



## 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 powder-free 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

|                                        | Product Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Material                               | Neoprene (Polychloroprene)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Color                                  | Green                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Shape                                  | Ambidextrous                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Cuff                                   | Beaded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Manufacturing/QMS Audit Standards      | ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms                                                                                                                                                                                                                                                                                                                                                                                                               |
| Regulatory                             | 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                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 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)<br><br><b>More sustainable packaging:</b> These sterile gloves are packed in recyclable plastic packaging* and delivered in recycled cardboard shipper cases.<br>*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 (5-5.5), S (6-6.5), M (7-7.5), L (8-8.5), XL (9), XXL (10)                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 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 <sup>-6</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Cleanroom Class                        | 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 | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Protein Level                          | N/A: contains no natural rubber latex                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Anti-static                            | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |



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| Physical Properties                                |                              |           |           |           |         |          | Testing Method  |
|----------------------------------------------------|------------------------------|-----------|-----------|-----------|---------|----------|-----------------|
| Sizes                                              | XS (5-5.5)                   | S (6-6.5) | M (7-7.5) | L (8-8.5) | XL (9)  | XXL (10) | EN 420          |
| Typical Length (mm/in)                             | 300 / 12                     |           |           |           |         |          |                 |
| Palm Width (mm/in)                                 | 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<br>≥0.5µm (counts / cm²)    | 850                          |           |           |           |         |          | IENT-RP-CC005.4 |
| Target Single Wall Palm<br>Thickness (mm/mil)      | 0.10 / 3.94                  |           |           |           |         |          | EN 455-2        |
| Target Single Wall<br>Finger Thickness<br>(mm/mil) | 0.12 / 4.72                  |           |           |           |         |          | EN 455-2        |
| Target Single Wall Cuff<br>Thickness (mm/mil)      | 0.07/2.76                    |           |           |           |         |          | EN 455-2        |
| Ultimate tensile strength<br>(MPa) During Aging    | Min. 14                      |           |           |           |         |          | ASTM D412-06a   |
| Force at Break (N)<br>During Aging                 | ≥ 6 N                        |           |           |           |         |          | EN 455-2        |

## IONIC CONTENT

| Concentration in µg/cm <sup>2</sup> | Typical      | Concentration in µg/cm <sup>2</sup> | 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 (5-5.5)  | S (6-6.5)   | M (7-7.5)   | L (8-8.5)   | XL (9)      | XXL (10)    |
|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| 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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