

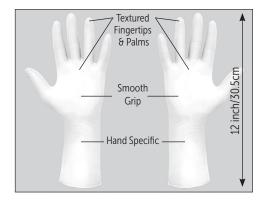
HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves For the Critical Cleanroom Environment

For Industrial Use Only

TECHNICAL DATA SHEET

Description

HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Cleanroom Gloves are designed for critical cleanroom environments such as pharmaceutical and biotechnology cleanroom manufacturing as well as sterile compounding cleanroom applications. These hand specific gloves are clean processed (washed repeatedly in deionized water) to ensure consistent control of low particles, extractables and endotoxin levels, and are recommended for use in ISO Class 3 or higher and Grade A/B/C/D cleanrooms. Because HALYARD* **PURE**ZERO* HG3 Sterile Cleanroom Gloves are made with an **accelerator-free**¹ nitrile polymer, there is a reduced risk of allergies and skin irritation associated with accelerator chemicals in other nitrile gloves.



Cleanliness Properties

| Max Particle Count | >0.5µm / cm ² <950 | IEST RP-CC005 |
|-------------------------------------|-------------------------------|---------------|
| Max Endotoxin Level | <20 EU | |
| Ionic Content (Extractable ions) | Max Level (ug/g) | IEST RP-CC005 |
| Calcium | 50 | |
| Chloride | 35 | |
| Magnesium | 5 | |
| Nitrate | 20 | |
| Potassium | 5 | |
| Sodium | 10 | |
| Sulfate | 10 | |
| Zinc | 25 | |
| Ammonium | 5 | |
| | | |
| | | |

| Physical Properties | |
|----------------------------------------|-----------------|
| AQL | 1.0 |
| Sterile | ✓ |
| Hand Specific Pairs | ✓ |
| Smooth Grip | \checkmark |
| Textured Fingertips and Palms | ✓ |
| Accelerator-Free ¹ | \checkmark |
| Low Dermatitis Potential | ✓ |
| Latex-Free | \checkmark |
| Powder-Free | ✓ |
| Silicone-Free | \checkmark |
| Static Dissipative in Use ² | ✓ |
| Tensile Strength ³ | 20 MPa (Target) |
| Ultimate Elongation ³ | 600% |
| Sterility Assurance Level (SAL) | 10-6 |
| Shelf Life | 5 Years |
| | |

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Glove Dimensions

| | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 10.0 |
|---------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| Glove Length (inch/cm) | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 |
| Width of Palm (mm) | 80 | 87 | 94 | 98 | 109 | 114 | 120 | 128 |
| Middle finger length (mm) | 70.8 | 72.4 | 80.6 | 83.9 | 86.0 | 90.1 | 92.7 | 96.2 |
| Finger Tip Thickness | 0.16 mm (6 mil) |
| Palm Thickness | 0.13 mm (5 mil) |
| Cuff Thickness | 0.10 mm (4 mil) |

Packaging Data

Triple layer packaging (poly pouch and poly bag plus case liner)

200 hand specific pairs per case: 2 gloves/poly wallet & pouch x 20 sealed pouches per bag x 10 PE bags per lined carton

Packaged in ISO Class 5 Cleanroom

Quality & Regulatory Standards

Compliant to these regulatory standards: ISO 9001 ISO 13485 Compliant to these food handling regulatory standards: FDA 21 CFR 177-2600 Commission Regulation (EU) No 10/2011 Japan Food Sanitation Act FDA 21 CFR part 820 accreditation CE 2797 PPE Category III according to Regulation (EU) 2016/425 EEC EN ISO 374-5:2016 Virus Protection EN ISO 374-1:2016/Type C K-Low Chemical Protection EN 420:2003 +A1:2009 Compliant with the REACH regulation Static Dissipative in Use Tested per ANSI/ ESD SP 15.1

Tested against EN 1149: Protective Clothing - Electrostatic Properties



Additional Glove Information

Recommended for use in ISO Class 3 or higher and Grade A/B/C/D cleanrooms.

Made in Thailand

Declaration of Conformity (DoC) and Certificates of Analysis (COA) and Certificates of Irradiation (COI) for every production lot available on-line at **halyardhealth.com/information**

Manufactured in our Safeskin Medical & Scientific (Thailand) Ltd. location

Ordering Information

HALYARD* PUREZERO* HG3 WHITE STERILE NITRILE GLOVES, HAND SPECIFIC, SMOOTH GRIP, TEXTURED FINGERTIPS AND PALMS

| Size | Code | Size | Code |
|------|-----------|------|-----------|
| 6.0 | CLN323260 | 8.0 | CLN323280 |
| 6.5 | CLN323265 | 8.5 | CLN323285 |
| 7.0 | CLN323270 | 9.0 | CLN323290 |
| 7.5 | CLN323275 | 10.0 | CLN323210 |

For additional information or samples, contact your local distributor or visit www.purezerogloves.com

1 Not formulated with these commonly used vulcanizing chemicals: Sulfur, Thiurams, Thiaxoles, Guanidines and Carbamates.

2 Tested against ANSI SP 15.1 and EN 1149 (Protective Clothing - electrostatic properties)

3 Tested per ASTM D6319, EN 455-2

This fact sheet has been created using the most recent information. In the interest of continuous improvement, the characteristics of the products may change without prior notice.

