Savillex
Science Contained

Savillex Life Sciences
10333 W. 70th St.
Eden Prairie, MN, 55344
www.savillex.com

Purillex® PFA Bottle eBook

APPLICATION NOTES AND SUCCESS STORIES

ABOUT PURILLEX® PFA BOTTLES

Savillex Purillex® PFA bottles deliver unmatched chemical purity, durability, and performance for demanding life sciences applications. These high-performance fluoropolymer containers are designed for ultra-pure sample and drug product storage and transport, ultra-trace analysis, and chemical handling in cleanroom, lab, and field enviroments. They resist aggressive chemicals, tolerate extreme temperatures, and prevent contamination. Savillex PFA bottles also offer superior chemical inertness, low trace metal content, and consistent quality trusted by leading labs and manufacturers worldwide.

CONTENTS

Flash Freezing in Fluoropolymer Bottles

APPLICATION NOTE

SAVILLEX | 10321 W. 70TH ST., EDEN PRAIRIE, MN, 55344
INFO@SAVILLEX.COM | 952.935.4100
WWW.SAVILLEX.COM

Savillex

APPLICATION NOTE

Flash Freezing in Fluoropolymer Bottles

ABSTRACT

Flash freezing is the process of rapidly lowering the temperature of a liquid so that larger ice crystals do not have the chance to form. These larger crystals can potentially damage proteins and other critical components of the liquid. Flash freezing is a common process for freezing bulk drug substance (BDS) and can lead to failure of typical BDS containers.

A standard method for flash freezing BDS is to immerse it in a liquid nitrogen bath. However, few product containers are designed to survive this type of flash freezing. Most containers used to store BDS have glass transition temperatures well above -196°C, and many containers structurally fail during the rapid descent through the glass transition. Even worse, these container failures are rarely detected until after the container is thawed, which can be days if not weeks or months after the freezing is completed.

Conversely, fluoropolymer materials typically do not change structurally after going through a typical flash freezing process. Therefore, a container system manufactured from fluoropolymers has the potential to not only survive this flash freezing, but to also continue retaining the same functionality it previously had when at room temperature.

This technical note outlines a study performed to test the integrity of fluoropolymer bottles being subjected to a flash freezing process down to liquid nitrogen temperatures (-196°C). The protocol was modeled after one used to flash freeze licensed biopharmaceutical products at a major pharmaceutical company. Bottles were frozen and then tested for integrity to ensure no structural breaches and no loss of closure seal. Bottles were also observed during the freezing process to ensure the bottles did not collapse; a common problem seen in bottles which lack the structural integrity required during flash freezing.

ABOUT PURILLEX® FLUOROPOLYMER BOTTLES

The container closure system of the Purillex® bottles has a superior design, which ensures a better seal and better protection of contents, even under flash freeze conditions. No cap inserts are used, ensuring single material contact with critical BDS product. The identical fluoropolymer resin is used for both the bottle and

closure. Both the bottle closure and preform are injection molded, ensuring precision functionality between bottle and closure (Figure 1).

Purillex bottles are made using a proprietary two-step stretch blow molding process (Figure 2). A bottle preform is injection molded, ensuring precision closure dimensions. The preform is then blown into a bottle while protecting the neck, lip, and threads. This ensures the critical dimensions of the bottle neck are maintained, allowing a precision seal.

1. The preform is preheated and loaded into the mold
2. Stretch rod is lowered inside the preform
3. Air passes through the stretch rod, which is slowly lowered as the bottle is blown

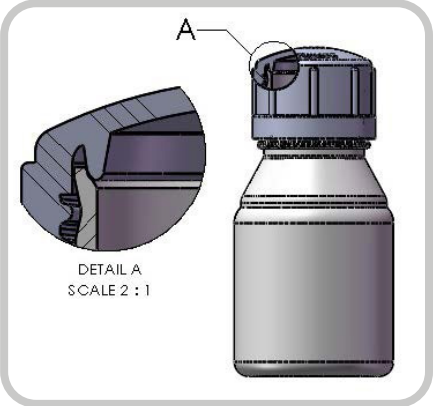


Figure 1: Injection molding ensures precise engagement & closure integrity

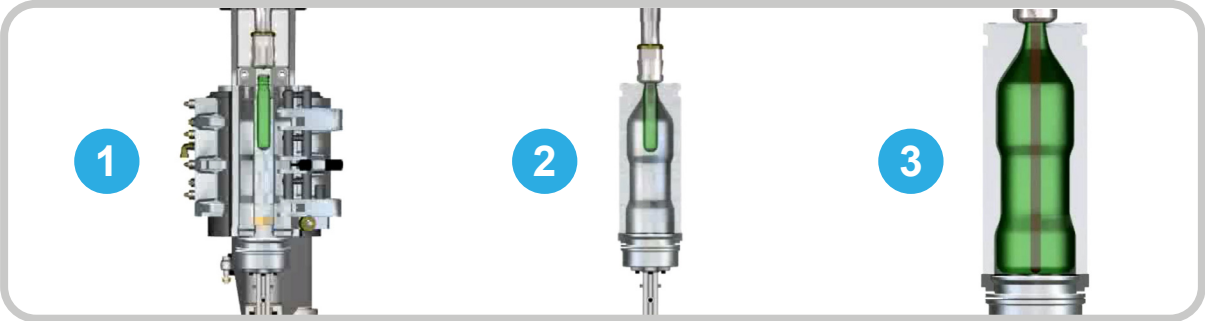


Figure 2: Stretch blow molding process

TEST METHOD 1 - BOTTLE FLASH FREEZE

TEST PREPARATION	Fourteen 1,000 mL (1 L) Purillex PFA bottles were selected for testing from the same bottle lot. All bottles underwent a thermal pretreatment consisting of a dry heat exposure cycle at 250°C for 120 minutes. This cycle was chosen as worstcase in terms of temperature and exposure time. Two additional control bottles were also exposed to the identical cycle, then immediately leak tested to 15 psig. This was to ensure the thermal pretreatment did not, on its own, cause bottle integrity issues. Each test bottle was filled with purified water to the minimum working volume of 200 mL and preconditioned at 21°C overnight. This volume was chosen as the worst case scenario for headspace air; in theory, more entrapped air in the bottle will increase the likelihood of bottle integrity failure due to rapid air pressure decrease.

TEST PROCEDURE	Bottle closures were tightened to the standard torque using a calibrated dial torque wrench. Each closure was brought to the proper torque and held at the value for 10 seconds. Six of the test bottles were then submerged in dry ice for 24 hours. After the 24-hour exposure, each bottle was visually inspected for integrity. Six of the test bottles were submerged in a liquid nitrogen bath for 30 minutes. After the bottles were removed from the bath, each bottle was visually inspected for integrity. All 12 test bottles were then thawed for a minimum of 24 hours prior to leak testing. Table 1 shows the bottles selected and the freeze cycle for each.

TEST METHOD 2 - HYDROSTATIC

TEST PROCEDURE	**Note:** 200 mL water remained in bottles after submersion test and was present during the integrity testing. Each closure was drilled, and a fitting was tapped into the closure. Caution was used to ensure the closure did not loosen or tighten during drilling and fitting installation. A pressure line was attached to the fitting, the bottle was supported in an inverted position, and was pressurized to 2 psi. After a five-minute period, the threaded area was inspected using backlighting to inspect for any water droplets. The container was then pressurized to 15 psi, and after another 5-minute period, the threaded area was inspected for any water droplets using backlighting.

TABLE 1 - BOTTLE EXPOSURE MATRIX

	EXPOSURE	
BOTTLE	**DRY ICE**	**LIQUID NITROGEN**
1		x
2	x	
3		x
4	x	
5		x
6	x	
7		
8		
9		x
10	x	
11		x
12	x	
13		x
14	x	

RESULTS

The two control bottles tested to ensure the dry heat preconditioning process did not compromise bottle integrity passed the leak testing method. They were also inspected to ensure no physical deformity of the closure thread area.

All six bottles submerged in dry ice for 24 hours maintained integrity. All six of these bottles passed the hydrostatic leak testing method at both test pressures after submersion.

All six bottles submerged in liquid nitrogen for 30 minutes maintained integrity. All six of these bottles passed the hydrostatic leak testing method at both test pressures after submersion.

Four of the bottles (#2, 6, 10, and 14) were submerged in liquid nitrogen a second time for 30 minutes and again inspected for wall collapse. The bottles were again thawed for a minimum of 24 hours and hydrostatically tested at 2 and 15 psig using the test method described above. All four of the bottles maintained integrity and again passed the hydrostatic leak testing method at both test pressures.

CONCLUSION

Evidence from this test protocol indicates that Savillex 1 L Purillex PFA bottles are suitable for dry heat sterilization at 250°C for 120 minutes and then flash freezing down to liquid nitrogen temperatures (-196°C) with no bottle collapse and no loss of bottle integrity. Several of the tested bottles passed integrity testing after exposure to a second flash freezing cycle.

This is a testament to the structural durability of fluoropolymer materials when exposed to temperature extremes. It is also illustrative of the strength and reliability of the Purillex bottle seal technology.

Click here to learn more about Purillex PFA bottles and shop online.

Savillex 10321 W. 70th St. | Eden Prairie, MN, 55344-3446 USA
Phone: 952.935.4100 | Email: info@savillex.com | www.savillex.com

Freeze Cycle Testing on Purillex® Fluoropolymer Bottles

APPLICATION NOTE

SAVILLEX | 10321 W. 70TH ST., EDEN PRAIRIE, MN, 55344
INFO@SAVILLEX.COM | 952.935.4100
WWW.SAVILLEX.COM

Savillex

APPLICATION NOTE

Freeze Cycle Testing on Purillex® Fluoropolymer Bottles

ABSTRACT

Storing frozen bulk drug substances (BDS) – including solutions, vaccines, blood components, and other process fluids – is common practice in life science applications.

Vessels used to store these fluids must not only be capable of withstanding long-term storage in frigid temperatures (e.g., -85°C or -196°C), but must also maintain integrity after repeated thawing and subsequent re-freeze. Bottles are a container of choice for freezing applications for a variety of reasons, including:

- Durability and convenience
- Compatibility with standard lab equipment
- Shelving, racking, & standard shipping containers
- Can be easily integrity tested during manufacture via pressure decay test methods
- They feature container closure systems that are ideal for torquing
- Most come with validated torque specifications, often with values and methods unique to each closure size and style

When utilizing standard laboratory bottles for freeze/thaw applications, one risk is sidewall paneling. Bottles panel for several reasons, including material selection, inadequate sidewall thickness, product design (cubical vs. round vs. oval shape), and, more nefariously, air egress due to poor closure/seal design, or inadequate closure application during use. In our experience, air egress is the most common cause of paneling in life science flash-freezing applications.

Purillex® fluoropolymer bottles are an excellent choice for freeze/thaw processes as the structure does not change when flash-frozen. Therefore, they not only have the potential to survive flash-freezing but also retain the same functionality as at room temperature. This technical note outlines a study performed to characterize the performance of fluoropolymer bottles with standard and two-piece closure systems after multiple freeze/thaw cycles, with a re-torque step added after each freeze cycle.

TEST OVERVIEW - FREEZE CYCLE TESTING

TEST PREPARATION	Purillex 1 L fluoropolymer bottles, filled to nominal volume, were frozen at -85°C for a minimum of 24 hours, the closure systems re-torqued, and then placed in a 37°C water bath until completely thawed. Per the procedure outlined below, visual inspection and integrity testing were the criteria by which the bottles were measured. Failure was defined as bottle material damage, paneling, or failure of integrity testing. All bottle assemblies tested were manufactured by Savillex using stretch blow molding technology, in which an injection molded preform is blown into the final bottle shape in a two-step process. Since the bottle threads and sealing surface are injection molded (during the preform molding), much greater precision and reproducibility of the bottle seal are attained. The closures used during testing included the standard one-piece closure and a two-piece closure designed for flash freezing applications. The two-piece closure has a floating insert integral to the design that allows for more precise sealing under challenging conditions. The two-piece closure is standard on the 1000 mL ETFE bottle.
TEST PROCEDURE	**Freeze Procedure** **Note: Each bottle assembly type was tested in triplicate* 1. Fill bottles to 1000 mL with tap water 2. Torque each bottle closure system to 45 inch-pounds 3. Place bottle in -85°C freezer allowing at least ½" of space between each 4. Allow the bottles to freeze for at least 24 hours **Thaw Procedure** 1. Remove bottles from freezer 2. Prior to placing in water bath, re-torque each bottle to 45 in-lb 3. Inspect each bottle for paneling, damage and leaks 4. Place in 37°C preheated recirculating water bath until completely thawed Once bottles reach maximum number of freeze/thaw cycles per Table 1, they were integrity tested per the following pressure decay test method. **Note: Water remained in bottles during integrity testing* 1. Drill and tap fitting into closure system and attach a pressure supply line 2. Support bottle in an inverted position 3. Pressurize to 2 psi; after 5-minute period, use back light to observe threaded area for water droplets 4. Pressurize to 15 psi; after 5-minute period, use back light to observe threaded area for water droplets Pass Criteria: No water droplets observed in the threaded area of the bottle closure system during the integrity test protocol described above.

TEST RESULTS - FREEZE CYCLE TESTING

All three bottle types passed integrity testing after up to 15 freeze thaw cycles. No bottle damage was observed and none of the bottles paneled post-thaw during the entire study. See Table 1 below for a results summary.

TABLE 1 - FREEZE CYCLE TESTING

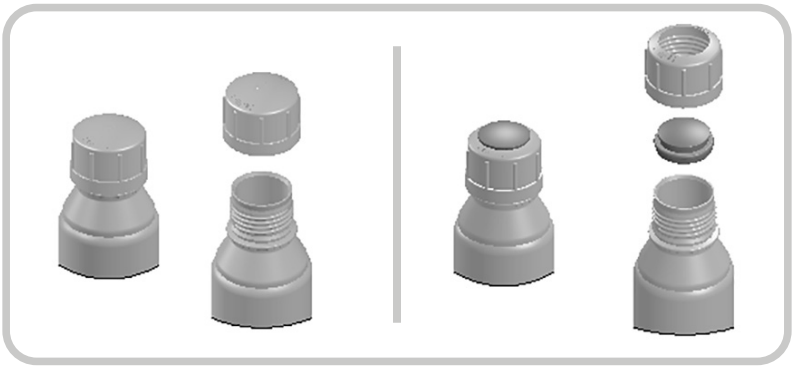
CONFIGURATION	BOTTLE	NUMBER OF CYCLES	FREEZE DAMAGE (Y/N)	PANELING POST THAW (Y/N)	INTEGRITY TEST
PFA	1	5	N	N	Pass
PFA	2	5	N	N	Pass
PFA	3	5	N	N	Pass
PFA	4	10	N	N	Pass
PFA	5	10	N	N	Pass
PFA	6	10	N	N	Pass
PFA	7	15	N	N	Pass
PFA	8	15	N	N	Pass
PFA	9	15	N	N	Pass
PFA2	1	5	N	N	Pass
PFA2	2	5	N	N	Pass
PFA2	3	5	N	N	Pass
PFA2	4	10	N	N	Pass
PFA2	5	10	N	N	Pass
PFA2	6	10	N	N	Pass
PFA2	7	15	N	N	Pass
PFA2	8	15	N	N	Pass
PFA2	9	15	N	N	Pass

TABLE 1 (CONTINUED) - FREEZE CYCLE TESTING

CONFIGURATION	BOTTLE	NUMBER OF CYCLES	FREEZE DAMAGE (Y/N)	PANELING POST THAW (Y/N)	INTEGRITY TEST
ETFE	1	5	N	N	Pass
ETFE	2	5	N	N	Pass
ETFE	3	5	N	N	Pass
ETFE	4	10	N	N	Pass
ETFE	5	10	N	N	Pass
ETFE	6	10	N	N	Pass
ETFE	7	15	N	N	Pass
ETFE	8	15	N	N	Pass
ETFE	9	15	N	N	Pass

CONCLUSIONS

Results indicate that both PFA and ETFE Purillex bottles are suitable for multiple flash freeze/thaw cycles down to -85°C with no visible material damage, leaks, paneling, headspace air egress, or loss of pressure integrity. Both the one-piece and two-piece closures performed identically during the study. The greater seal integrity of stretch blow molded bottles is a significant factor in preventing leaks and bottle paneling during freeze/thaw cycles. It is postulated that re-torque of the closure system after freezing is also a contributing factor in eliminating paneling and headspace air egress, as both have been observed periodically during previous studies where closure re-torque was not applied.



Standard 1-piece (left) and 2-piece (right) closures

TESTING EQUIPMENT

EQUIPMENT USED	BOTTLE ASSEMBLIES USED
Upright -85°C freezer	1000 mL PFA bottle and standard PFA closure (PFA)
19 L laboratory water bath	1000 mL PFA bottle and two-piece PFA closure (PFA2)
	1000 mL ETFE bottle and two-piece ETFE closure (ETFE)
**Fluoropolymer abbreviations: EFTE (ethylenetetrafluoroethylene), PFA (perfluoroalkoxy)*	

Click here to learn more about Purillex PFA bottles and shop online.

The Purillex family of PFA bottles

Savillex 10321 W. 70th St. | Eden Prairie, MN, 55344-3446 USA
Phone: 952.935.4100 | Email: info@savillex.com | www.savillex.com

Integrity Testing of Purillex® Containers for the Life Sciences

APPLICATION NOTE

SAVILLEX | 10321 W. 70TH ST., EDEN PRAIRIE, MN, 55344
INFO@SAVILLEX.COM | 952.935.4100
WWW.SAVILLEX.COM

Savillex

APPLICATION NOTE

Integrity Testing of Purillex® Containers for the Life Sciences

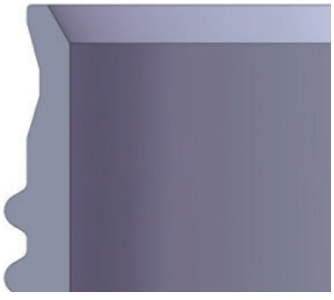
ABSTRACT

Container integrity testing is critical to ensuring leak-free operation of containers as well as protection of critical process solutions and final products. This testing is even more important when the process is an aseptic one. Container integrity can affect not only product sterility but also process yield, product stability, and several other key attributes. Poor integrity can cause product adulteration and loss, leading to higher costs and process downtime.

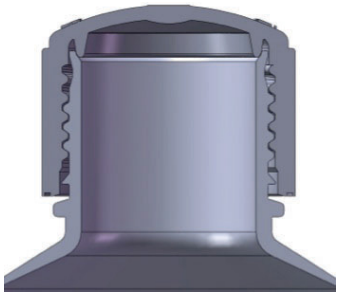
Currently, there are several direct and indirect methods for testing container integrity. Direct methods include pressure decay testing, burst testing, and helium leak testing. Other methods can include dye-penetrant testing, bacterial ingress testing, and container sterility testing. However, these methods are often not as precise, open to interpretation, and can be prone to operator error.

Fluoropolymer bottles, vials, and jars are the ideal containers for applications requiring absolute integrity because of their unmatched durability, strong seal integrity, and imperviousness to a very wide range of temperatures. Purillex® containers from Savillex are designed with ferrule-style closure systems, which are unmatched in the life science industry.

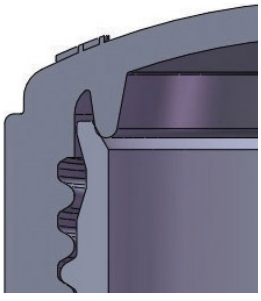
This technical note outlines three available methods to test Purillex PFA containers for container and closure system integrity in critical life science applications.



Purillex Bottle Neck - Lip Detail



Purillex Bottle Neck - Closure



Purillex Bottle Closure - Detail

TEST METHOD 1 - HYDROSTATIC PRESSURE DECAY

TEST BACKGROUND	Hydrostatic testing allows for the detection of leaks that only become obvious at elevated operating pressures. The added benefit is that fluid may leak from the system and be visually detectable with a very small change in pressure - even at a pressure below those detectable by pneumatic test systems. On the other hand, pneumatic tests are potentially more dangerous than hydrostatic tests because of the higher level of potential energy that is stored when compressing the gas.
TEST PREPARATION	All Purillex containers are tested using hydrostatic pressure decay testing prior to lot release. To prepare, a fitting is drilled and tapped into each container closure system and a pressure supply line is attached.
TEST PROCEDURE	1. Support water-filled container in an inverted position. 2. Pressurize to 2 psi. 3. After 5-minute period, observe threaded area using the backlight to observe for any water droplets. 4. Pressurize to 15 psi. 5. After 5-minute period, observe the threaded area using the backlight to check for any water droplets. 6. Pass criteria: No water droplets observable in the threaded area of the container closure system.

Pressurized integrity testing of Purillex containers

TEST METHOD 2 - PRESSURE AT FAILURE

TEST BACKGROUND	The pressure burst test is destructive and intended to measure the pressure at which an object will catastrophically fail or “burst”. This test is holistic and can help to determine overall container durability quickly, detect material defects, and ensure elements like uniform material thickness are in control.
TEST PROCEDURE	Samples from each lot of Purillex PFA containers are tested for pressure at failure. An object is attached to a test port and pressurized with regulated air during this test. Pressure sensors measure the pressure ramp rate and burst event, then compare them to predetermined limits for a pass or fail.

TEST METHOD 3 - HELIUM LEAK

TEST BACKGROUND	Helium leak testing is a method that quantitatively measures the associated leak rate for the test containers’ closure integrity using helium mass spectrometry.
TEST PREPARATION	Helium leak testing is performed on Purillex containers by customer request. This testing is often performed on containers used in extremely critical applications like master cell banking and long-term storage of process archive samples. Containers are prepared by torquing the closure to predetermined values using a calibrated torque wrench. The values applied are at or below the recommended closure torque values during use.
TEST PROCEDURE	The leak test method is performed per USP <1207> Package Integrity Evaluation - Sterile Products and according to ASTM F2391-05 (2016) standard test method for measuring package and seal integrity using helium as the tracer. Both vacuum and pressure mode are used during the test. A separate method feasibility study is often performed to confirm that the application of helium leak technology was fit for the assessment of the container closure system and to develop an appropriate technique for testing the container. Permeation trials are conducted to help differentiate between helium permeation through component materials and actual leakage.

CONCLUSION

Container integrity testing is crucial to ensure container integrity and protection of critical solutions. The three testing methods outlined in this technical note are routinely performed on Purillex PFA containers to ensure consistency, reliability, and product security during use.

Click here to learn more about Purillex containers and shop online.

Savillex 10321 W. 70th St. | Eden Prairie, MN, 55344-3446 USA
Phone: 952.935.4100 | Email: info@savillex.com | www.savillex.com

Purillex® PFA and FEP Bottle Extractables Testing

APPLICATION NOTE

SAVILLEX | 10321 W. 70TH ST., EDEN PRAIRIE, MN, 55344
INFO@SAVILLEX.COM | 952.935.4100
WWW.SAVILLEX.COM

Savillex

APPLICATION NOTE

Purillex® PFA and FEP Bottle Extractables Testing

ABSTRACT

Fluoropolymer (PFA and FEP) bottles are widely used in the pharmaceutical industry process stream for the storage and transfer of pharmaceutical intermediates including API (active pharmaceutical ingredient). They are also used for the bulk storage of temperature sensitive products such as vaccines. Fluoropolymers are ideally suited to these types of applications due to their chemical inertness, wide working temperature range (-200°C to 260°C) and cleanliness. The unique design features of Purillex™ PFA and FEP bottles, manufactured by Savillex, makes them the best choice for use in the biopharmaceutical industry. Purillex bottles are the only fluoropolymer bottles manufactured using stretch blow molding technology, which offers significant benefits for transfer and long term storage of valuable biopharmaceutical products. The wide mouthed GL45 closure is standard in the pharmaceutical industry and the superior sealing ability of the neck and closure ensures unmatched preservation of content integrity. Purillex bottles are non-cytotoxic, USP Class VI compliant, and manufactured in a cleanroom from the highest purity grades of virgin PFA and FEP resin, ensuring the highest levels of cleanliness.

In order to support end user product-contact evaluations for biopharmaceutical applications, Purillex bottles were subjected to extensive third party testing for organic and inorganic extractables. Both 7-day and 28-day extraction tests using multiple solvents at elevated temperatures were carried out. This technical note summarizes the test results, along with the methodology and instrumentation used. Complete reports[1, 2], with all analytical methodology and data for both Purillex PFA and FEP bottles are available upon request from Savillex - just reach out to us at info@savillex.com.

TEST OVERVIEW - EXTRACTABLES TESTING

TEST BACKGROUND	Measuring the type and amount of organic and inorganic compounds extracted from the surface of any material that comes into contact with a biopharmaceutical product is critical to validating it for use, since it directly impacts the safety, quality and purity of the product. Extractables testing (also referred to as forced extraction testing) employs test protocols that use aggressive extraction solutions and elevated temperatures, to simulate worst-case scenarios and is carried out by pharmaceutical companies to evaluate product-contact materials.

TEST PREPARATION	All testing was performed by the DuPont Corporate Center for Analytical Sciences, Wilmington, DE, USA. In order to thoroughly test the Purillex bottles, a range of extraction solutions, including more aggressive extraction solutions than those typically used, were selected and are listed below: • DDIW (ultrapure distilled deionized water) • pH3 acidic buffer solution (citrate buffer) • pH10 alkaline buffer solution (carbonate buffer) • Polar organic solvent (methanol) • Non-polar organic solvent (n-hexane) Two different types of Purillex bottle were tested: 250 mL PFA and 250 mL FEP. Six samples of each type were tested for each of the five extraction solutions. All bottles were manufactured using high purity grades of DuPont™ Teflon® PFA and FEP resin. The bottles were autoclaved at 121°C for 75-90 minutes, allowed to cool and rinsed with DDIW prior to use. One challenge with the use of complex extraction solutions is sourcing clean starting materials. The pH3 buffer was prepared using ACS grade anhydrous citric acid to create a 0.1 M citric acid solution. The pH10 buffer was prepared using ACS grade sodium carbonate and Sodium bicarbonate salts to create a 0.1 M carbonate solution. The methanol used for the extraction studies was semiconductor grade. The hexane used was HPLC grade. Despite the use of highest available purity reagents, blank contamination was an issue for some tests, as will be described later.
TEST PROCEDURE	The bottles were filled with 250 mL of the extraction solutions and the Purillex closure fitted and tightened. As with all Purillex bottles, no closure liner or seal is required. The bottles containing DDIW were kept at 70°C while the remaining extraction solutions were kept at 35°C. Of the six bottles filled with each of the extraction solutions, three bottles were sampled after seven days and the remaining three bottles were sampled after 28 days. The surface contact area of the bottles (total extractable area) was calculated to be 160.96 cm^2 (0.0161 m^2). **INSTRUMENTATION AND ANALYTES** The extracts were measured using the following techniques and instrumentation: **Organic Techniques** • HPLC (UV detection) – Agilent 1100 Series • LC/MS - Agilent 1100 Series MSD • GC - Agilent 7890A Series • GC-FID - Agilent 7890A Series/6850 FID

TEST PROCEDURE (continued)	• GC-MS - Agilent 7890A Series/5975C MSD • Total organic carbon – Analytik Jena multi N/C 2100S TOC analyzer • Conductivity – conductivity meter **Organic Analytes** • HPLC/UV/MS - four different methods were used to cover the widest possible range of compounds – APCI and ESI used in both positive and negative modes • GC-FID, GC/MS - direct and headspace analysis for semivolatiles and volatiles • TOC analyzer - inorganic carbon (IC) subtracted from total carbon to give TOC. IC was measured following a phosphoric acid digestion. **Inorganic Techniques** • ICP-MS – Thermo Element2 HR-ICP-MS (DDIW samples) • ICP-MS – Agilent 7500ce ICP-QMS (pH3 and pH10 samples) • ICP-MS – Agilent 7700x ICP-QMS (methanol and hexane samples) **Inorganic Analytes** In accordance with the requirements of methods currently being developed for the measurement of elemental impurities in pharmaceutical products, all analytes listed in USP Chapter 232 and ICH Guideline Q3D Classes 1, 2A, 2B and 3 were measured. The analyte list is: Ag, As, Au, Ba, Cd, Co, Cr, Cu, Hg, Ir, Li, Mo, Ni, Os, Pb, Pd, Pt, Rh, Ru, Sb, Se, Sn, Ti, and V.

Note:

- Mn was also analyzed but has been removed from the USP Chapter 232 analyte list
- The samples were measured using a combination of ICP-MS instrumentation as described above
- Full method details for both organic and inorganic analytes can be found in the complete reports[1, 2], available from Savillex on request

Purillex bottle family

TEST RESULTS - EXTRACTABLES TESTING

Organic Analytes

- **HPLC/UV/MS -** no detectable non-volatile compounds were found (no observable difference between blank and sample) in any of the extraction solutions, for both 7-day and 28-day extracts, and for both PFA and FEP.
- **GC-FID, GC/MS -** no detectable semivolatile or volatile compounds were found (no observable difference between blank and sample) in any of the extraction solutions, for both 7-day and 28-day extracts, and for both PFA and FEP.
- **TOC Analyzer -** no detectable TOC levels were found (no observable difference between blank and sample) in the DDIW, for both 7-day and 28-day extracts, and for both PFA and FEP. The other extraction solutions were not measured due to the fact that high levels of carbon were present in the blank solutions. Detection limit and quantitation limit for TOC were 0.48 and 1.69 mg/L respectively.
- **Conductivity -** conductivity changes could potentially indicate the extraction of compounds unidentified by other techniques. No significant change in conductivity was detected over 28 days.
- Chromatograms generated for each measurement are shown in the complete reports[1, 2].

Inorganic Analytes

Of all trace metals analysis techniques in common use, ICP-MS (especially HR-ICP-MS) is by far the most sensitive. While pharmaceutical analysis for trace metals has been typically performed by ICP-OES, it was decided to use the much more sensitive technique of ICP-MS. Full quantitative analysis (method of standard additions) was used throughout. Semiquantitative analysis, though faster, is only accurate to +/-30% at best, and so was not used. Due to the very high sensitivity of ICP-MS, it is very difficult to obtain very low blanks with organic or complex inorganic extraction solutions – even though ACS and semiconductor grade reagents were used. For this reason, hexane extract data was not reported since the hexane (HPLC grade) contained inorganic impurities, and the analysis of the hexane extract was indistinguishable from the blank.

Ultratrace levels of some metals were detected in some of the other sample extracts. The highest total levels were found in the pH3 buffer, as expected, due to its strong extraction power for metals. Even so, the total weight of all measured analytes extracted from each bottle by the pH3 buffer was less than 0.0125 ug (12.5 ng) - an extremely small amount. The other solutions extracted less than 0.0063 ug (6.3 ng). Expressed as analyte weight found per square meter of contact area with the bottle surface, all extracts were found to contain less than 1 ug/m^2 (total of all analytes measured).

Analyte concentrations were not significantly different in the PFA bottle extractions compared to the FEP bottle extractions, although the methanol extract in PFA had slightly lower analyte concentrations than in FEP. No significant concentration increase was observed in the 28-day extracts compared to the 7-day extracts.

A summary of the inorganic results is shown below. The complete reports[1, 2] express analyte concentration in the extract solution, on a per analyte basis, in ug/m^3. For convenience, the table below gives a total concentration (sum of all inorganic analytes) in ug/m3 for each solvent and bottle type. This is also expressed as total weight (ug) of inorganic analytes (sum of all inorganic analytes) extracted from each 250 mL bottle. Finally, this total weight of inorganic analytes extracted is expressed as weight per contact area (ug/m^2), using a value of 0.0161 m^2 for the contact surface area of a 250 mL bottle.

TABLE 1 - INORGANIC RESULTS

EXTRACT SOLUTION	BOTTLE TYPE	CONCENTRATION FOUND (sum of all inorganic analytes)	TOTAL WEIGHT FOUND PER 250 mL BOTTLE (sum of all inorganic analytes)	WEIGHT FOUND PER CONTACT AREA (sum of all inorganic analytes)
DDIW	PFA	<25 ug/m^3	<0.0063 ug	<0.39 ug/m^2
DDIW	FEP	<25 ug/m^3	<0.0063 ug	<0.39 ug/m^2
Methanol	PFA	<10 ug/m^3	<0.0025 ug	<0.16 ug/m^2
Methanol	FEP	<25 ug/m^3	<0.0063 ug	<0.39 ug/m^2
pH3 Buffer	PFA	<50 ug/m^3	<0.0125 ug	<0.78 ug/m^2
pH3 Buffer	FEP	<50 ug/m^3	<0.0125 ug	<0.78 ug/m^2
pH10 Buffer	PFA	<25 ug/m^3	<0.0063 ug	<0.39 ug/m^2
pH10 Buffer	FEP	<25 ug/m^3	<0.0063 ug	<0.39 ug/m^2

SUMMARY

Purillex PFA and FEP bottles, manufactured from DuPont™ Teflon® resins, were subjected to a comprehensive extractables test protocol featuring five different extraction solutions, for extended periods at elevated temperatures. The test protocol simulated extreme storage and handling conditions, enabling a rigorous product-contact evaluation of Purillex PFA and FEP bottles.

Analysis of the extraction samples was carried out using some of the latest analytical instrumentation, covering a range of techniques. Analytical protocols for organic extractables covered the widest possible range of non-volatile, semivolatile, and volatile compounds and none were detected in any of the solvents, for either bottle type. No extracted TOC was detected and conductivity measurements remained unchanged over 28 days. Analytical protocols for inorganic extractables employed state of the art ICP-QMS and HR-ICP-MS, operated in full quant mode, to measure all USP and ICH elements. The total amount of inorganic analytes extracted from the bottles was at the low ng level, corresponding to <1 ug/m^2 when expressed as total weight of extractables per contacted surface area.

Despite the aggressive extraction protocols used in the testing of Purillex PFA and FEP bottles, no extractable organic compounds were detected, and extractable inorganic compounds were measured at concentrations far below any level that may be stipulated by the various regulatory bodies around the world. The data and methodology contained in the associated complete test reports[1, 2], available on request from Savillex (send an email request to info@savilllex.com), may be used to support end user validation of Purillex PFA and FEP bottles for API product-contact applications.

RESEARCH SOURCES

RESOURCE	DESCRIPTION	DATE
PFA bottle extraction results	7-day and 28-day Extraction Results for Savillex PFA Bottles, DuPont, Wilmington, DE, USA	January 2014
FEP bottle extraction results	7-day and 28-day Extraction Results for Savillex PFA Bottles, DuPont, Wilmington, DE, USA	January 2014

Click here to learn more about Purillex bottles and shop online.

Savillex 10321 W. 70th St. | Eden Prairie, MN, 55344-3446 USA
Phone: 952.935.4100 | Email: info@savillex.com | www.savillex.com

Chemical Compatibility Guide for Savillex Products

APPLICATION NOTE

SAVILLEX | 10321 W. 70TH ST., EDEN PRAIRIE, MN, 55344
INFO@SAVILLEX.COM | 952.935.4100
WWW.SAVILLEX.COM

Savillex

APPLICATION NOTE

Chemical Compatibility Guide for Savillex Products

OVERVIEW - EFFECTS OF CHEMICALS ON PLASTICS

Savillex PFA labware

Chemicals can affect the strength, flexibility, surface appearance, color, dimensions or weight of plastics. The basic modes of interaction which cause these changes are:

1. Chemical attack on the polymer chain, with resultant reduction in physical properties, including oxidation; reaction of functional groups in or on the chain, and depolymerization
2. Physical change, including absorption of solvents, resulting in softening and swelling of the plastic; ermeation of solvent through the plastic, and dissolution in a solvent
3. Stress-cracking from the interaction of a “stress-cracking agent” with molded-in or external stresses

Mixing and/or dilution of certain chemicals in plastic labware can be potentially dangerous. The reactive combination of compounds of two or more classes may cause a synergistic or undesirable chemical effect. Other factors affecting chemical resistance include temperature, pressure and internal or external stresses (e.g., centrifugation), length of exposure and concentration of the chemical. As temperature increases, resistance to attack decreases.

Another concern is environmental stress cracking, which is the failure of a plastic material in the presence of certain types of chemicals. This failure is not a result of chemical attack. Simultaneous presence of three factors causes stress cracking: tensile strength, a stress cracking agent and inherent susceptibility of the plastic to stress cracking. Common stress cracking agents are detergents, surface active chemicals, lubricants, oils, ultra-pure water and plating additives such as brighteners and wetting agents. Relatively small concentrations of stress cracking agent may be sufficient to cause cracking. **Mixing and/or dilution of certain chemicals may result in reactions that produce excessive heat which may lead to product failure. Pre-test your specific usage and always follow correct lab safety procedures.**

NOTE: Although several polymers may have excellent resistance to various flammable organic chemicals and solvents, OSHA H CFR 29 1910.106 for flammable and combustible materials, or other local regulations, may restrict the volume of solvents which may legally be stored in an enclosed area.

CAUTION: Do not store strong oxidizing agents in plastic labware except those made of FEP or PFA. Prolonged exposure causes embrittlement and failure.

The Chemical Resistance Charts on the following pages are provided as general references for comparing Savillex PFA and FEP products with products manufactured of other common polymers. Because there are many different factors which can affect the chemical resistance of a given product, we recommend that you test under your own conditions. If any doubt exists about specific applications, please contact Savillex. These Chemical Resistance Charts can be used for all PFA and FEP labware including Purillex™ bottles.

Chemical	LDPE		HDPE		PP		PPCO		PMP		PETG		FEP		TFE		PFA		ECTFE		ETFE		PC		PVDF	
	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°
1,4-Dioxane, pure	G	F	G	G	N	N	G	F	F	N	-	-	E	E	E	E	E	E	E	F	E	F	N	N	N	N
2,2,4-Trimethylpentane, pure	F	N	F	N	F	N	F	N	F	N	-	-	E	E	E	E	E	E	E	G	E	G	N	N	E	E
2,4,6-Trinitrophenol, pure	N	N	N	N	N	N	N	N	E	E	-	-	E	E	E	E	E	E	G	F	G	F	N	N	G	N
2-Methoxyethanol, pure	E	G	E	E	G	F	E	E	E	E	F	N	E	E	E	E	E	E	E	G	E	E	N	N	E	E
2-Propanol, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Acetaldehyde, pure	G	N	G	F	G	N	G	N	G	N	-	-	E	E	E	E	E	E	G	F	E	E	N	N	N	N
Acetamide, saturated	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	G	N
Acetic Acid, 5%	E	E	E	E	E	E	E	E	E	E	F	N	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Acetic Acid, 50%	G	F	E	G	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	G	E	E	G	F	E	E
Acetic Acid, Glacial	G	N	G	G	E	G	E	G	G	G	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	G
Acetic Anhydride, pure	N	N	F	F	G	F	G	F	E	G	-	-	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Acetone, pure	G	N	N	N	F	N	N	N	E	E	N	N	E	E	E	E	E	E	E	G	G	N	N	N	N	N
Acetonitrile, pure	E	E	E	E	E	G	F	N	F	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	G	G
Acetophenone, pure	N	N	F	F	F	N	F	N	G	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Acrylonitrile, pure	E	E	E	E	F	N	F	N	F	N	-	-	E	E	E	E	E	E	E	G	E	G	N	N	G	N
Adipic Acid, pure	E	G	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Alanine, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	G	N
Allyl Alcohol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	G	E	G
Aluminum Chloride, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Aluminum Hydroxide, pure	E	G	E	E	E	G	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Aluminum Salts, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Amino Acids, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	G	N
Ammonia, 25%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Ammonia, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Ammonium Acetate, saturated	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	G	E	E
Ammonium Chloride, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Ammonium Glycolate, pure	E	G	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Ammonium Hydroxide, 5%	E	E	E	E	E	E	E	E	E	E	F	N	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Ammonium Hydroxide, 30%	E	G	E	E	E	G	E	G	E	G	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Ammonium Oxalate, pure	E	G	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Ammonium Salts, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	G	E	E
Amyl Alcohol, pure	E	E	E	E	E	F	E	E	G	F	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Amyl Chloride, pure	N	N	F	N	N	N	N	N	F	F	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Aniline, pure	E	G	G	F	E	G	G	F	G	F	-	-	E	E	E	E	E	E	G	N	E	G	N	N	E	F
Aqua Regia, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	N	N	G	N
Arsenic Acid, pure	G	F	E	E	E	E	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Benzaldehyde, pure	E	G	G	N	E	G	E	G	E	F	-	-	E	E	E	E	E	E	E	F	E	F	N	N	F	N
Benzenamine, pure	E	G	G	F	E	G	G	F	G	F	-	-	E	E	E	E	E	E	G	N	E	G	N	N	E	F
Benzene, pure	N	N	N	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	G	E	G	N	N	E	E
Benzoic Acid, saturated	E	E	E	E	E	G	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Benzol, pure	N	N	N	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	G	E	G	N	N	E	E
Benzyl Acetate, pure	E	G	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	G	E	G	F	N	-	-
Benzyl Alcohol, pure	N	N	F	N	G	G	N	N	G	G	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Boric Acid, pure	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Bromine, pure	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	F	N	E	E
Bromobenzene, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	G	N	E	F	N	N	E	E
Bromoform, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	G	F	E	F	N	N	E	E
Butadiene, pure	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Butyl Acetate, pure	G	F	G	F	F	N	G	F	F	F	-	-	E	E	E	E	E	E	E	G	E	G	N	N	F	N
Butyl Chloride, pure	N	N	N	N	N	N	N	N	F	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Butyric Acid, pure	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Calcium Chloride, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Calcium Hydroxide, concentrated	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Calcium Hypochlorite, saturated	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Carbazole, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	-	-
Carbon Disulfide, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	F	E	G	N	N	G	N
Carbon Tetrachloride, pure	F	N	G	F	G	F	N	N	N	N	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	E

E = No damage after 30 days of constant exposure. G = Little or no damage after 30 days of constant exposure.
F = Some effect after 7 days of constant exposure. N = Immediate damage may occur. Not recommended for continuous use.

Chemical	LDPE		HDPE		PP		PPCO		PMP		PETG		FEP		TFE		PFA		ECTFE		ETFE		PC		PVDF	
	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°
Caustic Potash, 30%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	G
Caustic Potash, 50%	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Caustic Potash, concentrated	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	G
Caustic Soda, 1%	E	E	F	F	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Caustic Soda, 50%	G	G	G	F	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Caustic Soda, concentrated	G	G	G	F	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Cedarwood Oil, pure	N	N	F	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	G	E	G	G	F	E	E
Cellosolve Acetate, pure	E	G	E	E	F	N	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	G	F	N	E	G
Chlorine, water solution	G	N	G	G	F	N	F	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Chlorine, wet gas	G	N	G	F	F	N	F	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Chlorine Wet Gas, 10%	G	N	G	F	F	N	F	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Chlorine, Dry Gas, 10%	G	N	E	F	F	N	G	N	G	N	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Chloroacetic Acid, pure	E	E	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	E	F	N	N	N
Chlorobenzene, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	G	F	E	E	N	N	E	E
Chloroform, pure	F	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	G	F	E	G	N	N	E	G
Chromic Acid, 10%	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Chromic Acid, 20%	E	E	E	E	G	G	G	F	E	E	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Chromic Acid, 50%	E	E	E	E	G	F	G	F	G	G	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	G
Chromic Acid: Surfuric Acid Mixture, 96%	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	N	N	E	G
Cinnamon Oil, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	G	F	-	-
Citric Acid, 10%	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Citric Acid, 1M	E	E	E	E	E	E	E	E	E	E	G	F	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Copper Sulfate, pure	E	E	E	E	E	E	E	E	E	E	E	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Cresol, pure	N	N	F	N	G	F	G	F	N	N	-	-	E	E	E	E	E	E	E	G	E	E	N	N	E	G
Cyclohexane, pure	F	N	F	N	G	N	F	N	N	N	G	N	E	E	E	E	E	E	E	G	E	E	E	F	E	E
Cyclohexanone, pure	N	N	F	N	F	N	F	N	G	F	N	N	E	E	E	E	E	E	E	E	E	E	N	N	G	N
Cyclopentane, pure	N	N	F	N	F	N	F	N	F	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Decahydronaphthalene, pure	G	F	E	G	N	N	G	F	F	N	-	-	E	E	E	E	E	E	E	E	E	E	E	-	-	-
Decalin, pure	G	F	E	G	N	N	G	F	F	N	-	-	E	E	E	E	E	E	E	E	E	E	E	-	-	-
Diacetone, pure	N	N	N	N	G	F	G	F	F	F	N	N	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Diacetone Alcohol, pure	F	N	E	E	G	F	E	F	E	E	-	-	E	E	E	E	E	E	E	G	E	G	N	N	F	N
Dibutyl Phthalate, pure	F	N	F	N	G	N	-	-	G	G	-	-	E	E	E	E	E	E	G	N	E	G	G	N	N	N
Diethyl Benzene, pure	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	E	F	N	E	E
Diethyl Ether, pure	N	N	F	N	F	N	N	N	N	N	E	-	E	E	E	E	E	E	E	G	E	E	N	N	E	G
Diethyl Ketone, pure	N	N	N	N	G	G	G	G	G	F	-	-	E	E	E	E	E	E	G	F	G	F	N	N	N	N
Diethyl Malonate, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	F	N	N	N
Diethylamine, pure	N	N	F	N	G	N	G	N	F	F	-	-	E	E	E	E	E	E	E	N	E	G	N	N	G	N
Diethylene Dioxide, pure	G	F	G	G	N	N	G	F	F	N	-	-	E	E	E	E	E	E	E	F	E	F	N	N	N	N
Diethylene Glycol, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Diethylene Glycol Monoethyl Ether, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	F	N	N	N
Dimethyl Acetamide, pure	F	N	E	E	E	E	E	E	F	G	-	-	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Dimethyl Formamide, pure	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	G	G	G	G	N	N	N	N
Dimethylsulfoxide, pure	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Dioxane, pure	G	F	G	G	N	N	G	F	F	N	-	-	E	E	E	E	E	E	E	F	E	F	N	N	N	N
Dipropylene Glycol, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	F	N	N
DMSO, pure	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Ethanol, 40%	E	G	E	E	E	E	E	E	E	G	G	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E

E = No damage after 30 days of constant exposure. G = Little or no damage after 30 days of constant exposure.
F = Some effect after 7 days of constant exposure. N = Immediate damage may occur. Not recommended for continuous use.

Chemical	LDPE		HDPE		PP		PPCO		PMP		PETG		FEP		TFE		PFA		ECTFE		ETFE		PC		PVDF	
	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°
Ether, pure	N	N	F	N	N	N	N	N	F	N	E	-	E	E	E	E	E	E	E	G	E	G	N	N	G	N
Ethyl Acetate, pure	E	E	E	E	G	N	G	F	F	N	N	N	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Ethyl Alcohol, 40%	E	G	E	E	E	E	E	E	E	G	F	N	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Ethyl Alcohol, 96%	E	G	E	G	E	E	E	E	E	G	F	N	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Ethyl Alcohol, pure	E	G	E	E	E	E	E	G	E	G	F	N	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Ethyl Benzene, pure	N	N	F	N	N	N	N	N	N	N	E	-	E	E	E	E	E	E	G	F	G	F	N	N	G	N
Ethyl Benzoate, pure	F	F	G	G	G	F	G	F	G	F	-	-	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Ethyl Butyrate, pure	G	N	G	F	G	N	G	N	F	N	-	-	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Ethyl Chloride, pure	F	N	N	N	F	N	F	N	F	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Ethyl Cyanoacetate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	F	N	N	N
Ethyl Lactate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	F	N	N	N
Ethylene Chloride, pure	N	N	N	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	N	E	E	N	N	E	E
Ethylene Glycol, pure	E	G	E	E	E	E	E	E	E	E	E	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Ethylene Glycol	E	G	E	E	G	F	E	E	E	E	F	N	E	E	E	E	E	E	E	G	E	E	N	N	E	E
Monomethyl Ether, pure																										
Ethylene Oxide, 100%	F	F	G	F	F	N	F	F	F	N	G	F	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Ethylene Oxide, gas	G	G	E	E	E	E	G	G	G	G	G	F	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Ethylene Oxide, pure	F	F	G	F	F	N	F	F	F	N	G	F	E	E	E	E	E	E	E	E	E	E	F	N	E	E
EtO, gas	G	G	E	E	E	E	G	G	G	G	G	F	E	E	E	E	E	E	E	E	E	E	E	E	E	E
EtO, pure	F	F	G	F	F	N	F	F	F	N	G	F	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Fatty Acids - saturated, pure	G	F	E	E	E	G	E	G	E	G	G	F	E	E	E	E	E	E	E	G	E	E	G	F	E	E
Fatty Acids - unsaturated, pure	G	F	E	E	E	G	E	G	E	G	G	F	E	E	E	E	E	E	E	G	E	E	G	F	E	E
Fluorides	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Fluorine, gas	F	N	G	N	N	N	F	N	F	N	-	-	E	G	E	G	E	G	E	F	G	N	G	F	G	N
Formaldehyde, 10%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Formaldehyde, 40%	E	G	E	G	E	E	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Formalin, 10%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Formalin, 40%	E	G	E	G	E	E	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Formic Acid, 3%	E	G	E	E	E	E	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Formic Acid, 50%	G	G	E	E	E	G	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Formic Acid, 85%	G	G	E	E	E	G	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Formic Acid, 100%	G	G	E	E	E	G	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Formic Acid, pure	G	G	E	E	E	G	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Freon TF, pure	E	G	E	G	E	G	E	G	F	N	-	-	E	E	E	E	E	E	E	G	E	G	G	N	E	E
Fuel Oil	F	N	G	F	E	F	E	G	G	F	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Gasoline	N	N	F	N	F	N	N	N	G	F	G	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Glutaraldehyde, pure	E	G	E	E	E	E	E	E	F	F	G	-	E	E	E	E	E	E	E	G	E	G	E	F	E	E
Glutaraldehyde Disinfectant	E	G	E	E	E	E	E	E	F	F	-	-	E	E	E	E	E	E	E	G	E	G	E	F	E	E
Glycerine, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Glycerol, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Hexane, pure	N	N	G	F	G	F	F	N	F	N	G	-	E	E	E	E	E	E	E	G	E	E	F	N	E	E
Hydrazine, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	G	F	G	N	N	N	E	E
Hydrobromic Acid, 69%	E	E	E	G	E	G	-	-	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Hydrochloric Acid, 5%	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Hydrochloric Acid, 20%	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Hydrochloric Acid, 35%	E	E	E	E	E	G	E	G	E	G	G	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Hydrofluoric Acid, 4%	E	E	E	E	E	E	E	G	E	E	F	N	E	E	E	E	E	E	E	E	E	E	G	G	E	E
Hydrofluoric Acid, 48%	E	E	E	E	E	G	E	E	E	G	N	N	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Hydrogen Peroxide, 3%	E	E	E	E	E	G	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E

E = No damage after 30 days of constant exposure. G = Little or no damage after 30 days of constant exposure.
F = Some effect after 7 days of constant exposure. N = Immediate damage may occur. Not recommended for continuous use.

Chemical	LDPE		HDPE		PP		PPCO		PMP		PETG		FEP		TFE		PFA		ECTFE		ETFE		PC		PVDF	
	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°
Hydrogen Peroxide, 30%	E	G	E	E	E	F	E	G	E	G	G	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Hydrogen Peroxide, 90%	E	N	E	E	E	F	E	G	E	G	G	-	E	E	E	E	E	E	E	E	E	F	E	E	G	N
Iodine Crystals, pure	N	N	N	N	E	E	F	N	G	N	-	-	E	E	E	E	E	E	E	E	E	G	G	N	E	E
Isobutanol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
iso-Butyl Alcohol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Isopropanol, 100%	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Isopropanol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
iso-Propanol, 100%	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Isopropyl Acetate, pure	G	F	E	G	G	F	G	F	G	F	-	-	E	E	E	E	E	E	E	G	E	G	N	N	G	N
Isopropyl Alcohol, 100%	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Isopropyl Alcohol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Isopropyl Benzene, pure	F	N	F	N	F	N	F	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	N	N	-	-
Isopropyl Ether, pure	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	N	N	E	G
Jet Fuel	F	N	F	N	F	N	F	N	F	N	-	-	E	E	E	E	E	E	E	E	E	E	G	N	E	E
Kerosene	F	N	F	N	F	N	N	N	G	F	G	-	E	E	E	E	E	E	E	E	G	F	E	-	E	E
Lacquer Thinner	N	N	F	N	F	N	F	N	F	F	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Lactic Acid, 3%	E	G	E	E	E	E	E	G	E	G	F	N	E	E	E	E	E	E	E	E	E	E	E	E	E	G
Lactic Acid, 85%	E	G	E	E	E	G	E	G	E	G	N	N	E	E	E	E	E	E	E	E	E	E	E	G	E	G
Lead Acetate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Magnesium Chloride, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
MEK, pure	N	N	N	N	E	G	E	G	F	N	G	-	E	E	E	E	E	E	G	F	E	G	N	N	N	N
Mercuric Chloride, pure	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Methanol, 100%	E	G	E	E	E	E	E	E	E	G	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Methoxyethyl Oleate, pure	E	G	E	E	E	G	E	G	E	G	G	-	E	E	E	E	E	E	E	E	E	E	F	N	-	-
Methyl Acetate, pure	F	N	F	F	G	F	G	F	E	E	N	N	E	E	E	E	E	E	E	G	E	G	N	N	E	N
Methyl Alcohol, 100%	E	G	E	E	E	E	E	E	E	G	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Methyl Alcohol, pure	E	G	E	E	E	E	E	E	E	G	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Methyl Ethyl Ketone, pure	N	N	N	N	E	G	E	G	F	N	G	-	E	E	E	E	E	E	G	F	E	G	N	N	N	N
Methyl Isobutyl Ketone, pure	N	N	N	N	G	F	G	F	F	F	N	N	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Methyl Propyl Ketone, pure	N	N	F	N	G	F	G	F	F	F	N	N	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Methylene Chloride, pure	N	N	F	N	F	N	F	N	F	N	N	N	E	E	E	E	E	E	F	N	G	N	N	N	E	G
Methyl-t-Butyl Ether, pure	N	N	F	N	F	N	F	N	E	E	N	N	E	E	E	E	E	E	E	G	E	G	N	N	E	E
MIBK, pure	N	N	N	N	G	F	G	F	F	F	N	N	E	E	E	E	E	E	E	G	E	G	N	N	N	N
Mineral Oil	G	N	E	E	E	F	E	E	E	G	G	N	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Mineral Spirits	F	N	F	N	F	N	F	N	E	E	G	-	E	E	E	E	E	E	E	G	E	G	F	F	E	E
n-Amyl Acetate, pure	G	F	E	G	G	F	G	F	G	F	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	G
n-Butanol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
n-Butyl Acetate, pure	G	F	G	F	G	F	G	F	G	F	-	-	E	E	E	E	E	E	E	G	E	G	N	N	G	N
n-Butyl Alcohol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
n-Decane, pure	F	N	F	N	F	N	F	N	F	N	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
n-Heptane, pure	N	N	F	F	F	F	F	F	F	F	E	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Nitric Acid, 10%	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Nitric Acid, 20%	E	E	G	G	F	F	G	F	E	E	G	-	E	E	E	E	E	E	E	E	E	E	E	G	E	G
Nitric Acid, 50%	G	F	F	N	F	N	F	N	F	N	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	G
Nitric Acid, 70%	F	N	F	N	N	N	N	N	F	N	N	N	E	E	E	E	E	E	E	E	E	G	G	N	N	N
Nitrobenzene, pure	N	N	N	N	N	N	N	N	F	N	N	N	E	E	E	E	E	E	E	G	E	G	N	N	G	N
Nitromethane, pure	N	N	F	N	F	N	F	N	E	F	N	N	E	E	E	E	E	E	E	F	E	G	F	N	E	G
n-Octane, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
o-Dichlorobenzene, pure	F	N	N	N	F	N	F	N	F	N	N	N	E	E	E	E	E	E	E	N	E	F	N	N	E	E

E = No damage after 30 days of constant exposure. G = Little or no damage after 30 days of constant exposure.
F = Some effect after 7 days of constant exposure. N = Immediate damage may occur. Not recommended for continuous use.

Chemical	LDPE		HDPE		PP		PPCO		PMP		PETG		FEP		TFE		PFA		ECTFE		ETFE		PC		PVDF	
	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°
Oil, Cedarwood	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	G	F	E	E
Oil, Cinnamon	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	G	G	F	-	-
Oil, Mineral	G	N	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Oil, Pine	G	N	F	N	E	G	E	G	G	F	-	-	E	E	E	E	E	E	E	G	E	G	G	F	E	E
Orange Oil	F	N	G	F	G	F	G	F	F	F	-	-	E	E	E	E	E	E	E	E	E	E	F	F	E	E
Oxalic Acid, 10%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	G
Ozone, pure	G	N	G	N	F	N	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
p-Chloroacetophenone, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	N	N	N
p-Dichlorobenzene, pure	F	N	N	N	G	F	G	F	G	F	N	N	E	E	E	E	E	E	E	N	E	F	N	N	E	E
Perchloric Acid, 70%	G	N	G	N	G	N	G	N	G	N	-	-	E	E	G	F	E	E	E	G	E	G	N	N	E	G
Perchloric Acid, concentrated	G	N	G	N	G	N	G	N	G	N	-	-	G	F	G	F	G	F	G	F	G	F	N	N	E	G
Perchloric Acid, pure	G	N	G	N	G	N	G	N	G	N	-	-	G	F	G	F	G	F	G	F	G	F	N	N	E	G
Perchloroethylene, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	G	E	E	N	N	E	E
Petroleum	N	N	G	N	N	N	N	N	G	F	-	-	E	E	E	E	E	E	E	E	E	E	F	F	E	E
Phenol, 50%	N	N	N	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	G	E	E	N	N	E	G
Phenol, 100%	N	N	N	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	G	E	F	N	N	E	G
Phenol, Crystal	F	N	G	F	G	N	G	N	F	G	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	G
Phenol, liquid	N	N	N	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	G	E	F	N	N	E	G
Phosphoric Acid, 5%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Phosphoric Acid, 85%	E	N	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Picric Acid, pure	N	N	N	N	N	N	N	N	E	E	-	-	E	E	E	E	E	E	G	F	G	F	N	N	G	N
Pine Oil, pure	G	N	F	N	E	G	E	G	G	F	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Potassium Chloride, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Potassium Hydroxide, 1%	E	E	F	F	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Potassium Hydroxide, 30%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	G
Potassium Hydroxide, concentrated	E	E	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	G
Potassium Permanganate, pure	E	E	E	E	E	G	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Propane, gas	N	N	E	E	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Proprionic Acid, pure	F	N	E	F	E	G	E	G	E	F	-	-	E	E	E	E	E	E	E	F	E	G	N	N	E	E
Propylene Glycol, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Propylene Oxide, pure	E	G	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	N	N	E	F	G	F	N	N
Pyridine, pure	N	N	N	N	E	E	N	N	F	N	-	-	E	E	E	E	E	E	N	N	E	G	N	N	N	N
Resorcinol, 5%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	F	G	F	E	E
Resorcinol, saturated	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Salicylaldehyde, pure	E	G	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	N	E	G	G	F	E	G
Salicylic Acid, powder	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Salicylic Acid, saturated	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
sec-Butanol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
sec-Butyl Alcohol, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Silicone Oil, pure	E	G	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Silver Acetate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Silver Nitrate, pure	E	G	E	E	E	E	E	G	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Skydrol LD4 Aviation Hydraulic Fluid	G	F	E	G	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	E	N	N	E	F
Sodium Acetate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Sodium Carbonate, pure	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Sodium Dichromate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Sodium Hydroxide, 1%	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E

E = No damage after 30 days of constant exposure. G = Little or no damage after 30 days of constant exposure.
F = Some effect after 7 days of constant exposure. N = Immediate damage may occur. Not recommended for continuous use.

Chemical	LDPE		HDPE		PP		PPCO		PMP		PETG		FEP		TFE		PFA		ECTFE		ETFE		PC		PVDF	
	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°	20°	50°
Sodium Hydroxide, 10%	E	E	E	E	E	E	E	E	E	E	G	-	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Sodium Hydroxide, 50%	G	G	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Sodium Hydroxide, concentrated	G	G	E	E	E	E	E	E	E	E	N	N	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Sodium Hypochlorite, 15%	E	F	E	G	F	N	G	N	E	E	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Stearic Acid, pure	E	E	G	G	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Sulfur Dioxide, dry gas	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Sulfur Dioxide, liquid (46 psig)	N	N	F	N	E	E	N	N	N	N	-	-	E	E	E	E	E	E	E	E	E	G	G	N	E	E
Sulfur Dioxide, wet gas	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Sulfur Dioxide, pure	N	N	F	N	E	E	N	N	N	N	-	-	E	E	E	E	E	E	E	E	E	G	G	N	E	E
Sulfur Salts, pure	F	N	G	F	F	N	F	N	F	N	-	-	E	E	E	E	E	E	E	E	E	G	F	N	F	N
Sulfuric Acid, 6%	E	E	E	E	E	E	E	E	E	E	E	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Sulfuric Acid, 20%	E	E	E	E	E	E	E	G	E	E	E	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
Sulfuric Acid, 30%	E	E	E	E	E	E	E	G	E	E	G	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Sulfuric Acid, 60%	E	G	E	G	G	F	G	F	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Sulfuric Acid, 96%	G	G	F	N	F	N	F	N	G	F	N	N	E	E	E	E	E	E	E	E	E	E	N	N	E	E
Sulfuric Acid, 98%	G	G	F	N	F	N	F	N	G	F	N	N	E	E	E	E	E	E	E	E	E	G	N	N	E	G
Sulfuric Acid, concentrated	G	G	F	N	N	N	N	N	N	N	N	N	E	E	E	E	E	E	E	E	E	G	N	N	N	N
Tartaric Acid, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	E	E
TCA, pure	F	N	F	N	G	F	F	N	E	E	-	-	E	E	E	E	E	E	E	F	E	G	F	N	E	G
tert-Butanol, pure	E	G	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
tert-Butyl Alcohol, pure	E	G	E	E	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Tetrahydrofuran, pure	F	N	F	N	G	F	G	F	F	F	-	-	E	E	E	E	E	E	N	N	G	F	N	N	N	N
THF, pure	F	N	F	N	G	F	G	F	F	F	-	-	E	E	E	E	E	E	N	N	G	F	N	N	N	N
Thionyl Chloride, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	N	N	N	N
Tincture of Iodine	E	G	G	F	E	E	G	N	N	N	-	-	E	E	E	E	E	E	E	E	E	E	G	N	E	G
Toluene, pure	F	N	N	N	N	N	N	N	F	F	N	N	E	E	E	E	E	E	E	G	E	E	N	N	E	E
Tributyl Citrate, pure	G	F	E	G	G	F	G	F	G	F	-	-	E	E	E	E	E	E	E	G	E	G	N	N	E	F
Trichloroacetic Acid, pure	F	N	F	N	G	F	F	N	E	E	-	-	E	E	E	E	E	E	E	F	E	G	F	N	E	G
Trichloroethane, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	E	E	G	N	N	N	E	E
Trichloroethylene, pure	N	N	N	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	N	N	E	E	N	N	E	E
Triethylene Glycol, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	-	-
Tripropylene Glycol, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	G	-	-
Tris Buffer Solution, pH 11	E	G	E	G	E	G	E	G	E	G	F	N	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Tris Buffer Solution, pH 7.0	E	G	E	G	E	G	E	G	E	G	G	G	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Trisodium Phosphate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	G	N	E	E
Turpentine	F	N	F	N	F	N	N	N	F	N	G	-	E	E	E	E	E	E	E	E	E	E	F	N	E	E
Undecyl Alcohol, pure	E	F	E	G	E	G	E	G	E	G	-	-	E	E	E	E	E	E	E	G	E	G	G	F	E	E
Urea, pure	E	E	E	E	E	E	E	E	E	G	-	-	E	E	E	E	E	E	E	E	E	E	G	F	E	E
Vinylidene Chloride, pure	N	N	F	N	N	N	N	N	N	N	-	-	E	E	E	E	E	E	G	F	G	F	N	N	E	E
Xylene, pure	N	N	F	N	N	N	F	N	F	N	-	-	E	E	E	E	E	E	E	E	E	G	N	N	E	E
Zinc Chloride, 10%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Zinc Stearate, pure	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Zinc Sulfate, 10%	E	E	E	E	E	E	E	E	E	E	-	-	E	E	E	E	E	E	E	E	E	E	E	E	E	E

E = No damage after 30 days of constant exposure. G = Little or no damage after 30 days of constant exposure.
F = Some effect after 7 days of constant exposure. N = Immediate damage may occur. Not recommended for continuous use.

RESIN CODE REFERENCES

ABBREVIATION	FULL RESIN NAME
ECTFE	Halar ECTFE* (ethylene-chlorotrifluoroethylene copolymer)
ETFE	Tefzel ETFE* (ethylene-tetrafluoroethylene)
FEP	Teflon FEP* (fluorinated ethylene propylene)
HDPE	High-density polyethylene
LDPE	Low-density polyethylene
PC	Polycarbonate
PETG	Polyethylene terephthalate copolymer
PFA	Teflon PFA* (polyfluoroalkoxy)
PMP	Polymethylpentene
PP	Polypropylene
PPCO*	Polypropylene copolymer
PVDF	Polyvinylidene fluoride
TFE	Teflon TFE* (tetrafluoroethylene)
TMX	Thermanox
PMX	Permanox

**Halar is a registered trademark of Solvay Solexis*
**Teflon and Tefzel are registered trademarks of DuPont*
**PPCO has replaced polyallomer (PA) in all products*

CLICK HERE TO VIEW OUR FULL PRODUCT LINE ON SAVILLEX.COM

Savillex 10321 W. 70th St. | Eden Prairie, MN, 55344-3446 USA
Phone: 952.935.4100 | Email: info@savillex.com | www.savillex.com

Savillex Life Sciences
10333 W. 70th St.
Eden Prairie, MN, 55344
www.savillex.com

Fluoropolymer Packaging for Cell Therapy Product

SUCCESS STORY

Photo provided by Vericel Corporation

ABOUT SAVILLEX

Savillex specializes in providing high-quality containers and containment designed for critical applications across a broad spectrum of pharmaceutical and biopharmaceutical processes. Our range of products ensures reliability and performance in the most demanding life science environments. Every product we sell is designed to help the scientific community to preserve sample integrity, ensure regulatory compliance, facilitate reliable data, and safeguard your assets.

CHALLENGE

Evolving standards for packaging advanced, autologous cell-based therapies.

SOLUTION

Purillex® 100 mL PFA bottle.

RESULT

Improved ease of use by surgeons and critical quality attributes met.

Vericel Corporation, based in Cambridge, Massachusetts, develops and manufactures advanced, autologous cell-based therapies that use a patient's own healthy cells to treat serious diseases and conditions.

One such cell therapy product marketed by Vericel is MACI® (autologous cultured chondrocytes on porcine collagen membrane).

Due to evolving standards in container closure integrity testing, Vericel felt it necessary to revisit and potentially improve the way in which they package and ship their MACI implant. This is what led them to partner with Savillex.

Chief among Vericel's reasons for wanting to choose a fluoropolymer product was the material's lack of reactivity and sturdiness. Fluoropolymer products from Savillex also come with a comprehensive validation binder documenting acceptable extractable levels and container closure integrity.

Vericel ultimately selected Savillex's 100 mL Purillex PFA bottle as the primary packaging used to store and transport MACI, which the FDA regulates under an approved biologics license.

When asked about working with Savillex, John Duguid, Executive Director, Research & Development at Vericel Corporation stated, "Savillex proved highly responsive to Vericel's requests and provided all the rigorous documentation needed for submission in this heavily regulated industry."

The updated MACI packaging proved easier for surgeons to use and allows the product to retain all its critical quality attributes. As an added benefit, the Purillex PFA bottles were made available pre-sterilized and ready-to-use.

"Savillex proved highly responsive to Vericel's requests and provided all the rigorous documentation needed for submission in this heavily regulated industry."

- John Duguid, Executive Director, Research & Development

CLICK HERE TO LEARN MORE ABOUT OUR PFA BOTTLES