



Ansell

USP General Chapter Solutions <800> & <797>

*Hazardous Drugs in a
Healthcare Setting*

November 8, 2022 Revisions

WHAT IS USP 800?*

USP (United States Pharmacopeia) General Chapter <800> is a guide for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment.

USP General Chapter <797> is a guide for sterile compounding, or otherwise altering a drug product.

Both sets of standards provide guidelines for the appropriate handling of hazardous medications during:



*USP 800 Handling hazardous drugs in healthcare settings www.usp.org/usp800

USP 800 MANDATES

Two pairs of chemotherapy gloves are required for administering antineoplastic hazardous drugs and hazardous drug compounding.

Chemotherapy gloves must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor).

When used for sterile compounding, the outer chemotherapy gloves must be sterile.

Chemotherapy gloves must be powder-free because powder can contaminate the work area and can absorb and retain hazardous drugs.

Chemotherapy gloves should be changed every 30 minutes.

USP 797 MANDATES

All gloves must be sterile and IPA compatible.

Sterile USP-grade isopropyl alcohol is required for intermittent disinfection of gloves.









After disinfecting gloves with isopropyl alcohol, allow 30 seconds of kill time before resuming use.

High risk compounding requires the same garbing and gloves as required for ISO Class 5 processes.






*Best practice recommends to change gloves between tasks. Ansell offers specialty gloves tested against hazardous compounds. Ansell recommends choosing a glove designed for use in cleanroom environments.

ASTM D6978 TESTED GLOVES WITH FDA CLEARANCE†









Recommended for pharmaceutical compounding and patient administration

SURGICAL GLOVE SOLUTIONS	KEY PRODUCTS AND SPECIFICATIONS	
<p>GAMMEX® PI Plus Glove-In-Glove™ System</p>  	<ul style="list-style-type: none"> • Polyisoprene • Tested in accordance with ASTM D6978 and US FDA cleared in a non-patient care application such as pharmaceutical compounding • Final Release AQL: 0.65 • Sterile • United States Ergonomics Certified • Outer: Standard thickness; Inner- Micro-thickness • Outer: Natural Color; Inner: Green • Protects against Type I (latex) allergies and minimizes Type IV (chemical) allergies 	<ul style="list-style-type: none"> ✦ A.R.T™ Pinhole Barrier Technology ✦ DERMASHIELD™ Donning Aid Technology ✦ ERGOFORM™ Ergonomic Design Technology ✦ PI-KARE™ Skin-friendly, non-sensitizing PI Technology SUREFIT™
<p>GAMMEX® Non-Latex PI</p>  	<ul style="list-style-type: none"> • Polyisoprene • Tested in accordance with ASTM D6978 and US FDA cleared • Final Release AQL: 0.65 • Sterile • United States Ergonomics Certified • Standard thickness • Protects against Type I (latex) allergies and minimizes Type IV (chemical) allergies 	<ul style="list-style-type: none"> ✦ A.R.T™ Pinhole Barrier Technology ✦ DERMASHIELD™ Donning Aid Technology ✦ ERGOFORM™ Ergonomic Design Technology ✦ PI-KARE™ Skin-friendly, non-sensitizing PI Technology SUREFIT™
<p>GAMMEX® PI Hybrid</p>  	<ul style="list-style-type: none"> • Polyisoprene and Neoprene Blend • Tested in accordance with ASTM D6978 and US FDA cleared • Final Release AQL: 0.65 • Sterile • United States Ergonomics Certified • Standard thickness • Protects against Type I (latex) allergies and minimizes Type IV (chemical) allergies 	<ul style="list-style-type: none"> ✦ A.R.T™ Pinhole Barrier Technology ✦ DERMASHIELD™ Donning Aid Technology ✦ ERGOFORM™ Ergonomic Design Technology SUREFIT™
<p>GAMMEX® Non-Latex PI Textured</p> 	<ul style="list-style-type: none"> • Polyisoprene • Tested in accordance with ASTM D6978 and US FDA cleared • Final Release AQL: 0.65 • Sterile • Textured external finish: Firm instrument grip in wet or dry conditions • Standard thickness • Protects against Type I (latex) allergies and minimizes Type IV (chemical) allergies 	<ul style="list-style-type: none"> ✦ A.R.T™ Pinhole Barrier Technology ✦ DERMASHIELD™ Donning Aid Technology ✦ PI-KARE™ Skin-friendly, non-sensitizing PI Technology SUREFIT™
<p>GAMMEX® Non-Latex PI Green</p> 	<ul style="list-style-type: none"> • Polyisoprene • Tested in accordance with ASTM D6978 and US FDA cleared • Final Release AQL: 0.65 • Sterile • Standard thickness • Protects against Type I (latex) allergies and minimizes Type IV (chemical) allergies 	<ul style="list-style-type: none"> ✦ A.R.T™ Pinhole Barrier Technology ✦ DERMASHIELD™ Donning Aid Technology SUREFIT™

†Gloves with ASTM D6978 Testing and FDA clearance are suitable for all HD usage as defined by USP 800.







SURGICAL GLOVE SOLUTIONS	KEY PRODUCTS AND SPECIFICATIONS	
<p>GAMMEX® Non-Latex</p> 	<ul style="list-style-type: none"> • Neoprene • Tested in accordance with ASTM D6978 and US FDA cleared • Final Release AQL: 0.65 • Sterile • Standard thickness • 100% chemical-accelerator free 	<ul style="list-style-type: none"> ◆ A.R.T™ Pinhole Barrier Technology ◆ DERMASHIELD™ Donning Aid Technology
<p>GAMMEX® Non-Latex Sensitive</p>  	<ul style="list-style-type: none"> • Neoprene • Tested in accordance with ASTM D6978 and US FDA cleared • Final Release AQL: 0.65 • Sterile • SENSOPRENE™ Technology for comfort and sensitivity without compromising on durability • United States Ergonomics Certified • Protects against Type I (latex) and Type IV (chemical) allergies • 100% chemical-accelerator free 	<ul style="list-style-type: none"> ◆ A.R.T™ Pinhole Barrier Technology ◆ DERMASHIELD™ Donning Aid Technology ◆ ERGOFORM™ Ergonomic Design Technology ◆ SENSOPRENE™ Ultra Thin Neoprene Technology
<p>ENCORE® Latex Acclaim</p>  	<ul style="list-style-type: none"> • Natural Rubber Latex • Tested in accordance with ASTM D6978 and US FDA cleared • Final Release AQL: 0.65 • Sterile • United States Ergonomics Certified • Standard thickness 	<ul style="list-style-type: none"> ◆ A.R.T™ Pinhole Barrier Technology ◆ DERMASHIELD™ Donning Aid Technology ◆ ERGOFORM™ Ergonomic Design Technology SUREFIT™



EXAM GLOVE SOLUTIONS	KEY PRODUCTS AND SPECIFICATIONS
<p>MICRO-TOUCH® Sterile</p> 	<ul style="list-style-type: none"> • Nitrile • ASTM D6978 • Final Release AQL: 1.5 • Sterile • Available in singles and pairs • 12" extended cuff for extra protection • US FDA 510K cleared
<p>MICRO-TOUCH® Nitrile</p> 	<ul style="list-style-type: none"> • Nitrile • ASTM D6978 • Final Release AQL: 1.5 • Non-Sterile • Tested for use with over 55 chemicals • US FDA 510K cleared
<p>MICRO-TOUCH® Nitrile E.P</p> 	<ul style="list-style-type: none"> • Nitrile • ASTM D6978 • Final Release AQL: 1.5 • Non-Sterile • 12" extended cuff for extra protection • US FDA 510K cleared
<p>MICRO-TOUCH® MICRO-THIN™ Nitrile</p> 	<ul style="list-style-type: none"> • Nitrile • ASTM D6978 • Final Release AQL: 1.5 • Non-Sterile • MICRO-TOUCH® Micro-Thin Nitrile • 300 Box Count economical value • US FDA 510K cleared
<p>MICRO-TOUCH® NITRAFREE™</p> 	<ul style="list-style-type: none"> • Nitrile • ASTM D6978 • Final Release AQL: 1.5 • Non-Sterile • Protects against Type I (latex) and Type IV (chemical) allergies • US FDA 510K cleared
<p>MICRO-TOUCH® AFFINITY™</p> 	<ul style="list-style-type: none"> • Neoprene • ASTM D6978 • Final Release AQL: 1.5 • Non-Sterile • High chemical resistance • US FDA 510K cleared
<p>MICRO-TOUCH® Central Supply – SPD Plus ULNCS</p> 	<ul style="list-style-type: none"> • Nitrile • ASTM D6978 • Final Release AQL: 1.5 • Non-Sterile • Powder-Free • 16"/400mm-long for extended protection to the elbow • US FDA 510K cleared
<p>MICRO-TOUCH® NITRAFREE™ Blue</p> 	<ul style="list-style-type: none"> • Nitrile • ASTM D6978 • Final Release AQL: 1.5 • Non-Sterile • Protects against Type I (latex) and Type IV (chemical) allergies • Powder-Free • US FDA 510K cleared

CLEANROOM SOLUTIONS FOR PREPARATION AND PHARMACEUTICAL COMPOUNDING

Recommended for cleanroom preparation and sterilization

CLEANROOM GLOVES	KEY PRODUCTS AND SPECIFICATIONS
 <p>BioClean™ BNPS</p>	<ul style="list-style-type: none"> • 16" Hand specific sterile nitrile • Tested against permeation standard ASTM D6978 for cytotoxic drugs
GOGGLES	KEY PRODUCTS AND SPECIFICATIONS
 <p>BioClean™ BCAP</p>	<ul style="list-style-type: none"> • Autoclavable extra wide lens goggles • Indirect ventilation system • Toughened polycarbonate, anti-scratch & anti-fog lens
FACEMASKS	KEY PRODUCTS AND SPECIFICATIONS
 <p>BioClean™ BDBS</p>	<ul style="list-style-type: none"> • Sterile pouch-style facemask • High bacterial, particle & viral filtration efficiency • Large breathing chamber • Ultrasonically sealed edges
GARMENTS	KEY PRODUCTS AND SPECIFICATIONS
 <p>BioClean™ S-BDSH</p>	<ul style="list-style-type: none"> • 100% aseptic donning procedure • Tested against permeation standard ASTM D6978-05 for cytotoxic drugs, using method ASTM F739-12 <p>Note: To be worn underneath chemo protection apron, not to be worn as a single layer when handling chemo drugs.</p>
APRONS	KEY PRODUCTS AND SPECIFICATIONS
 <p>BioClean™ S-BCAS</p>	<ul style="list-style-type: none"> • Tested against permeation standard ASTM D6978-05 for cytotoxic drugs, using method ASTM F739-12 • Ultrasonically bonded sleeve seams with protective tape
SLEEVES	KEY PRODUCTS AND SPECIFICATIONS
 <p>BioClean™ S-BCSC</p>	<ul style="list-style-type: none"> • Chemotherapy Sterile protective sleeve cover • Ultrasonically bonded seams • Tested against permeation standard ASTM D6978-05 for cytotoxic drugs, using method ASTM F739-12

Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of gloves/gowns/garments/goggles/facemasks/accessories for a specific application. Please see product validation pack for specific data on use of products with cytotoxic drugs. Products used for protection against such drugs must be selected specifically for the type of chemicals used.

➔ For more information on these or any other Ansell safety solutions, please contact your Ansell representative at customersolutionsus@ansell.com or 1-855-868-5540

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