

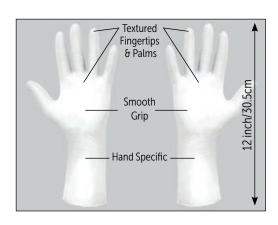
HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves

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 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.



Manufactured at OUR OWN Safeskin Facility in Thailand.

Clean	liness	Pro	perties
-100			

Max Particle Count (>0.5 µm)	<950 Particles/cm ²	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	7	
Ammonium	5	

Physical Properties

AQL	0.65
Sterile	✓
Hand Specific Pairs	✓
Smooth Grip	✓
Textured Fingertips and Palms	✓
Accelerator-Free ¹	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Static Dissipative in Use	✓
Tensile Strength ²	35 MPa (Target)
Ultimate Elongation ²	600%
Sterility Assurance Level (SAL)	10-6
Shelf Life	3 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 (6.3 mil)							
Palm Thickness	0.13 mm (5.1 mil)							
Cuff Thickness	0.10 mm (3.9 mil)							

Packaging Data

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

200 hand specific pairs per case: 2 gloves/poly wallet ϑ 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

ISO 14001

Compliant to these food handling regulatory standards:

FDA 21 CFR 177-2600

FDA 21 CFR 180.22

Commission Regulation (EU) No 10/2011

CE 2797 PPE Category III according to Regulation (EU) 2016/425 EEC

EN 16523-1:2015+A1:2018

EN ISO 374-2:2019

EN ISO 374-4:2019

EN ISO 374-5:2016 Bacteria, Fungi, and Virus Protection

EN ISO 374-1:2016+A1:2018/ Type B

EN ISO 21420:2020 Dexterity Classification: Level 5

Compliant with the REACH regulation

RoHS 2011/65/EU Annex II

Static Dissipative in Use

Tested per ANSI/ ESD SP 15.1

Meets USP <800> Guidelines

C € 2797







 ${\bf 1} \ Not formulated with these commonly used vulcanizing chemicals: Sulfur, Thiurams, Thiaxoles, Guanidines and Carbamates.$

2 Tested per ASTM D412

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.

Additional Glove Information

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

Tested against 29 chemicals, 14 chemotherapy drugs and Fentanyl.

Made in Thailand

Declaration of Conformity (DoC), Certificates of Analysis (COA) and Certificates of Processing (COP) for every production lot available online at **halyardhealth.com/information**

Storage Instructions

HALYARD* **PURE**ZERO* Nitrile Gloves shall be stored in conditions where the product is kept dry (away from moisture), away from direct sunlight, away from sources of heat, and away from radioactive sources.

Distributor Information



Size	Code		Size	Code
6.0	602-4189	_	8.0	602-4193
6.5	602-4190		8.5	602-4194
7.0	602-4191		9.0	602-4195
7.5	602-4192		10.0	602-4196

For more information

www.integritycleanroom.co.uk

Official Distributor for Halyard Health

