

## **Fusion S-BFAP**

Sterile Disposable Neoprene (Polychloroprene Cleanroom Glove)

# Sterile polychloroprene cleanroom gloves, combining tactility and comfort

- Assured comfort and tactility: Easy to don and doff and ideal for double gloving, BioClean™ Fusion (Sterile) S-BFAP neoprene gloves' optimal thickness levels maintain comfort and tactility with prolonged use
- Allergy protection: As these powderfree disposable gloves are made from latex-free polymers, they eliminate Type I latex allergy risks
- Enhanced cuff design: Their beaded, extended-length cuff design combines a secure fit with additional arm coverage, boosting hand and wrist protection
- Minimized contamination risks: They come in non-particulating EasyTear packaging, reducing contamination risks in the cleanroom environment
- CAUTION: Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations

#### **KEY FEATURES & BENEFITS**

- Optimal thickness: Assured comfort and tactile sensitivity
- Latex-free neoprene formulation: Type I allergy risks eliminated
- Extended beaded cuff design: Enhanced hand protection

#### **Industries**

- Controlled and Critical Environments
- Production and Manufacturing
- Lab and R&D
- Sterile Processing Department





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#### **TECHNICAL DATA SHEET**

Material Neoprene (Polychloroprene)  Color Green  Shape Ambidextrous  Beaded  Manufacturing/QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms  Regulatory/Standard Compliance  Cuff Standards CE 0493, EN ISO 21420:2020, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Category III, UKCA  One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)
Color Shape Ambidextrous  Beaded  Manufacturing/QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms  Regulatory/Standard Compliance  CE 0493, EN ISO 21420:2020, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Category III, UKCA  One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed
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Cuff Manufacturing/QMS Audit Standards  Regulatory/Standard Compliance  Ce 0493, EN ISO 21420:2020, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Category III, UKCA  One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed
Manufacturing/QMS Audit Standards  Regulatory/Standard Compliance  ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms  CE 0493, EN ISO 21420:2020, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Category III, UKCA  One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed
Standards  Regulatory/Standard Compliance  NEBB Certified Cleanrooms  CE 0493, EN ISO 21420:2020, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 455 Part 2, Category III, UKCA  One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed
Compliance 2, Category III, UKCA  One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed
Packaging  More sustainable packaging: These sterile gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases.  *Inner wrap, pouch, bag and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.
Storage Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.
Country of Origin Indonesia
Available sizes XS (5.5 - 6), S (6.5 - 7), M (7.5 - 8), L (8.5 - 9), XL (9.5 - 10), 2XL (10.5-11)
Powder Content Powder-Free
External Glove Surface Textured Fingers
Internal Glove Surface Polymer Coated
Sterilization Method GAMMA irradiation (25 kGy)
Sterilization Minimum Dose 25kGy
Sterility Assurance Level 10-6
Cleanroom Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
Shelf Life Five (5) years from date of manufacture.
Tested for use with Chemotherapy Drugs
Protein Level N/A: contains no natural rubber latex
Anti-static Yes





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Physical Properties							Testing Method
Sizes	XS (5.5 - 6)	S (6.5 - 7)	M (7.5 - 8)	L (8.5 - 9)	XL (9.5 - 10)	2XL (10.5-11)	
Typical Length (mm/in)			EN 420				
Palm Width (mm/in)	76/3	86/3.4	95/3.7	106/4.2	115/4.5	120/4.7	
Freedom from Holes	1.5 AQL						EN 374-2
Typical Particle Count ≥0.5µm (counts / cm²)	850						IEST-RP-CC005.4
Target Single Wall Palm Thickness (mm/mil)	0.10 / 3.94						EN 455-2
Target Single Wall Finger Thickness (mm/mil)	0.12 / 4.72						EN 455-2
Target Single Wall Cuff Thickness (mm/mil)	0.07/2.76						EN 455-2
Ultimate tensile strength (MPa) During Aging	Min. 14						ASTM D412-06a
Force at Break (N) During Aging	≥6 N						EN 455-2

#### **IONIC CONTENT**

Concentration in µg/cm²	Typical	Concentration in µg/cm²	Typical	
Ammonium	0.003	Nitrate	0.884	
Bromide	Not Detected	Nitrite	Not Detected	
Calcium	0.652	Phosphate	Not Detected	
Chloride	0.194	Potassium	0.315	
Fluoride	Not Detected	Sodium	0.099	
Lithium	Not Detected	Sulphate	0.025	
Magnesium	0.007	Zinc	Not Detected	

#### **ORDERING INFORMATION**

SIZE	XS (5.5 - 6)	S (6.5 - 7)	M (7.5 - 8)	L (8.5 - 9)	XL (9.5 - 10)	2XL (10.5-11)
REORDER NO.	S-BFAP-5055	S-BFAP-6065	S-BFAP-7075	S-BFAP-8085	S-BFAP-9090	S-BFAP-1010

#### PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE









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