



## Fusion S-BFAP

Sterile Polychloroprene Cleanroom  
Glove Compatible with Class 10 (ISO 4)  
Environments

NE

Neoprene

# Ultra-clean, tactile sterile polychloroprene cleanroom glove with proven chemical protection

BioClean Fusion Sterile Polychloroprene Cleanroom Gloves contain no natural latex proteins, are comfortable and thin to reduce wearer fatigue and increase tactility. The Fusion is double-donnable and features a beaded cuff for strength.

- Increased tactility
- Powder-free & latex-free
- Beaded cuff for strength
- Non-particulating EasyTear packaging



### Industries

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

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### TECHNICAL DATA SHEET

#### PRODUCT INFORMATION

Fusion S-BFAP	
Material	Neoprene (Polychloroprene)
Color	Green
Shape	Ambidextrous
Cuff	Beaded
Manufacturing/QMS Audit Standards	Manufacturing QMS Audit Standards ISO 9001 PPE Regulation 2016 425 Module D
Regulatory/Standards Compliance	CE 0598, EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 420:2003 + A1:2009, EN 455 Part 2, Food Contact, ISO 9001:2015, Category III
Packaging	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)
Storage	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition
Country of Origin	Malaysia
Available sizes	5-5.5, 6-6.5, 7-7.5, 8-8.5, 9.0, 10
Powder Content	Powder-Free
External Glove Surface	Textured Fingers
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 <sup>-6</sup>
Cleanroom Compatibility	ISO Class 4 & EU GMP Grade A
Shelf Life	Five (5) years from date of manufacture.
Tested for use with Chemotherapy Drugs	Yes
Protein Level	50 µg/g or less of total extractable protein



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## PHYSICAL PROPERTIES

	Typical Values						Testing Method
	5-5.5	6-6.5	7-7.5	8-8.5	9	10	
Length (mm/in)	300 / 12						EN420
Palm Width	76/3	86/3.4	95/3.7	106/4.2	115/4.5	120/4.7	
Freedom from Holes	0.65 AQL Performance Level 3						EN 374-2
Typical Particle Count > 0.5µm (counts / cm <sup>2</sup> )	850						TEST-RP-CC005.4
Minimum Single Wall Palm Thickness (mm/mil)	0.10 / 3.94						EN455-2
Minimum Single Wall Finger Thickness (mm/mil)	0.12 / 4.72						EN 455-2
Minimum Single Wall Cuff Thickness (mm/mil)	0.07/2.76						EN 455-2
During Ageing							
Force at Break (N)	≥ 9 N						EN 455-2

## IONIC CONTENT

Concentration in µg/cm <sup>2</sup>	Typical	Upper	Concentration in µg/cm <sup>2</sup>	Typical	Upper
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	5-5.5	6-6.5	7-7.5	8-8.5	9	10
Fusion S-BFAP	REORDER NO.	S-BFAP-5055	S-BFAP-6065	S-BFAP-7075	S-BFAP-8085	S-BFAP-9090	S-BFAP-1010

For additional information visit us at [www.ansell.com](http://www.ansell.com), or call us at

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## Performance Standards and Regulatory Compliance



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