitive lab samples, and those requiring sterilization are commonly packaged in Type I borosilicate glass. Type I glass can be subject to chemical attack under certain conditions, so container selection must be made carefully for very low and very high pH applications. Most glass laboratory apparatus are Type I borosilicate glass.

Even though Type I glass has the highest chemical durability, there still may be some sensitivity with certain packaged products. For applications where standard Type I glass does not provide sufficient protection against alkali extraction and pH shifting, internal surface treatment can be used to further improve the chemical durability of the container. This surface enhancement may become especially important for pH sensitive products packaged in small containers because smaller containers have a higher surface area to volume ratio. See the USP Type II description for an explanation of the internal surface treatment process. It should be noted that the USP does not place any additional durability requirements on surface treated Type I glass.

USP Type II

USP Type II glass is soda-lime glass that has been treated with sulfur compounds to de-alkalize the interior surface of the container. This treatment results in a container with high chemical resistance because alkali is removed from the glass surface prior to use. The amount of ions available to leach into the product is reduced thus, the container durability is increased. Extraction salts will be present on the interior surface of new sulfur treated containers, and the containers may require washing prior to use. Type II glass is less chemically durable than Type I glass, but is more chemically durable than Type III glass. It can be used for acidic and neutral parenteral preparations that remain below pH 7 during their shelf life.



USP Type III

USP Type III is a soda-lime glass with moderate chemical resistance. It is typically acceptable for packaging dry powders that will be dissolved into solutions or buffers that are insensitive to alkali.

Type III glass may not be suitable for autoclaved products because the autoclaving process will accelerate the glass corrosion reaction. Dry heat sterilization processes are typically not a problem for Type III containers.

Factors other than USP Type

Handling Considerations

It is important to consider filling and processing steps when choosing a container. Both mechanical and thermal stresses are important factors. For a given thermal expansion range, a typical tubing vial with thin, uniform walls will withstand thermal shock better than a molded glass container.

The physical design of the container will play a part in the amount of thermal and mechanical shock resistance it exhibits. It is often necessary to make a compromise between high resistance to mechanical shock and high resistance to thermal shock.



Light Sensitivity

Light sensitive products must be packaged in amber glass. Amber glass is formulated to absorb light in the Ultra Violet region of the electromagnetic spectrum. Test methods and specification limits for light protection can be found in the current revision of the U. S. Pharmacopoeia.

Specific Ion Sensitivity

If a product is sensitive to the presence of particular ions, the composition of the glass container should be considered. For example, products that contain sulfate salts may experience the formation of precipitates if packaged in glass with barium or calcium in the formulation. In this example, it would be desirable to avoid glass that contains barium and calcium. A second example is pre-cleaned containers for environmental sampling. Even though the containers are clean, the chemical durability characteristics of the glass have not been altered. Thus, it would not be feasible to test the samples for low levels of sodium, because the sample will extract sodium from the container's surface.

Determining a Glass Container Thread Finish

GPI refers to the **Glass Packaging Institute**, which is responsible for establishing and issuing uniform voluntary standards regarding the types and finishes produced by American glass manufacturers. When a container finish is designated as 20-400, it means that the diameter across the outside of the threads is approximately 20mm. (See 'T' dimension on illustration.) The 400 designates a specific style of thread. Table 6 shows average dimensions for comparison and to aid in sizing. The actual dimensions may vary slightly, but should be close enough for proper determination of thread finish.

Other Variables to Consider

1. Container size and physical design. Narrow mouth vs. wide mouth, tall vs. short, etc.
2. Color. Is light sensitivity an issue? Is amber glass needed?
3. Shelf life. How long are you planning to store a sample or product in the container?
4. Method of fabrication. Molded or tubing based?
5. Processes the container will undergo. Storage conditions (freezing or heat); washing, sterilization; method of sealing; humidity; hot or cold filling; de-pyrogenation.
6. Storage after filling. Time (shelf life needed); heat, cold, moisture; shipping conditions; light exposure.
7. Product composition. Dry powder; pH; concentration of ions; physico-chemical properties.
8. Closure type. Wide mouth vs. narrow mouth; septa lined open top closure; closed closure; liner material; sealing needed; threaded closure or crimp seal.

Opening Dimension of Glass Containers with Thread Finish

The minimum opening dimension 'I' of a glass container can be found if the container's thread finish is known. If the thread size of the container is 38-400, the 'I' can be determined from Table 6 by looking down the 'T' Dimension column (far left) until you find the number 38. Follow this row to the right, until you come to the 'I' min. column that is listed under the number 400. This number is the minimum opening of the container. The opening can be larger, but it should not be smaller.

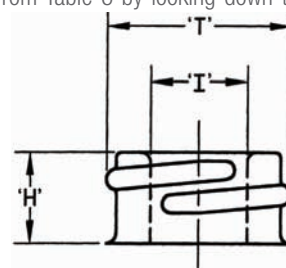


Table 6 Glass Thread Finish Dimensions (Dimensions are in millimeters)

'T' Dim (mm)	400		410		415		425		430	
	'H'	'I' min	'H'	'I' min	'H'	'I' min	'H'	'I' min	'H'	'I' min
8	-	-	-	-	-	-	6.53	2.90	-	-
10	-	-	-	-	-	-	6.86	3.76	-	-
13	-	-	-	-	11.23	5.54	7.49	5.54	-	-
15	-	-	-	-	13.89	6.55	7.49	6.55	-	-
18	9.04	8.26	13.03	8.26	15.42	8.26	-	-	15.34	6.86
20	9.04	10.26	13.82	10.26	18.59	10.26	-	-	15.34	7.92
22	9.04	12.27	14.61	12.27	21.01	12.27	-	-	15.34	10.41
24	9.78	13.11	16.15	13.11	24.05	13.11	-	-	16.43	11.68
28	9.78	16.26	17.73	16.26	27.23	16.26	-	-	18.39	13.34
30	9.86	16.59	-	-	-	-	-	-	19.30	14.43
33	9.86	20.09	-	-	-	-	-	-	19.69	17.86
35	9.86	22.23	-	-	-	-	-	-	-	-
38	9.86	25.07	-	-	-	-	-	-	24.03	21.03
40	9.86	27.71	-	-	-	-	-	-	-	-
43	9.86	29.59	-	-	-	-	-	-	-	-
45	9.86	31.78	-	-	-	-	-	-	-	-
48	9.86	35.08	-	-	-	-	-	-	-	-
51	9.98	37.57	-	-	-	-	-	-	-	-
53	9.98	40.08	-	-	-	-	-	-	-	-
58	9.98	44.07	-	-	-	-	-	-	-	-
60	9.98	47.07	-	-	-	-	-	-	-	-
63	9.98	50.09	-	-	-	-	-	-	-	-
66	9.98	53.09	-	-	-	-	-	-	-	-
70	9.98	57.07	-	-	-	-	-	-	-	-
75	9.98	61.57	-	-	-	-	-	-	-	-
77	11.99	64.67	-	-	-	-	-	-	-	-
83	11.99	69.93	-	-	-	-	-	-	-	-
89	13.21	74.12	-	-	-	-	-	-	-	-
100	14.78	84.94	-	-	-	-	-	-	-	-
110	14.78	94.92	-	-	-	-	-	-	-	-
120	17.02	104.93	-	-	-	-	-	-	-	-

Sterilization of Glass Containers

Although most types of glass are sterilizable by either steam or dry heat, certain techniques are recommended for specific types of glass. Most Type I borosilicate glass is suitable, when proper techniques are followed, for sterilization and de-pyrogenation. Type III is not recommended for repeated steam sterilization, although this may be appropriate on a single use basis. Recommended autoclave cycles are 121°C @ 15 psig for 20 minutes. Closures should be left loose on the containers. Proper care must be given when venting back to atmosphere or there may be damage to the containers.

Dry heat sterilization can be achieved at a temperature of 160°C for 2 to 3 hours, but glass containers are capable of withstanding sterilization temperatures up to 500°C without noticeable degradation of the glass. Repeated dry heat sterilization of containers containing a fair amount of moisture may be susceptible to glass flaking. Inversion of the container and good ventilation would prevent this from occurring. Inspect glass containers for chips, cracks, and scratches before each use and discard if damage is evident, as breakage may occur during sterilization if used. Glass containers may also be sterilized using gas or chemicals. Ethylene oxide (EtO), formaldehyde, or peroxide gas is generally used when heat and pressure cannot be used due to material limitations. Chemical disinfectants normally used are quaternary ammonium compounds, iodophors, formalin, benzalkonium chloride, and ethanol.

Glass containers may also be sterilized using irradiation, however, the process changes the color of the glass, which may not be acceptable for most applications. There is glass tubing available, which will not change color when irradiated. This would be available for those interested in large quantity orders of tubing vials only.

Mold Lubricants and Residues

Modern high-speed mold production of glass containers requires the use of release agents or coatings on the metal mold equipment to prevent sticking and malformation of the bottles in the molding process. A variety of coatings or lubricants are used to provide optimum viscosity and function according to the particular needs of the individual piece of process equipment as well as service conditions.

The coatings are compounded from colloidal graphite and sulfur suspended in hydrocarbon oils and waxes with small amounts of modifiers such as calcium soaps and greases. This "mold dope" is replenished through periodic swabbing of the mold equipment. The hot forming temperature and the subsequent lehr annealing (1000 – 1100°F) process will burn off the volatile sulfur and organic oils and waxes. Portions of carbon can remain since the major component (graphite) is very slowly decomposed and oxidized in the process. Quality control in manufacturing employs a number of devices (both automatic and manual) to eliminate the small percentage of product that has excess graphite spots.

Pressure & Vacuum in Glass Vessels

Because the conditions under which glassware is used vary widely, there is no guarantee against breakage. Always exercise care to protect personnel and property when using any vessel with vacuum or pressure. Never subject glassware showing visible signs of damage (chipped, cracked or scratched) to pressure or vacuum.

Weathering of Glass Containers

When glass containers are formed, the surface of the glass is enriched in alkali. The annealing process further enhances this effect. This phenomena is usually of no practical consequence and goes unnoticed, but in certain circumstances, it interferes with further processing of the container. As glass is exposed to the atmosphere, a complex reaction occurs on the surface between the alkali on the glass and gasses in the air. These reactions are commonly known as weathering. The reaction produces salts, which can absorb water from the air. It is these salts that are the source of surface related decorating problems. Weathering salts are composed of a mixture of various hydrates of sodium carbonate and sulfate along with minor amounts of similar calcium salts. Weathering is a normal condition and such salts are always found on glass surfaces as they are exposed to the atmosphere. The quantity and crystal appearance will vary depending upon time, humidity and temperatures of storage. These salts are easily removed by water rinsing.

All glass weathers, but some are more resistant than others. Borosilicate glass is most resistant, followed by durable soda-lime, and common soda lime. Since glass containers can be decorated in a myriad of ways, the weathering of glass must be considered in selecting a method that is effective and trouble free. Table 5 (see page 9) is a rough guide to the decorating and labeling of glass.

The surface treatments used to remove weather salts or remove the alkali that cause weathering are somewhat limited. Since the salts are water soluble, a simple wipe with a wet cloth or washing prior to decoration or pressure sensitive labeling is effective in most cases.

Heat and humidity cycling or storing glass in a confined space promotes weathering. Keeping the glass under constant low humidity is effective in slowing weathering as it keeps the surface dry and reduces the salt build-up. Dry heating the container just prior to decorating or pressure sensitive labeling is sometimes successful.

A layer of absorbed moisture on the glass prevents good adhesion of pressure sensitive labels. Water based adhesives, however, would be no problem. Several possible solutions to the problem can be suggested:

1. Simply storing the containers in an area of low humidity for several days may solve the problem.
2. Washing or wiping the ware with warm water. This removes the weathering salts and allows the achievement of a moisture-free surface.
3. Heating the ware will dry the surface and allow good adhesion of the labels. Heating will not remove the salts so the heating must be accomplished shortly before labeling.

The presence of dry salts on the ware will not cause a problem, but the salts can again, rapidly absorb moisture.

Weathering Chart

(√ = O.K.)

	Borosilicate	Soda-Lime
Rate of Weathering	Very slow (months)	Slow under low humidity. Rapid under high humidity. (typically weeks)
Pressure Sensitive Labels	√	√ Success varies with amount of weathering
Glue Labels	√	√
Ceramic Screen	√	√
Organic Screen	√	√
Gold	√	√ If not severely weathered

Safety Coated Containers

A plastisol coating was developed to contain glass fragments and allow for a controlled release of the contents in the event of container breakage. The coating:

- Adds impact, thermal shock, and slip resistance
- Contains glass - prevents flying fragments and cuts
- Contains contents - reduces risk of chemical exposure and inhalation. Allows time for proper disposal.

The coating material is plastisol, which is a dispersion of a fine particle size PVC resin (polyvinyl chloride) in a plasticizer where stabilizers, fillers, modifiers, colorants, and other compounding ingredients may be added. When the plastisol is heated, the suspended PVC particles begin to swell and absorb the surrounding liquid plasticizer. When the temperature is increased to over 300°F, fusion of the particles occurs and the particles coalesce into a homogeneous mass. The coating process is a heat-and-time related process that determines coating weight and thickness and is controlled by machine line speeds and oven temperatures. The more heat, the heavier the coating, and the slower the line, the heavier the coating.

Non-autoclavable coated containers can be used successfully at 121°C (250°F) and below. Do not use above 300°F or over direct heat or flame. The coating is not dry heat sterilizable. Coating will yellow and burn with high heat exposure but will continue to protect until black.

Labeling Adhesives for Coated Glass Containers

Labeling of plastisol coated glass containers has always been somewhat of a problem. It is important to select a face stock and adhesive combination with the proper performance characteristics for the intended product and application. It is recommended that prior to the selection of any adhesive, the customer contact the adhesive manufacturer or supplier and discuss the application requirements.

For on-line and pressure sensitive labeling of plastisol coated glassware, an acrylic based adhesive with low rubber and vinyl content is recommended. Other label adhesives will usually extract the plasticizer from the coating, become soft, bleed through the label, and eventually lose adhesion. Acrylics block the plasticizer extraction and allow the initial adhesion to remain undisturbed. There are, however, many variations of acrylic based adhesives and some are more effective than others. Adhesives are usually formulations of several chemicals that are combined in a variety of ratios and available in many forms. It is for these reasons, that accelerated age testing is advisable.

When selecting an adhesive for a specific application, consideration should be given to the necessary bond strength and duration, moisture, UV, heat, and solvent resistance. There is no substitute for proper testing of the proposed materials under actual usage conditions. The final decision should be made by the customer to choose the label/adhesive combination that meets the requirements of the specific use.



Autoclave Sterilization Recommendations for Autoclavable Coated Containers

The suggested conditions for steam sterilization are 121°C (250°F) @ 15 psig for 20 minutes. Portions of the coating may absorb a small amount of water vapor and appear cloudy after autoclaving, however, the cloudiness will disappear as the coating dries. To speed clearing, glassware can be dried in an oven at 49 – 66°C (120 – 150°F). Autoclaving effects on the coating will vary slightly due to equipment, container size and configuration, procedure, and frequency of procedure. It is recommended that containers not be autoclaved touching each other to avoid possible sticking problems. Also, it is recommended that the autoclave pressure be allowed to return to zero before removing glassware. A sudden release of pressure may cause the coating to separate from the glass and produce air pockets under the coating.

Evaluation of a sample is the best way to determine if the safety coating will work for your application.

Recycling Safety Coated Containers

For after-use disposal, PVC safety coated containers create a unique situation in that they are a composite package of glass and plastic. Depending on the application, there are four ways to handle the disposal of coated containers:

Reuse

In the laboratory or industrial setting, coated containers can be washed, dried, and reused, perhaps for the collection of hazardous waste in the laboratory.

Recycle

For consumer pharmaceutical and cosmetic applications, coated glass containers should be able to go into residential glass recycling collection. Coated glass makes up such a small percentage of total glass collected that it should not present any recycling problems (variations in state and county recycling programs make it difficult to generalize).

For large quantity industrial or laboratory applications, recycling coated glass containers, as a whole, can create two problems: the grinding of the coated glass into cullet could be difficult, and the PVC in the glass furnace might create organic chlorides in the glass mixture which would affect the final pH of the glass. Also, if a hazardous material was packaged in the containers, many recyclers do not want to accept the glass.

The plastic coating can be cut and peeled from the container and the glass and the plastic jacket recycled, but for safety reasons this is not recommended. Both glass and PVC are recyclable materials. Stripped coatings are recycled into garden hoses and floor mats.

Technical Assistance

Give us a call if you need technical assistance

800.225.1437 (U.S. & Canada Only) 856.825.1100

Business Hours: 8:00 AM to 5:00 PM EST in U.S.A.

Landfill

Coated containers can be crushed and safely landfilled. The plastic jacket is made of PVC material, which is very chemically stable and does not leach out harmful chemicals into groundwater. In fact, PVC is often used to make liners for landfill sites.

Incinerate

Coated containers can be incinerated. PVC is often blamed for the release of toxic dioxins and hydrochloric acid (HCL). However, research has shown that dioxins and hydrochloric acid are generated no matter what amount of PVC is present in the waste. Incinerator operating conditions and temperatures determine the amounts produced. Hydrochloric acid, which can cause acid rain, can be controlled in a modern incinerator equipped with a proper scrubber.

The safety coating was developed to contain the glass fragments and allow for a controlled release of the contents in the event of container breakage. In addition, the coating adds impact, thermal shock, and slip resistance, prevents flying fragments and cuts, and reduces risk of chemical exposure and inhalation. Few, if any, alternative-coating materials have been found that perform as well or better than PVC plastisol.

Recycling Glass

Most household glass containers are manufactured from soda-lime glass. All of our soda-lime glass may be recycled in the same manner after performing any necessary decontamination procedures. Borosilicate glass must not be mixed and recycled with soda-lime glass.

General Cleaning of Glassware

Handle glassware carefully. Most damage to glassware occurs during cleaning.

Glassware should be washed as soon as possible after use to avoid caking of residue. It is important to not let soiled glassware dry out. If immediate cleaning is not possible, the glassware should be put to soak in water. Use of a cleaning agent is recommended. Glassware should not be cleaned with harsh or abrasive cleaners. It is recommended that a mild detergent or non-abrasive cleaner be used. Hard utensils, wire brushes or bottle brushes with wire cores, should not be used for cleaning. It is recommended that a sponge brush that is soft and flexible be used. Scratched glassware is prone to breakage during freezing or heating.

After washing, the glassware should be rinsed with tap water to remove any cleaning agent residue. After the tap water rinse, the glassware should be rinsed with distilled or deionized water. Dry the glassware inverted on racks or pegboards. Inspect the glassware for chips, cracks, and scratches on the inside and outside. Do not use glassware with visible signs of damage.

Ophthalmic Applications:

When using plastics for ophthalmic applications, it is important to know that many mold release agents contain zinc stearate which is not generally well suited for ophthalmic applications. There are resins that are zinc stearate free. If you are looking for a packaging for ophthalmic use, give us a call and we can supply you product in zinc stearate free resin.

Terminal Sterilization:

Terminal sterilization is defined as a process whereby a product is sterilized in its final container and which permits the measurement and evaluation of quantifiable microbial lethality. All customers should work with a sterilization provider to validate cycle to assure sterility.

Things to watch for:

Steam Sterilization – 121°C for 30 minutes (Standard Cycle)

- Melting Point of Plastics
LDPE, LLDPE, MDPE and HDPE should not be steam sterilized. They may melt in the autoclave. Degradation of the plastic may occur.
- Pressure
When steam sterilizing, the increase in temperature will create pressure inside the container. When using a stopper and seal closure system this can put pressure on the stopper causing pressure against the seal. When you are using a center tear or full tear seal this pressure can create the potential to break the seal along the perforation lines.

Gamma Radiation Sterilization (Standard Dose is 2.5 Megarads)

- Glass
When using radiation sterilization clear glass will discolor. If over sterilized, glass can start to flake. There is a specialty clear glass called Cerium that will not discolor, however, Cerium is more expensive and is a custom item.
- Plastic
For most applications the proper dose of radiation on plastic should not cause any problems unless it is exposed to an excessive amount of radiation or exposed more than once. When plastics are overexposed they become brittle and may start cracking. The exception to this is with Polypropylene. Polypropylene will discolor when exposed to radiation. You can avoid this discoloration by ensuring the PP resin is of a radiation grade.

How is Sterilization Regulated?

CGMP regulations in 21 CFR

- Part 210: Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General (1978)
- Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals (1996)
- 210 & 211 available at: www.fda.gov/cder/dmpq/
- Parts 808, 812 & 820: Medical Device - CGMP Final Rule; Quality System Regulation (1996)
- Available at www.fda.gov/cdrh/humfac/frqsr.html
- A written agreement with contract sterilizer is required.

Useful References:

- ANSI/AAMI/ISO standards and TIRs available at www.aami.org
- USP 25 – order from www.usp.org

Plastic Manufacturing Terminology

Blow Mold

Cavity that receives the Preform, which will be blown into the desired shape.

Blow Pin

Used in Extrusion Blow Molding. Hollow tube that pierces Preform and introduces air to blow Preform into shape of Blow Mold.

Cavity

That part of the mold, which contains the reverse image of the product being formed.

Cold Runner

Flow channel for heat-softened polymer, which goes from the Plastifier to the mold cavities. Polymer in the flow channel is cooled with shaped parts in cavities and is later removed, reground, and reused.

Core

That part of a mold that allows the internal shaping of a product such as the internal threads of a closure.

Core Rod

Used in Injection Blow and Injection Stretch Blow Molding. Used in conjunction with a Preform Mold to manufacture a Preform. The Preform is formed around the Core Rod creating a hollow tube, which will then be transferred to a Blow Mold where air will be introduced forcing the Preform to take the shape of the Blow Mold cavity.

Extrusion Blow Molding

A molding process whereby heat-softened polymer is forced into the shape of a hollow tube. While still soft, a mold closes around the tube, pinching the top and bottom of the tube closed. A Blow Pin is introduced, and air is forced through the pin forcing the tube to take the shape of the Blow Mold cavity.

Flame Treating

A method of rendering inert thermoplastic objects receptive to inks, lacquers, paints, adhesives, etc. in which the object is bathed in an open flame to promote oxidation of the surface of the article. Polyolefins (HDPE, LDPE, PP, etc) are primarily those polymers that are flame treated.

Flash

Extra plastic attached to molded ware along the parting line, which must be removed before the part can be considered finished.

Gate

Used in Injection, Injection Blow, and Injection Stretch Blow Molding. The orifice through which the heat-softened polymer enters the cavity.

Hot Runner

Flow channel for heat-softened polymer, which goes from the Plastifier to the mold cavities. Polymer in the flow channel is kept softened so there is no runner material to grind up and reuse.

Hopper

Conical feed reservoir into which polymer pellets are loaded. These pellets then fall into a heated barrel (Plastifier), sometimes through a metering device.

Injection Blow Molding

A molding process in which heat-softened polymer is injected from a Plastifier into a mold cavity creating a Preform, which is then transferred to a Blow Mold where air is blown into the Preform, forcing it to take the shape of the Blow Mold cavity.

Injection Molding

A molding process whereby a heat-softened polymer is injected from a Plastifier into a relatively cool cavity, which gives the article the desired shape.

Injection Stretch Blow Molding

A molding process whereby Preforms are introduced into a cavity, stretched axially by a Stretch Rod, and then blown circumferentially to the shape of the Blow Mold cavity.

Melt Index

The amount, in grams, of a thermoplastic resin, which can be forced through a 0.0825 inch orifice when subjected to 2160 gms. force in 10 minutes at 190°C.

Mold

Contains the cavity or cavities of a desired part in which a heat-softened polymer is shaped.

Mold Seam

A line formed at the point of contact of the Mold halves.

Neck Ring

Part of the mold assembly, which forms the neck and finish of a container.

Nozzle

Hollow cored orifice that is screwed into the extrusion end of the Plastifier. The nozzle is designed to form a seal under pressure between the Plastifier and the Mold or Runner system. The front end of a nozzle may be either flat or spherical in shape.

Plastifier

Assembly whereby polymer pellets are fed from a Hopper into a barrel where they drop onto a turning screw which forces the pellets forward. Heater bands wrapped around the barrel melt the pellets as they are forced forward along the inside of the barrel. The molten polymer is then forced out the end of the barrel through the nozzle.

Preform

Used in Blow Molding processes. Heat-softened polymer is formed into a shape similar to a thick test tube with neck threads. This tube is subsequently inflated while inside a Blow Mold to create the shape of the desired article.

Regrind

A thermoplastic from a processor's own production that has been reground or re-pelletized after having been previously processed by molding.

Release Agent

A lubricant that facilitates molding.

Stretch Rod

Used in Injection Stretch Blow Molding. A rod that is introduced into the Preform to stretch it in an axial direction prior to the Preform being blown into the shape of the cavity.

Thermoplastic

Material that will repeatedly soften when heated and harden when cooled.

Plastic Resins

Listed below are the primary resins used in the manufacture of our products. Following are some of the characteristics and features of these resins. Also listed is the number assigned by the Society of the Plastics Industry (SPI) plastic recycling code system.

High Density Polyethylene (HDPE)

Flexible but more rigid than LDPE. Natural color is milky white, semi-translucent depending on density. Good impact strength and stress crack resistance. Good chemical resistance. Good vapor barrier but poor gas barrier. Sterilizable via EtO or gamma radiation.

Low Density Polyethylene (LDPE)

Very flexible, natural milky color, translucent with high impact strength. Excellent for mild and strong buffers, good chemical resistance. Good water vapor and alcohol barrier properties. Poor gas barrier, sterilizable with EtO or gamma radiation. Good stress crack and impact resistance.

Linear Low Density Polyethylene (LLDPE)

Very flexible, natural milky color, translucent with high impact strength. Excellent for mild and strong buffers, good chemical resistance. Good water vapor and alcohol barrier properties. Poor gas barrier, sterilizable with EtO or gamma radiation. Good stress crack and impact resistance.

Polybutylene Terephthalate (PBT)

Good chemical resistance, clear color, resistant to water, weak acids and bases at room temperature. Can be sterilized by EtO and autoclaving, at temperatures up to 180°C.

Polycarbonate (PC)

Rigid and strong, excellent clarity. High impact strength. Poor barrier properties.

Polyethylene Terephthalate (PET)

Semi-rigid to rigid depending on wall thickness. Natural color - clear and transparent. Good alcohol and solvent barrier; good gas and fair moisture barrier. Good to fair chemical barrier; not good for strong acids or bases. Good moldability. Sterilizable through EtO and gamma radiation. Good stress crack and impact resistance at room temperature and above.

Polypropylene (PP)

Rigid, solid, durable in container or closure forms. Opaque, natural grayish yellow in natural form. Excellent stress crack and impact resistance. Excellent moisture barrier, good oil and alcohol barrier, poor gas barrier properties. Good chemical resistance. Sterilizable with EtO or autoclaving.

Polyvinyl Chloride (PVC)

Flexible to rigid. Good for coatings; fair water and good oxygen barrier. Transparent to yellowish color in natural state. Good chemical resistance. Sterilizable by EtO. Good impact and some stress crack resistance. Poor recycling due to chloride residues.

PTFE (FEP, PFA)

Polytetrafluoroethylene, fluorinated ethylene propylene, perfluoroalkoxy. All fluoropolymers feature opaque characteristics, excellent chemical resistance, good heat stability and thermal shock resistance. All are autoclavable, heat, and gas sterilizable.

Table 7. Typical Properties of Plastics

	HDPE	LDPE	LLDPE	PET	PP	PS	PVC	PTFE
Max. Temp °C	120	80	50	60	135	70	70	240
Transparency	transl	transl	transl	transp	transl	transp	transl	opaq
Sterilization* **								
Autoclave	no	no	no	no	yes	no	no	yes
Gas	yes	yes	yes	yes	yes	yes	yes	yes
Dry Heat	no	no	no	no	no	no	no	yes
Radiation	yes	yes	yes	yes	no	yes	no	no
Disinfectants	yes	yes	yes	yes	yes	no	yes	yes
Density g/cm ³	0.95	0.92	0.92	1.33	0.90	1.06	1.34	2.15
Flexibility	semi	flex	flex	semi	rigid	rigid	rigid	rigid
Brittleness Temp °C	-100	-100	-76	-10	0	+20	-30	-110
Tensile Strength, psi	4000	2400	2000	8000	5000	6000	5000	4000

**Depends on thickness and relates to containers and closures. Because there are many grades of resins and processing methods, the above information should be used as a general guideline only.

Table 8. Permeability of Plastics

		HDPE	LDPE	LLDPE	PET	PP	PS	PVC	PTFE
N ₂	See Note 1	42	180		0.8	44	50	2	—
O ₂	See Note 1	150	500		5	90-140	185-485	4	—
CO ₂	See Note 1	580	2700		15	650	1160	4	—
Moisture	See Note 2	0.3	1.3		2.0-4.0	0.3-0.7	8.5	1.0-5.0	—

Note 1: Units are cc x mil /100 in² x day x atm @ 25°C

Note 2: Units are g x mil /100 in² x day @ 38°C, 50 - 90% RH

Factors for the Selection of a Plastic Container

Plastic containers have been developed for a variety of applications across many different industries over the years. There are many different types of polymers used in the creation of these containers to help fill the demands for the various applications. Polymers offer a variety of properties, each having different levels of importance with different users depending on the application. Some users may have flexibility within their product formula or filling process thus the focus on economical containers while others may need containers that are stronger, autoclavable, transparent, sterilized, etc., therefore requiring more specifications. WHEATON Science Packaging can help with polymer selection through comprehension of the customer's product, goals, and adaptability. Several questions should be posed to gather this understanding.

Some examples include:

- What is the container size and physical design. Narrow mouth vs. wide mouth, tall vs. short, etc.?
- Must the package be transparent, translucent, opaque or colored for either marketing or light protection?
- Are there specific shipment and storage conditions such as refrigeration, freezing, exclusion of light, etc.?
- Are there governmental regulations pertaining to the product?
- How is the product going to be dispensed by the user?
- Have any tests been run in plastic? Were they unsuccessful and why? What type of plastics?

Many things govern polymer suitability for package use.

These include:

- Permeation/Barrier
- Sorption Characteristics
- Chemical Resistance
- Stress Crack Resistance
- Rigidity/Flexibility
- Impact Resistance
- Sterilizability
- Recyclability
- Temperature Resistance
- Mold Release

Table 9. Packageability of Plastic Containers

Requirement	PC	PE	PET	PP	PS	PVC
Lightweight	6	2	5	1	3	6
Clarity	1	3	1	2	1	1
Toughness	3	1	2	3	9	8
Water Adsorption	6	2	3	2	4	2
Water Vapor Permeability	7	2	5	2	5	4
CO ₂ Permeability	1	6	2	5	9	3
O ₂ Permeability	8	7	2	6	8	2
Resistance: Acids	4	2	4	2	4	2
Resistance: Alkalis	7	2	2	2	2	2
Resistance: Oils	4	4	2	3	4	2
Resistance: Solvents	6	3	2	3	6	4
Resistance: High Humidity	6	1	1	1	1	1
Resistance: Sunlight	4	4	1	4	5	5
Resistance: Heat (hot fill)	1	3	1	2	5	1
Resistance: Cold	1	1	2	4	5	9

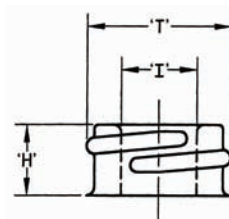
This chart is a generalization to aid in selection; there are many forms, thicknesses and various copolymers and additives available. The lower the number, the better the property. 1=Excellent; 9=Poor. (PE Properties are the same for HDPE & LDPE as well).

Biological Properties of Plastics

Plastic products and containers are considered to be biologically inert. For example polyethylenes, fluoropolymers, polypropylene, polystyrene, and polycarbonate are considered to be non-toxic to cell cultures. Distilled water for preparing culture media can be collected and stored in polyethylene containers.

Determining a Plastic Container Thread Finish

When a container finish is designated as 24-410, it means that the diameter across the outside of the threads is approximately 24mm. (See 'T' dimension on illustration.) The 410 designates a specific style of thread. Table 10 shows average dimensions for comparison and to aid in sizing. The actual dimensions may vary slightly.



Opening Dimension of Plastic Containers with Thread Finish

The minimum opening dimension 'I' of a plastic container can be found if the container's thread finish is known. If the thread size of the container is 38-400, the 'I' can be determined from either Table 10 by looking down the 'T' Dimension column (far left) until you find the number 38. Follow this row to the right, until you come to the 'I' min. column that is listed under the number 400. This number is the minimum opening of the container. The opening can be larger, but it should not be smaller.

Table 10 Plastic Thread Finish Dimensions (Dimensions are in millimeters)

'T' Dim (mm)	400		410		415		425	
	'H'	'I' min	'H'	'I' min	'H'	'I' min	'H'	'I' min
13	—	—	—	—	11.48	5.54	7.87	5.54
15	—	—	—	—	14.15	6.55	7.87	6.55
18	9.42	8.25	13.28	8.25	15.67	8.25	—	—
20	9.42	10.26	14.07	10.26	18.85	10.26	—	—
22	9.42	12.27	14.86	12.27	21.26	12.27	—	—
24	10.16	13.11	16.41	13.11	24.31	13.11	—	—
28	10.16	15.59	17.98	15.59	27.48	15.59	—	—
30	10.24	16.59	—	—	—	—	—	—
33	10.24	20.09	—	—	—	—	—	—
35	10.24	22.22	—	—	—	—	—	—
38	10.24	25.07	—	—	—	—	—	—
40	10.24	27.71	—	—	—	—	—	—
43	10.24	29.59	—	—	—	—	—	—
45	10.24	31.77	—	—	—	—	—	—
48	10.24	35.08	—	—	—	—	—	—
51	10.36	37.57	—	—	—	—	—	—
53	10.36	40.08	—	—	—	—	—	—
58	10.36	44.07	—	—	—	—	—	—
60	10.36	47.07	—	—	—	—	—	—
63	10.36	50.09	—	—	—	—	—	—
66	10.36	53.09	—	—	—	—	—	—
70	10.36	57.07	—	—	—	—	—	—
75	10.36	61.57	—	—	—	—	—	—
77	12.37	64.67	—	—	—	—	—	—
83	12.37	69.93	—	—	—	—	—	—
89	13.59	74.12	—	—	—	—	—	—
100	15.16	84.94	—	—	—	—	—	—
110	15.16	94.92	—	—	—	—	—	—
120	17.40	104.93	—	—	—	—	—	—

Sterilization of Plastics

There are a variety of plastic materials and methods by which these plastic materials can be sterilized. However, not all plastics can be sterilized by every method. An understanding of sterilization methods, problems that can occur, and terms associated with sterilization is helpful in determining plastic and plastic ware capability and performance. The following is presented to assist in gaining that understanding.

Exposure To Non-Sterile Conditions Causes Non-Sterility

While temperature and time used to melt thermoplastics kills microorganisms, manufactured ware will not remain sterile unless it is made and maintained in a sterile environment. Plastic ware is not “sterile as manufactured” since:

- ware is not blown with sterile air
- ware may be exposed to non-sterile conditions immediately after manufacture
- ware may contact non-sterile atmosphere, bags, boxes, personnel, etc. during packing after ware manufacture or during unpacking at the filling location
- low particulate does not mean sterile

Producing ware under a shroud and using “particulate-free” or “low particulate” clean room bags does not result in sterile ware. These steps only reduce particulate in and on the ware to a lower level than would be present if ware were produced in an “unshrouded” production situation. In the future, molding may be performed in clean rooms and sterile conditions maintained after ware manufacture, however, until that time, ware cannot be represented as being sterile as molded. Until then, a secondary sterilization process must be performed.

Terms Associated with Sterilization

Bioburden

This is the number of microorganisms (bacteria, virus, fungi, etc.) present. Microbiologists can test for these. When sterilizing ware, it is important to eliminate the bioburden to prevent further microbial growth.

Pyrogens

A pyrogen, which means fever causing, is a remnant of bacteria that contains chemicals called endotoxins. Endotoxins can cause fever leading to death. Several tests exist to identify endotoxin contamination. Something may be sterile, but still have pyrogens on it. Glass can be sterilized and de-pyrogenated at the same time. Exposure to high temperature (600°F or higher) will kill microorganisms AND burn up endotoxins. The higher the temperature, the shorter the exposure time needed for de-pyrogenation. Most plastic ware is incapable of being exposed to these high temperatures. Therefore, plastic ware may be sterilized but, if it needs to be de-pyrogenated, it is usually washed with pyrogen free water.

Sterilization Techniques

Sterilization techniques are designed to kill microorganisms. There are varieties of sterilization methods, however the three basic approaches used to sterilize plastic ware are:

- Ethylene Oxide (EtO) Exposure
- Steam Autoclave
- Radiation (gamma radiation, electron beam radiation)

Tests should always be run on plastic ware to determine suitability for a given sterilization method.

Ethylene Oxide

Ethylene oxide (EtO) is a toxic, cancer causing gas. Technology and worker protection legislation allow continued EtO use. Most plastic can be EtO sterilized. EtO must contact the surfaces to be sterilized. There are several ways EtO sterilization can be accomplished.

Pure EtO

Empty ware in an open bag or ware in a sealed bag with a “breather” window, is placed in a chamber. Air is evacuated and moisture introduced (dry microorganisms are resistant to EtO sterilization).

Pure EtO is flooded into the chamber. Chamber internal pressure is kept lower than external pressure to ensure gas will not leak. Exposure time varies depending on ware and bioburden. After exposure, the chamber is purged with filtered sterile air to eliminate residual EtO.

Dilute EtO

Since it is safer than pure EtO, a 10-15% mixture of EtO with inert gas is used. Empty ware in an open bag or ware in a sealed bag with a “breather window” is placed in a chamber. Air is evacuated, and moisture is introduced (dry microorganisms are resistant to EtO sterilization). Dilute EtO is flooded into the chamber and the chamber’s temperature increased up to 60°C (140°F). Exposure time of 4 to 24 hours varies depending on ware, bioburden, and sterilization parameters. After exposure, the chamber is purged with filtered sterile air to eliminate residual EtO.

Most plastic ware is capable of being EtO sterilized. However, zinc stearate process aid, used in injection blow molding, can cause precipitants (particulate) to form in liquid products packaged in EtO sterilized ware.

Therefore, only special LDPE grades and colorants that do not require zinc stearate for injection blow molded ware should be treated used with EtO sterilization processes. Additionally, tests should always be run on plastic ware to determine suitability for a given sterilization method.

Steam Autoclave

Autoclaving can sterilize empty OR filled, sealed ware. The effect of temperature AND moisture kills microorganisms. Autoclaving involves exposing ware for a time to steam. The autoclave acts like a pressure cooker, allowing the steam temperature to get above the boiling point of water (100°C=212°F). Typically, autoclaving is done at 15 psi (pounds per square inch) steam being at 121°C (250°F).

Autoclaving Empty Ware

Empty ware must withstand autoclaving temperature for the exposure time. If it does not, parts will distort. Of the common plastics, polypropylene (PP) and polycarbonate (PC) have enough heat resistance to be autoclaved. Generally, PP homopolymer is slightly more heat resistant than PP copolymer. Also, there is a grade of a new transparent plastic material identified as a cyclic olefin copolymer (COC) that is capable of withstanding steam autoclave sterilization.

If empty ware becomes distorted due to autoclave sterilization, it may be due to:

- High stresses molded into the ware during manufacture
- Unusual hot spots in the autoclave
- Use of the wrong plastic

Tests should always be run on plastic ware to determine suitability for a given sterilization method.

Autoclaving Filled, Sealed Ware

Autoclave sterilization of filled, sealed ware, is also known as "Terminal Sterilization". Many companies prefer terminal sterilization IF their product can withstand the rigors. Autoclave temperature must be minimally 121°C (250°F). Of the common plastics, polypropylene (PP) and polycarbonate (PC) have enough heat resistance to be autoclaved. Also, there is a grade of a new transparent plastic material identified as a cyclic olefin copolymer (COC) that is capable of withstanding steam autoclave sterilization. However, autoclaving filled, sealed plastic ware is tricky. Temperature and pressure in the autoclave must be controlled and balanced with temperature and pressure being generated in the filled, sealed ware during autoclave heat up AND cool down. If not, ware could be crushed or ballooned. Special autoclaves are sold to enable this temperature/pressure balancing act.

If filled, sealed containers become distorted during autoclave sterilization. This may be due to:

- Improper balancing of temperature/pressure upon heating or cooling
- High stresses molded into ware at the time of manufacture
- Unusual hot spots within the autoclave chamber
- Use of the wrong plastic

Tests should always be run on plastic ware to determine suitability for a given sterilization method.

Autoclaving Closures

Polypropylene (PP) closures should be capable of withstanding steam autoclave sterilization. However, autoclaving may cause blooming of additives in PP. PP homopolymer is more heat resistant than PP copolymer. Linerless closures (closures with specially molded-in sealing features) may or may not be acceptable for autoclaving dependent on many factors (e.g. as application torque, autoclave conditions, closure design, etc.) If a closure is lined, the liner and the adhesive used to affix the liner inside the closure must also be considered. Lastly, PP closures applied to containers present a special case. Closures are designed with tolerances that cause interference between the closure and container. This interference results in stress. Since all thermoplastics become softer as temperature increases, stress may be relieved or closure dimensions may change upon autoclaving. This can result in closure torque reduction or seal loss.

If closures distort or a torque retention problem results, it may be due to:

- High stresses molded into ware at the time of manufacture
- Unusual hot spots within the autoclave chamber
- Use of the wrong plastic

Due to moisture absorption, pulp liners are NOT anticipated to be acceptable for autoclaving. Tests should always be run on plastic ware and liner/adhesive combinations to determine suitability for a given sterilization method.

Radiation

Ware is exposed to ionizing radiation that knocks electrons off atoms it contacts. Ionizing radiation is lethal to microorganisms because of its destructive effect upon the contents of living cells. There are two common sources of ionizing radiation used for sterilization:

- Cobalt 60 (gamma radiation) OR
- Electron beam or E-beam (high energy electrons)

The amount of radiation from either Cobalt 60 or electron beam is measured in MegaRads (MRads) or KiloGrays (KGy). One MegaRad equals ten KiloGrays. Because gamma sterilization and E-beam both use radiation, packaging materials react similarly in both systems.

Cobalt 60 Gamma Radiation

A gamma radiation sterilization facility consists of a thick walled concrete maze in a room built around a well filled with water. In the well are a number of pencil-sized steel rods impregnated with radioactive Cobalt. Articles to be sterilized are placed on conveyors that bring them through the concrete maze into the room where the radioactive rods are located. The number of rods raised from the well and the exposure time controls the degree of exposure. After exposure, ware is conveyed from the room via the maze.

A radiation dose sufficient to kill bacteria and spores is about 2.5 MRads. To minimize costs plus attain sterilization, bioburden is determined then the minimum dosage plus a safety factor is selected.

Gamma radiation has high penetrating power (about 50 cm or close to 20 inches of the same unit-density material). Thus, many parts can be packed together for sterilization. In this instance, the dosage reaching the center of ware multi-packs is validated. Slightly higher doses occur at the outside edges of multi-packs.

Usually, empty packaging components are sterilized via gamma radiation. Since effects of radiation are cumulative, twice the normal dose is sometimes examined to insure minimal problems.

Listed below are thermoplastic materials that are recognized as capable of being gamma radiation sterilized, although tests should always be run on plastic ware to determine suitability for a given sterilization method:

- Low Density Polyethylene
- Linear Low Density Polyethylene
- High Density Polyethylene (those containing phosphite stabilizers may yellow)
- Polyethylene Terephthalate
- Polystyrene
- Polycarbonate
- Nylon
- Cyclic Olefin Copolymers (a newly emerging group of polymers)
- Polyethylene Naphthalate (a newly emerging group of polymers)

Problems can occur when gamma radiation sterilizing polyvinyl chloride (PVC) or fluoropolymers (PTFE, etc.).

Important Note About Polypropylene Gamma Radiation Sterilization

Normal PP grades yellow noticeably and exhibit long term embrittlement when sterilized via gamma radiation techniques. Special radiation resistant PP grades, having special stabilizers, are available for radiation sterilization.

Also, if ware is to be colored, then the concentrate carrier should be a radiation resistant grade of PP. PP copolymers are more radiation resistant than PP homopolymers. Tests should always be run on plastic ware to determine suitability for a given sterilization method.

Electron Beam (E-Beam) Radiation

An E-beam radiation sterilization facility consists of a protective maze built around an E-beam generator. The E-beam generator delivers a high dose of electrons focused in a narrow beam at the items to be sterilized. After exposure, ware is conveyed from the maze.

A radiation dose sufficient to kill bacteria and spores is about 2.5 MRads. To minimize costs and attain sterilization, bioburden is determined and the minimum dosage plus a safety factor is selected.

Electrons from the E-beam generator have limited penetrating power (a 10-MeV E-beam will penetrate only about 5 cm or 2 inches of a unit-density material). Thus, a limited number of parts can be packed together for sterilization. The dosage reaching the center of a ware multi-pack is validated. Higher dosages will occur at the outside edges of ware multi-packs.

Usually, empty packaging components are sterilized via E-beam. Since effects are cumulative, twice the normal dose is sometimes examined to insure minimal problems.

Listed below are thermoplastic materials that are recognized as capable of being electron beam radiation sterilized, although tests should always be run on plastic ware to determine suitability for a given sterilization method:

- Low Density Polyethylene
- Linear Low Density Polyethylene
- High Density Polyethylene (those containing phosphite stabilizers may yellow)
- Polyethylene Terephthalate
- Polystyrene
- Polycarbonate
- Nylon
- Cyclic Olefin Copolymers (a newly emerging group of polymers)
- Polyethylene Naphthalate (a newly emerging group of polymers)
- Problems can occur when E-beam sterilizing polyvinyl chloride (PVC) or fluoropolymers (PTFE, etc.)

Important Note About Polypropylene E-Beam Sterilization

Normal PP grades yellow noticeably and exhibit long term embrittlement when sterilized via E-Beam. Special PP grades, having special stabilizers, are available for E-beam sterilization. Also, if ware is to be colored, then the concentrate carrier should be a radiation resistant grade of PP. PP copolymers are more radiation resistant than PP homopolymers. Tests should always be run on plastic ware to determine suitability for a given sterilization method.

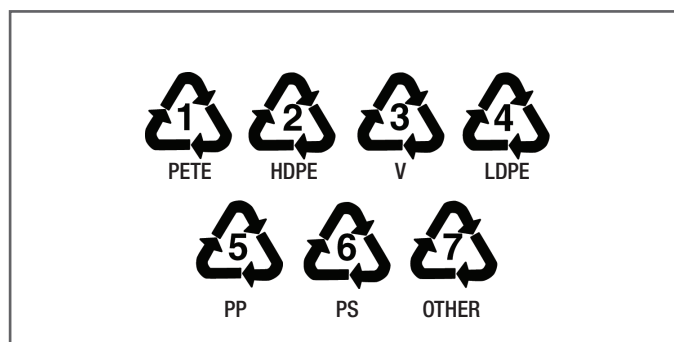


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Resin Identification Codes

WHEATON follows the Society of the Plastics Industry (SPI) guidelines for marking plastic containers with the appropriate resin identification code numbers as shown below:

WHEATON Science Packaging mold-marks our containers on the bottom with the appropriate resin identification code. These codes are to assist in identifying material used to manufacture ware to aid in recycling efforts.



1 = PETE (polyethylene terephthalate) (PET)

2 = HDPE (high density polyethylene)

3 = V (vinyl/polyvinyl chloride) (PVC)

4 = LDPE (low density polyethylene)

5 = PP (polypropylene)

6 = PS (polystyrene)

7 = Other



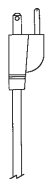
PET Media Bottle

Plug Styles

The following Plug Styles can be used with WHEATON magnetic stirrers, roller culture apparatus, incubators and pumps.



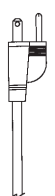
Plug Code "A": North America Plug



Bahamas	Guatemala	Philippines
Bolivia	Haiti	Puerto Rico
Brazil	Honduras	Saudi Arabia
Canada	Jamaica	Singapore
Costa Rica	Korea, S	Sweden
Dominican Rep.	Libya	Taiwan
El Salvador	Nicaragua	United States
Ecuador	Norway	Venezuela
Guam	Panama	Virgin Islands
Peru		



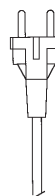
Plug Code "B": Japan Plug



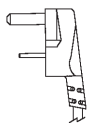
Bolivia
Japan



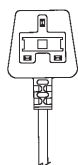
Plug Code "C": Continental Europe Plug



Austria	Hungary	Slovakia
Belgium	Iceland	Slovenia
Bolivia	Indonesia	Singapore
Bulgaria	Latvia	Sweden
Czech. Rep	Lithuania	Spain
Egypt	Luxembourg	Tahiti
Estonia	Mozambique	Turkey
Finland	Netherlands	USSR (former)
France	Poland	Vietnam
Germany	Portugal	Yugoslavia (former)
Greece	Romania	Zaire (Rep. of)



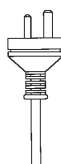
Plug Code "D": United Kingdom Plug



Bahrain	Kuwait	Tanzania
Belgium	Malaysia	Trinidad
Bermuda	Mauritius	& Tobago
Cyprus	Malta	United Arab
England	Nigeria	Emirates
Myanmar	N. Ireland	United Kingdom
Ghana	Oman	Wales
Hong Kong	Qatar	Zambia
Ireland	Scotland	Zimbabwe
Iraq	Singapore	Zimbabwe
Jordan	Sudan	
(Rep. of)		



Plug Code "F": Australia/China Plug



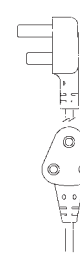
Argentina
Australia
China (People's Rep. of)
Fiji
New Zealand
Papua New Guinea
Uruguay



Plug Code "G": Italy/Chile Plug



Chile
Italy



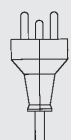
Plug Code "J": India Plug

Bangladesh
India
Pakistan
South Africa
Sri Lanka
Uganda

Special Plug Styles



Plug Code "I": Denmark Plug



Denmark
Greenland



Plug Code "K": Israel Plug



Israel
Jamaica



Plug Code "L": Switzerland Plug



Switzerland

Additional plug styles are available through special order. Please contact Technical Services for additional information.

How to Use a Socorex Pipette®

Abstract

Pipettors are precision tools that, when used properly, will provide years of trouble-free service. However, many users do not receive training to use this common laboratory utensil.

Procedure

Socorex Pipettors are precision tools that will help you efficiently perform your research and testing tasks. Like any tools, your pipettor should be used and stored with care to provide the best possible results.

The information below applies to Socorex Pipettors as well as other manufacturers' pipettors. All air displacement pipettors work on the same principle. A plunger is used to displace air—when the plunger is returned to its initial position (upper stop), it creates a vacuum that is used to draw liquid into the disposable tip. The pipette is calibrated such that the vacuum draws a volume of water as indicated on the volume setting. Liquids lighter than water are pulled further into the tip, so these liquids will pipette to a larger volume. Similarly, liquids heavier than water pipette to a lesser volume. In the case of either lighter or heavier liquids, compared with water, the volume dispensed will be different than that indicated on the pipettor. Pushing the plunger pushes air, which then pushes on the liquid in the tip, which is dispensed.

It is important that you use approved tips with your pipettors to ensure accuracy. Using unapproved tips may lead to inconsistent results.

Normal Pipetting

1. Fit the tip, set the volume (variable pipettors only), and press down the plunger to the first stop (metering stroke) with your thumb. Immerse the tip 2-3mm into the sample while holding the pipettor vertically.
2. Slowly retract the pipetting plunger while watching the liquid fill the tip. You should not observe bubbles or turbulence, which indicate gasses being pulled from the liquid. These gasses affect the vacuum that draws the liquid, reducing the amount of liquid aspirated into the pipette tip.
3. When the pipetting plunger has been retracted to its upper stop, remove your thumb, since the absence of pressure increases the precision of the pipettor. Slowly withdraw the pipettor from the liquid. Wipe any drops on the outside of the tip on the wall of the vessel you are drawing liquid from.
4. To dispense the liquid, hold the tip against the side of the receiving container at a slight angle. Use your thumb to push down the pipetting plunger to the first stop, and hold it for one second. After one second, push the button to the second stop. Pushing to the second stop blows out any liquid left in the tip.

For work with volatile solvents, such as methanol, you may perform this procedure on a “dummy” sample to saturate the system with vapor. This may improve accuracy, as presaturating the air will reduce the tendency to “blow out” the liquid before you are ready to dispense the sample. You should saturate the tip in this fashion every time you change tips.



Reverse Pipetting

Reverse pipetting is used to aspirate an additional volume of liquid. This technique is useful when working with thick, viscous liquids. This is also useful for volatile solvents.

1. Press the pipetting plunger with your thumb to the second stop. This is different from the procedure listed above for regular operation.
2. Holding the pipettor vertically, slowly retract the plunger to its upper stop. Wait for the liquid to properly fill the tip. With viscous liquids, this will take longer than when pipetting water. A larger amount of liquid will be aspirated than normal operation since the plunger was pushed to the second stop.
3. When dispensing, push the plunger only as far as the first stop. Wipe any liquid hanging on the tip on the side of the receiving container. Any remaining liquid will be discarded with the tip.

Working Position

When aspirating the sample, the pipettor must be held vertically, or else too much liquid will be drawn in. Tilting the pipettor by 30 degrees causes nearly 1% more liquid to be drawn!

When dispensing the sample, the tip should be held at an angle against the container to draw out the liquid in the tip. Under normal pipetting operations, analytical chemists will recognize the pipettor as a “to contain” pipettor.

When aspirating the sample, the tip should generally be immersed to 2-3mm. Placing the tip deeper into the sample allows pressure from the liquid to help push the sample into the tip, reducing accuracy.

Working Conditions

Under ideal conditions, the sample should have the same temperature used to calibrate the pipettor. Cold liquids are denser than warm liquids. If the pipettor was calibrated at room temperature, but used in a cold-room, smaller samples than expected would be dispensed.

Storage

Pipettors should be stored in an appropriate rack or stand. This reduces the risk of scratching or damaging the nose cone. Damage to the nose cone could result in a poor seal to the pipet tip, which will reduce accuracy.

Testing & Calibration

You should periodically check the operation of your pipettor by checking its calibration.

Socorex air-displacement pipettors are warranted for calibration for 2 years. Under modern quality management such as GLP/GMP, ISO-9000, or regulatory requirements, you should test your pipettors' calibration. If a pipettor is dropped, or you suspect any type of damage, you should check the calibration.

Testing is generally performed gravimetrically, using an analytical balance. Calibration is usually done at room temperature, away from drafts or direct sunlight. The actual calibration details vary between pipettors, and are listed in the instructions.

Common Acronyms

Al	Aluminum
Al Foil	Aluminum Foil
Al ₂ O ₃	Aluminum Oxide
ASTM	American Society for Testing and Materials
B ₂ O ₃	Boric Oxide
Ba	Barium
BaO	Barium Oxide
CaO+ MgO	Calcium Oxide Magnesium Oxide
CFR	Code of Federal Regulations
COP	Cyclic Olefin Copolymer
COE	Coefficient of Expansion
Dia	Diameter
EPDM	Ethylene- Propylene Diene Monomer
EtO	Ethylene Oxide
FDA	Food and Drug Administration
Fe	Iron
Fe ₂ O ₃	Iron Oxide
GPI	Glass Packaging Institute
HDPE	High Density Polyethylene
I ₂	Molecular Iodine
K	Potassium
LDPE	Low Density Polyethylene
MaO ₂	Manganese Oxide
Mg	Magnesium
Mil	1 Thousandth of an Inch
Na	Sodium
Na ₂ O+K ₂ O	Sodium Oxide Potassium Oxide
NTU	Nephelometric Turbidity Units
PBT	Polybutylene Terephthalate
PC	Polycarbonate
PE	Polyethylene
PET (PETE)	Polyethylene Terephthalate
PP	Polypropylene
ppm	Parts per million
PS	Polystyrene
PTFE	Polytetrafluoroethylene
PVC (V)	Polyvinyl chloride
SBR- Styrene	Styrene-Butadiene Rubber
Si	Silicon
SiO ₂	Silicon Oxide
SO ₃	Sulfur Trioxide
SPI	The Society of the Plastics Industry, Inc.
Ti	Titanium
TiO ₂	Titanium Oxide
USP	US Pharmacopeia
Zn	Zinc
ZnO	Zinc Oxide

Common Conversion Factors

Convert From	Convert Into	Multiply By
Angstrom units	Centimeter	1.0 x 10 ⁸
	Microns	0.0001
	Millimeters	1.0 x 10 ⁻⁷
	Mils	3.9370 x 10 ⁻⁶
Atmospheres (std.)	Bars	1.01325
	Inches of Hg @ 32°F	29.9213
	Millibars	1013.25
	Mm of Hg @ 0°C	760.0
	Torr	760.0
Bars	Atmospheres (std.)	0.98692
	Inches of Hg @ 32°F	29.5299
	Millibars	1000.00
	Mm of Hg @ 0°C	750.062
	Torr	750.062
Centimeters	Angstrom units	1.0 x 10 ⁸
	Inches	0.39370
	Microns	1.0 x 10 ⁴
	Millimeters	10.0
	Mils	393.701
Cubic Centimeters	Cubic Inches	0.06102
	Drams (fluid)	0.27051
	Gallons (UK liquid)	2.1997 x 10 ⁻⁴
	Gallons (US liquid)	2.6417 x 10 ⁻⁴
	Liters	1.0 x 10 ⁻³
	Milliliters	1.0
	Ounces (UK liquid)	0.03519
	Ounces (US liquid)	0.03381
Cubic Inches	Cubic Centimeters	16.3871
	Drams (fluid)	4.43290
	Gallons (UK liquid)	3.6046 x 10 ⁻³
	Gallons (US liquid)	4.3290 x 10 ⁻³
	Liters	0.01639
	Milliliters	16.3871
	Ounces (UK liquid)	0.57674
Ounces (US liquid)	0.55411	
Drams (fluid)	Cubic Centimeters	3.69672
	Cubic Inches	0.22559
	Gallons (UK liquid)	8.1316 x 10 ⁻⁴
	Gallons (US liquid)	9.7657 x 10 ⁻⁴
	Liters	3.6967 x 10 ⁻³
	Milliliters	3.69672
	Ounces (UK liquid)	0.13011
Ounces (US liquid)	0.12500	
Gallons (UK liquid)	Cubic Centimeters	4546.09
	Cubic Inches	277.419
	Drams (fluid)	1229.76
	Gallons (US liquid)	1.20095
	Liters	4.54609
	Milliliters	4546.09
	Ounces (UK liquid)	160.0
Ounces (US liquid)	153.722	
Gallons (US liquid)	Cubic Centimeters	3785.41
	Cubic Inches	231.0
	Drams (fluid)	1023.99
	Gallons (UK liquid)	0.83267
	Liters	3.78541
	Milliliters	3785.41
	Ounces (UK liquid)	133.228
Ounces (US liquid)	128.0	
Grams	Kilograms	1.0 x 10 ⁻³
	Ounces (avdp)	0.03527
	Ounces (troy)	0.03215
	Pounds (avdp)	2.2046 x 10 ⁻³
	Pounds (troy)	2.6791 x 10 ⁻³
Inches	Angstrom units	2.540 x 10 ⁸
	Centimeters	2.54
	Microns	25400.0
	Millimeters	25.40
	Mils	1000.0
Inches of Hg @ 32°F	Atmospheres (std.)	0.03342
	Bars	0.03386
	Millibars	33.8639
	Mm of Hg @ 0°	25.4000
	Torr	25.4000
Kilograms	Grams	1000.00
	Ounces (avdp)	35.2739
	Ounces (troy)	32.1505
	Pounds (avdp)	2.20462
	Pounds (troy)	2.67921
Liters	Cubic Centimeters	1000.03
	Cubic Inches	61.0237
	Drams (fluid)	270.510
	Gallons (UK liquid)	0.21997
	Gallons (US liquid)	0.26418
	Milliliters	1000.03
	Ounces (UK liquid)	35.1951
	Ounces (US liquid)	33.8149

Convert From	Convert Into	Multiply By
Microns	Angstrom units	10000.0
	Centimeters	1.0 x 10 ⁻⁴
	Inches	3.9370 x 10 ⁻⁵
	Millimeters	1.0 x 10 ⁻³
	Mils	0.03937
Millibars	Atmosphere (std.)	9.8692 x 10 ⁻⁴
	Bars	1.0 x 10 ⁻³
	Inches of Hg @ 32°F	0.02953
	Mm of Hg @ 0°C	0.75006
	Torr	0.75006
Milliliters	Cubic Centimeters	1.0000
	Cubic Inches	0.06102
	Drams (fluid)	0.27051
	Gallons (UK liquid)	2.1997 x 10 ⁻⁴
	Gallons (US liquid)	2.6417 x 10 ⁻⁴
	Liters	1.0 x 10 ⁻³
	Ounces (UK fluid)	0.03519
	Ounces (US fluid)	0.03381
Millimeters	Angstrom units	1.0 x 10 ⁷
	Centimeters	0.10
	Inches	0.03937
	Microns	1000.0
Mils	39.3701	
Millimeters Hg@0°C	Atmospheres (std.)	1.3158 x 10 ⁻³
	Bars	1.3332 x 10 ⁻³
	Inches of Hg @ 32°F	0.03937
	Millibars	1.333221
	Torr	1.0
Mils	Angstrom units	254000.0
	Centimeters	2.540 x 10 ⁻³
	Inches	1.0 x 10 ⁻³
	Microns	25.40
	Millimeters	0.0254
Ounces (avdp)	Grams	28.3495
	Kilograms	0.02835
	Ounces (troy)	0.91146
	Pounds (avdp)	0.06250
	Pounds (troy)	0.07596
Ounces (troy)	Grams	31.1035
	Kilograms	0.03110
	Ounces (avdp)	1.09714
	Pounds (avdp)	0.06857
	Pounds (troy)	0.08333
Ounces (UK liquid)	Cubic Centimeters	28.4131
	Cubic Inches	1.73387
	Drams (fluid)	7.68603
	Gallons (UK liquid)	6.250 x 10 ⁻³
	Gallons (US liquid)	7.8125 x 10 ⁻³
	Liters	0.02841
	Milliliters	28.4131
	Ounces (US liquid)	0.96076
Ounces (US liquid)	Cubic Centimeters	29.5735
	Cubic Inches	1.80469
	Drams (fluid)	8.0
	Gallons (UK liquid)	6.5053 x 10 ⁻³
	Gallons (US liquid)	7.8125 x 10 ⁻³
	Liters	0.02957
	Milliliters	29.5735
Ounces (UK liquid)	1.04084	
Pounds (avdp)	Grams	453.592
	Kilograms	0.45359
	Ounces (avdp)	16.0
	Ounces (troy)	14.5833
	Pounds (troy)	1.21528
Pounds (troy)	Grams	373.242
	Kilograms	0.37324
	Ounces (avdp)	13.1657
	Ounces (troy)	12.0
	Pounds (avdp)	0.82286
Torr	Atmospheres (std.)	1.3158 x 10 ⁻³
	Bars	1.3332 x 10 ⁻³
	Inches of Hg @ 32°F	0.03937
	Millibars	1.33322
	Mm of Hg @ 0°C	1.0
Temperature	°C = (°F - 32) x 0.56	
	°F = (°C x 1.8) + 32	
Power	Amperage = Wattage / Voltage	
	Voltage = Wattage / Amperage	
	Wattage = Voltage x Amperage	

WHEATON Industries Commitment to... Our Customers, Associates and Community



WHEATON Industries is committed to excellence in Environment, Health, and Safety (EHS). As a socially responsible corporate citizen, we will conduct our business in accordance with all applicable legal standards and strive to meet the highest ethical standards. We shall serve to promote a safe and healthy environment, while seeking to improve the quality of life for our associates, contractors, visitors, and the community.

This commitment is supported at all levels of the organization and is the individual and collective responsibility of all WHEATON Associates.

Through our EHS management system and continuous improvement initiatives we shall:

- Promote a positive "Safety First" lifestyle both at work and at home.
- Provide education and training to ensure that each associate is experienced and competent to perform their duties safely.
- Apply our EHS policies and procedures to all contractors, vendors, and suppliers.
- Identify and eliminate foreseeable workplace hazards in our pursuit of zero injuries.
- Meet or exceed all EHS regulatory requirements and applicable laws.
- Reduce environmental impacts and conserve natural resources.
- Integrate EHS as an essential part of our every day business.

Going Green!

- WHEATON Industries is taking initiatives towards protecting our environment. As a company, we have implemented several programs to remove hazardous material from our warehouses and manufacturing plants, reduce our waste, reduce our pollution output, and recycle our aluminum and plastics.
- WHEATON Industries Inc. is committed to supporting the WEEE and RoHS Directives. For specific information regarding our policies, please visit our web site, www.wheatonpkg.com.



We will supply products and services that consistently meet or exceed our customers' expectations and requirements, on time, every time. Through continuous improvements, communications, and measurable quality objectives we will continuously strive for excellence in everything we do.

Through the personal involvement of all our Associates, we will pursue these commitments to achieve profitable growth for our stakeholders.



As a means of meeting or exceeding our business goals, we focus our Continuous Improvement resources on initiatives that provide maximum value for all stakeholders.

Additionally, we seek to embed a Continuous Improvement mindset in our culture and personal behaviors through extensive participation of our Associates, use of proven training, tools and techniques, and the celebration of our successes.

WHEATON Science Packaging

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CART ₂	Computer Aided Roller Technology
Crimpmaster	Crimping station
E-Z Ex-Traction	High recovery vials
Omnispense	Automatic dispenser for low-medium viscosity fluids
SciLutions	Value added services
Shorty Vial	Vial with low profile
Uni-Dose	Disposable container for individual medication
Unispense	Automatic Dispenser
V Vial	Vial with conical interior
Vacule	Cryogenic ampule
Loctagon	Octagon shaped bottom that locks into rack
ELITE Packaging Vials	Polypropylene micro vials
Crimpenstein	Electric Crimper/Decrimper

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NextGen	V vials with a non-ground base
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Stepper™	Socorex ISBA
Viton®	DuPont Dow Elastomers, LLC

Chemical Compatibility

Chemical	Container Materials					Closure Liner Materials						Closure Materials				Septa and Stopper Materials					
	Glass	HDPE	LDPE	PET	PP	Al Foil	LDPE	Poly-Vinyl	SBR	Silicone	PTFE	PBT	Phenolic	PP	Urea	Butyl Rubber	EPDM	Natural Rubber	Silicone	PTFE	Viton
acetic acid, glacial	A	A	B	A	A	A	B	B	C	B	A	C	A	A	D	B	B	B	B	A	D
acetone	A	D	D	C	B	A	D	D	D	B	A	D	A	B	A	B	A	B	B	A	D
acetonitrile	A	A	A	B	A	A	A	D	B	D	A	—	A	A	—	D	B	D	D	A	D
acrylonitrile	A	A	A	B	B	B	A	D	C	D	A	—	D	B	—	D	A	D	D	A	D
ammonium sulfide	A	A	A	—	A	D	A	A	B	A	A	—	A	A	C	A	A	A	A	A	C
benzene	A	D	D	C	D	B	D	D	D	D	A	A	A	D	A	D	D	D	D	A	A
bleach	A	A	B	C	B	D	B	A	D	B	A	C	D	B	—	A	A	D	B	A	A
boric acid	A	A	A	A	A	D	A	A	A	A	A	A	B	A	—	A	A	A	A	A	A
carbonic acid	A	A	A	—	A	B	A	A	B	A	A	—	—	A	—	A	A	A	A	A	A
chlorobenzene	A	C	D	B	C	A	D	D	D	D	A	B	A	C	B	D	D	D	D	A	A
chloroform	A	C	C	D	D	A	C	D	D	D	A	D	A	D	A	D	D	D	D	A	A
dichloromethane	A	C	D	D	C	D	D	D	D	D	A	D	C	C	B	D	D	D	D	A	B
diethylamine	A	C	D	—	B	A	D	D	B	B	A	—	—	B	—	B	B	B	B	A	C
dimethyl formamide	A	A	A	B	A	A	A	D	D	B	A	—	A	A	—	D	B	D	B	A	D
dimethyl sulfoxide (DMSO)	A	A	A	B	A	A	A	D	D	D	A	—	—	A	—	D	A	D	D	A	D
dioxane	A	B	B	A	D	D	B	D	D	D	A	B	A	D	—	B	B	D	D	A	D
ether	A	C	D	A	D	B	D	D	D	D	A	—	B	D	B	D	C	D	D	A	C
ethyl acetate	A	B	B	B	C	B	B	D	D	C	A	C	A	C	B	C	C	D	C	A	D
ethyl alcohol	A	A	A	A	A	B	A	B	A	B	A	A	B	A	A	A	A	A	B	A	A
ethylene glycol	A	A	A	A	A	B	A	A	A	A	A	A	B	A	B	A	A	A	A	A	A
formaldehyde	A	A	A	B	A	A	A	C	B	B	A	—	B	A	A	A	A	C	B	A	C
formic acid 50%	A	A	B	—	A	C	B	B	B	C	A	A	C	A	D	A	A	B	C	A	C
gasoline	A	C	D	B	C	A	D	D	D	D	A	A	B	C	A	D	D	D	D	A	A
glycerine	A	A	A	—	A	A	A	C	A	B	A	—	A	A	—	A	A	A	B	A	A
heptane	A	C	D	B	C	A	D	C	D	D	A	A	A	C	A	D	D	D	D	A	A
hexane	A	B	D	C	B	A	D	D	D	D	A	A	B	B	—	D	D	D	D	A	A
hydrochloric acid (HCL) 50%	A	A	A	B	A	D	A	B	D	D	A	C	A	A	D	A	D	B	D	A	A
hydrofluoric acid (HF) 50%	D	A	A	C	A	D	A	C	D	D	A	C	D	A	D	C	D	C	D	A	A
hydrogen peroxide 50%	B	A	A	B	A	A	A	C	C	B	A	B	D	A	D	B	B	B	B	A	A
iodine	A	C	D	A	C	A	D	C	B	A	A	—	—	C	—	B	B	D	A	A	A
isopropyl alcohol	A	A	A	A	A	A	A	B	B	A	A	A	A	A	—	A	A	A	A	A	A
methyl alcohol	A	A	A	B	A	A	A	C	A	A	A	B	B	A	A	A	A	A	A	A	D
methyl ethyl ketone (MEK)	A	D	D	B	B	A	D	D	D	D	A	C	A	B	—	A	B	D	D	A	D
methylene chloride	A	C	D	D	C	D	D	D	D	D	A	D	C	B	B	D	D	D	D	A	B
nitric acid 50%	A	C	B	C	C	D	B	B	D	D	A	C	B	C	D	C	D	C	D	A	B
pentane	A	C	C	—	D	A	C	D	D	D	A	—	—	D	—	D	D	D	D	A	A
perchloric acid 50%	B	B	B	B	B	D	B	D	D	D	B	—	—	B	—	B	B	D	D	B	A
phenol 50%	A	D	D	D	D	A	D	C	D	D	A	D	A	D	—	D	C	D	D	A	A
phosphoric acid 50%	A	A	A	B	A	B	A	B	D	D	A	B	B	A	D	B	B	D	D	A	A
picric acid	A	D	D	B	D	A	D	D	B	D	A	—	A	D	D	B	B	B	D	A	A
potassium hydroxide	D	A	A	D	A	D	A	A	B	C	A	C	D	A	—	A	A	B	C	A	B
sodium hydroxide 50%	D	A	B	D	A	D	B	C	A	B	A	C	D	A	C	A	A	A	B	A	B
sodium peroxide	A	B	B	—	B	C	B	A	B	D	A	—	B	B	D	A	A	B	D	A	A
sodium thiosulfate	A	A	A	B	A	A	A	A	B	A	A	—	A	A	B	A	A	B	A	A	A
sulfuric acid 50%	A	A	A	B	B	C	A	C	D	D	A	B	C	B	D	D	C	D	D	A	A
tetrahydrofuran (THF)	A	C	C	A	B	A	C	D	D	D	A	D	A	B	—	C	C	D	D	A	D
toluene	A	C	C	C	C	A	C	C	D	D	A	D	A	C	—	D	D	D	D	A	B
trifluoroacetic acid (TFA) 50%	A	A	A	B	A	—	A	A	—	D	—	—	—	A	—	—	A	—	D	—	—
vegetable oil	A	B	B	A	A	A	B	A	D	A	A	A	A	A	A	C	C	D	A	A	A
xylene	A	C	D	C	D	A	D	D	D	D	A	C	A	D	B	D	D	D	D	A	A

(Tests conducted at room temp) **A** - Resistant **B** - Limited Resistance **C** - Poor Resistance **D** - Not Resistant **—** - Unknown
SBR ...styrene butadiene rubber **HDPE** ... high density polyethylene **LDPE** ... low density polyethylene **PET** ... polyethylene terephthalate **PP** ... polypropylene **Al Foil** ... aluminum foil
PTFE ... (tetrafluoroethylene) **PBT** ... polybutylene terephthalate **Urea** ... urea **EPDM** ... ethylene propylene diene monomer **Viton** ... (fluoroelastomer)

Although the information in this chart was acquired from reputable sources, it should only be used as a guide in selecting a container and closure system. Because so many factors can affect the chemical resistance of a material, in-house testing under actual conditions should be performed. WHEATON accepts no responsibility for the accuracy of this data or for any consequences resulting from its use.