



# BioClean-D™ Coverall with Hood - Sterile S-BDCHT

## Lightweight, sterile antistatic coverall with hood, for protection from varied chemicals

- **Reduced contamination risks:** The BioClean-D Coverall with Hood - Sterile S-BDCHT features a front zip with a sealable cover and a protective flap to reduce leakage through the seams, and is manufactured in compliance with ISO cleanroom standards
- **Specialized protection:** This disposable coverall is manufactured using Ansell's innovative CleanTough™ material to deliver a low-linting, antistatic, sterile coverall that protects against a range of chemicals\*
- **Enhanced fit:** This BioClean™ coverall is also equipped with an elasticated hood, back, cuffs and ankles, as well as thumb loops to ensure a secure hold and enhanced fit



*\*Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations.*

### Key Features and Benefits

- **Protective flap and zip with sealable cover:** Fewer contamination risks
- **CleanTough™ fabric:** For a lightweight, low-linting disposable coverall
- **Thumb loops:** Secure hold and improved fit

### Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Pharmaceutical Manufacturing
- Biotechnology Manufacturing
- Medical Device Manufacturing





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## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

|                                   |  |
|-----------------------------------|--|
| <b>Material</b>                   | CleanTough™  |
| <b>Audit Standards</b>            | ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms   |
| <b>Standards</b>                  | ASTM F739, CE 0598, EN ISO 13688:2013, EN 1149-5:2018, EN 13934-1, EN 13935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 14325, ISO 11137-1:2006, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009                     |
| <b>Packaging Overview</b>         | One piece aseptically folded per sealed inner PE bag; one inner bag per sealed outer PE bag; 20 outer bags per lined carton (20 pieces). Please note: Size 3XL and 4XL are 15 pieces per carton and subject to Minimum Order Quantity and lead time. |
| <b>Country Of Origin</b>          | China  |
| <b>Sterilization Method</b>       | GAMMA irradiation (25 kGy)   |
| <b>Sterilization Minimum Dose</b> | 25kGy  |
| <b>Sterility Assurance Level</b>  | 10 <sup>-6</sup>   |
| <b>Cleanroom Class</b>            | Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms   |
| <b>Shelf Life</b>                 | Three (3) years from date of manufacture.  |
| <b>Construction</b>               | Bound seams with single needle stitching   |
| <b>Characteristics</b>            | *NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, and so are ideal for use in a static-safe environment.   |

### PARTICLE SHEDDING TEST RESULTS

| TEST                                 | RESULT                     |
|--------------------------------------|----------------------------|
| Particle Shedding (Helmke Drum Test) | ≥ 0.5Qm (counts/min) <2000 |

### ASTM F739-12 TEST METHOD RESULTS

| DRUG                     | Mean Breakthrough Time (MBT), Minutes<br>Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 Qg/cm <sup>2</sup> /min |
|--------------------------|--|
| CISPLATIN                | >240   |
| CARMUSTINE               | <6   |
| CYCLOPHOSAMIDE           | 217 (275,162,215)  |
| DOXORUBICINHYDROCHLORIDE | >240   |
| 5-FLUOROURACIL           | >240   |
| METHOTREXATE             | >240   |
| ETOPOSIDE                | >240   |
| PACLITAXEL               | <10  |
| THIOTEPA                 | 30 (28,30,33)  |

Results achieved under controlled laboratory conditions, by accredited external testing laboratory.

### SIZE CHART

S-BDCHT-XS; Size: XS, Chest: 76-84cm (30"-33"), Height: 158-164cm (5'2"-5'4")  
 S-BDCHT-S; Size: S, Chest: 84-92cm (33"-36"), Height: 164-170cm (5'4"-5'6")  
 S-BDCHT-M; Size: M, Chest: 92-100cm (36"-39"), Height: 170-176cm (5'6"-5'9")  
 S-BDCHT-L; Size: L, Chest: 100-108cm (39"-42"), Height: 176-182cm (5'9"-6'0")  
 S-BDCHT-XL; Size: XL, Chest: 108-116cm (42"-45"), Height: 182-188cm (6'0"-6'2")  
 S-BDCHT-2XL; Size: 2XL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")  
 S-BDCHT-3XL; Size: 3XL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")  
 S-BDCHT-4XL; Size: 4XL, Chest: 132-140cm (51"-54"), Height: 200-206cm (6'6"-6'8")



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## MATERIAL PERFORMANCE TEST RESULTS

| TEST   | RESULT                 | PERFORMANCE CLASS |
|--|------------------------|-------------------|
| Abrasion Resistance  | 10 to 100 cycles       | 1                 |
| Flex Cracking Resistance                                     | 5,000 to 15,000 cycles | 3                 |
| Puncture Resistance  | 8 N                    | 1                 |
| Trapezoidal Tear Resistance Cross Direction (CD)             | CD 29.3 N              | 2                 |
| Trapezoidal Tear Resistance Machine Direction (MD)           | MD 55.5 N              | 3                 |
| Tensile Strength Cross Direction (CD)                        | CD 48 N                | 1                 |
| Tensile Strength Machine Direction (MD)                      | MD 97 N                | 2                 |
| Repellence to Liquids - 30% H <sub>2</sub> SO <sub>4</sub>   | 96.3%                  | 3                 |
| Repellence to Liquids - 10% NaOH                             | 97.6%                  | 3                 |
| Repellence to Liquids - O-Xylene                             | 95.7%                  | 2                 |
| Repellence to Liquids - Butan-1-ol                           | 96.6%                  | 3                 |
| Penetration by Liquids - 30% H <sub>2</sub> SO <sub>4</sub>  | 0%                     | 3                 |
| Penetration by Liquids - 10% NaOH                            | 0%                     | 3                 |
| Penetration by Liquids - O-Xylene                            | 0%                     | 3                 |
| Penetration by Liquids - Butan-1-ol                          | 0%                     | 3                 |
| Inward leakage of aerosols of fine particles <sup>1</sup>    | Pass                   | N/A               |
| Resistance to penetration by spray (Spray Test) <sup>1</sup> | Pass                   | N/A               |
| Seam Strength <sup>2</sup>                                   | 70 N                   | 2                 |
| Electrostatic Charge Half Decay Time, t <sub>50</sub> (secs) | 0.07                   | PASS              |

1. All interfaces with additional PPE were taped during testing, as required by the standards.

2. Seam not destroyed

## ORDERING INFORMATION

|         | SIZE        | XS, S, M, L, XL, XXL   | XXXL, XXXXL                 |
|---------|-------------|--|-----------------------------|
| S-BDCHT | REORDER NO. | S-BDCHT-XS, S-BDCHT-S, S-BDCHT-M, S-BDCHT-L, S-BDCHT-XL, S-BDCHT-XXL | S-BDCHT-XXXL, S-BDCHT-XXXXL |

### Performance Standards and Regulatory Compliance



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Please see product validation pack or contact Ansell customer service for specific data on use of garments with cytotoxic drugs. Garments used for protection against such drugs must be selected specifically for the type of chemicals used.

