usp<797> usp<800> Product Guide



usp<797> and usp<800> Facts and Product Selection Guide



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Fast Facts:

WIPING:

Floors, walls, ceilings, shelving, hard surfaces, contaminated gloves, and supplies removed from shipping cartons are to be wiped with 70% Sterile Isopropyl Alcohol.

GLOVES:

- Only use gloves labeled as ASTM-tested chemotherapy gloves.
- Use powder-free gloves
- Avoid gloves with defects, pin-holes or weak spots.
- Wear two pairs of ASTM-tested gloves when compounding, administering, managing a spill, and disposing of Hazardous Drugs. For sterile preparations, only the outer glove needs to be sterile. Wear the inner glove under the gown cuff and the outer glove over the cuff. Place gloves with long cuffs over the cuff of the gown to protect the wrist and forearm.

APPAREL

- Wear disposable gowns that have been tested to resist permeability by HDs and will protect the individual from contact of any HD's.
- Wear garments that cover the head, sleeves, and shoes.
- Eye and face protection shall be worn when handling HD's outside an engineering control.

| | Minimum Apparel Recommendations by Cleanroom Class | | | | | | |
|--------------------------|--|-------------------------|------------------------|----------------------|---------------------|--|--|
| | ISO 8 (Class 100,00) | ISO 7 Class (10,000) | ISO 6 (Class 1,000) | ISO 5 (Class 100) | ISO 4 (Class 10) | | |
| Beard Cover Face Mask | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | | |
| Boots | | | \checkmark | \checkmark | \checkmark | | |
| Coverall | | | \checkmark | \checkmark | \checkmark | | |
| Gloves | | | | \checkmark | \checkmark | | |
| Hair Cover | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | | |
| Hood | | | | \checkmark | \checkmark | | |
| Frock | \checkmark | \checkmark | | | | | |

Cleanroom Classification Chart

| Class | FED STD 209E Equivalent | Maximum concentration limits (particles/m ³ of air) for particles equal to and larger than the sizes listed below | | | | | |
|-------|-------------------------------|---|------------|------------|------------|-----------|----------|
| | | 0.1 micron | 0.2 micron | 0.3 micron | 0.5 micron | 1 micron | 5 micron |
| ISO 1 | | 10 | 2 | | | | |
| ISO 2 | | 100 | 24 | 10 | 4 | | |
| ISO 3 | 1 | 1,000 | 237 | 102 | 35 | 8 | |
| ISO 4 | 10 | 10,000 | 2,370 | 1,020 | 352 | 83 | |
| ISO 5 | 100 | 100,000 | 23,700 | 10,200 | 3,520 | 832 | 29 |
| ISO 6 | 1,000 | 1,000,000 | 237,000 | 102,000 | 35,200 | 8,320 | 293 |
| ISO 7 | 10,000 | | | | 352,000 | 83,200 | 2,930 |
| ISO 8 | 100,000 | | | | 3,520,000 | 832,000 | 29,300 |
| ISO 9 | | | | | 35,200,000 | 8,320,000 | 293,000 |



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usp<797> usp<800> Sterile Wipes

Features & Benefits

- Validated to SAL (Sterility Assurance Level) of 10⁻⁶ in accordance with standards and recommended practices of the ANSI/AAMI/ISO 11137:2006 guidelines
- Cobalt-60 Gamma Irradiated
- Meets and exceeds <USP>797 and <USP>800 requirements for critical contamination control
- · Each package is identified with a lot number for traceability
- · Each case of material includes a Certificate of Sterility
- Available in Dry and Presaturated
- Materials include: Poly-cellulose, Polyester and Polypropylene

Presaturated Sterile Wipes - ISO Class 3-4

| Part Number | Product Description | Size | Saturation | Wipes/bag | Packaging |
|---------------|-----------------------|---------|------------|-----------|--------------|
| FS-ULT70-99CB | Sealed-edge polyester | 9" × 9" | 70% IPA | 30 | 10 bags/case |

Presaturated Sterile Wipes - ISO Class 5

| Part Number | Product Description | Size | Saturation | Wipes/bag | Packaging |
|------------------|----------------------|----------|------------|-----------|--------------|
| FS-NTP-911-35CB | Polypropylene | 9" x 11" | 70% IPA | 35 | 20 bags/case |
| FS-NT1-912CB | Polyester /Cellulose | 9" x 12" | 70% IPA | 35 | 20 bags/case |
| FS-NT203-99.40CB | 100% Polyester | 9" x 9" | 70% IPA | 40 | 24 bags/case |

Dry Sterile Wipes - ISO Class 5

| Part Number | Product Description | Size | Wipes/bag | Packaging |
|-------------|----------------------|-----------|-----------|--|
| NT10-99CB | Polyester/ Cellulose | 9" x 9" | 25 | 6 Bags/Master Bag 10 Master Bags/Case |
| NT10-1212CB | Polyester/ Cellulose | 12" x 12" | 20 | 6 Bags/Master Bag 7 Master Bags/Case |

Also Available: Non-Sterile Dry and Presaturatured Wipes



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usp<797> usp<800> Protective Apparel

Shoe & Boot Covers

| Product Name | ltem | Description | Sizes | Color | Packaging |
|---|---------------------|--|------------|-----------|-------------------|
| Non-Skid Shoe Covers | | Polypropylene material with non- skid base | L, XL, 2XL | Blue | 300/Case |
| Super Non-Slip Shoe Covers (water-resistant) | GAH-SC-S- (SIZE) | Polyethylene, non-woven material with sticky outer coating | L, XL | | 300 PCS / CASE |
| Boot Covers | GAH-BC-(SIZE) | Polypropylene material with PVC sole and CPE & PPE outer coating | XL | : \//hita | 100 PCS / CASE |

Bouffant Caps & Hoods

| Product Name Item | | Description | Sizes | Color | Packaging |
|-------------------------|----------------------|--|----------|----------------|------------------------------|
| Polypropylene Bouffants | | Lightweight, breathable polypropyl- ene material; latex-free | | Blue, White | 100/Bag, 10 Bags/ Case |
| Pleated Bouffants | GAH-BP-(SIZE)-WH-P | Pleated; lightweight, breathable polypropylene material; latex-free | 21", 24" | | 100/Bag, 10 Bags/ Case |
| 8000 | GAH-HOOD-(BL/ WH) | Complete head coverage; light- weight, breathable polypropylene material; latex-free | XL | Blue, White | 100/Bag, 10 Bags/ Case |

Face Masks & Beard Covers

| Product | Product Item Description | | Color | Packaging |
|----------------------------------|---|--|-------|------------------------------|
| Class 10-100 Face Mask | FM-PUE.18 (Earloop) FM-PUH.18 (Headloop) | 3-Ply face mask with polyurethane ear or head loop, cleanroom packaged | White | 50/Bag, 20 Bags/Case |
| Class 1,000-10,000 Face Masks | FM-OPE.18 (Earloop) FM-OPH.18 (Headloop) | 3-Ply face mask with flat OP ear or head loop, cleanroom packaged | White | 50/Bag, 20 Bags/Case |
| Beard Covers | | Lightweight, breathable polypropylene material; latex-free | | 100/Bag, 10 Bags/ Case |



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Contamination Control

Tacky Floor Mats & Frames White, Blue, or Grey Multiple sizes available Cleanroom Gloves Sterile Chemo-Rated and Non-Sterile Available GRAB - EEL

GRAB-EEZ Cleanroom Wipe Dispenser



Custom Logo Tacky Floor Mat Frames Your logo or custom graphic!



Tacky Roller Mops Available in Foam or Film Multiple sizes available



Cleanroom Mops



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