Nitril-Handschuhe PUREZERO HG3 (blue)

pure11-Nr.: 05210, Hersteller: HALYARD

STERIL ZYTO

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105210
- Material: Nitril
- Handspezifisch
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Texturierte Fingerspitzen
- Gammasterilisiert
- Ausgezeichnetes Fingerspitzengefühl und hohe Tastempfindlichkeit
- Sicherer Halt durch gute Griffigkeit
- Vulkanisationsbeschleunigerfrei
- Mehrfach in deionisiertem Wasser gewaschen
- Beständig gegen eine Vielzahl von Zytostatika
- Statisch dissipatives Verhalten im Gebrauch, getestet nach EN 1149
- Gut geeignet zum Double-Gloving

Empfohlene Reinraumklassen

ISO	3	4	5	6	7	8	9
GMP			A/B		C	D	

Produktvarianten

pure11-Nr.: 052106

Farbe: Hellblau / Größe: 6,0 / Herst.-Nr.: CLN923260 / VE: 300 Paar

pure11 GmbH
Bavariafilmplatz 7 | D-82031 Grünwald
Geschäftsführer: Gitte Hansen, Julian Kropp
AG München HRB 171307

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pure11-Nr.: 052106b
Farbe: Hellblau / Größe: 6,5 / Herst.-Nr.: CLN923265 / VE: 300 Paar

pure11-Nr.: 052107
Farbe: Hellblau / Größe: 7,0 / Herst.-Nr.: CLN923270 / VE: 300 Paar

pure11-Nr.: 052107b
Farbe: Hellblau / Größe: 7,5 / Herst.-Nr.: CLN923275 / VE: 300 Paar

pure11-Nr.: 052108
Farbe: Hellblau / Größe: 8,0 / Herst.-Nr.: CLN923280 / VE: 300 Paar

pure11-Nr.: 052108b
Farbe: Hellblau / Größe: 8,5 / Herst.-Nr.: CLN923285 / VE: 300 Paar

pure11-Nr.: 052109
Farbe: Hellblau / Größe: 9,0 / Herst.-Nr.: CLN923290 / VE: 300 Paar

pure11-Nr.: 0521010
Farbe: Hellblau / Größe: 10,0 / Herst.-Nr.: CLN923210 / VE: 300 Paar

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HALYARD

Sterile HALYARD* **PURE**ZERO* HG3 Nitrilhandschuhe, hellblau,

für die kritische Reinraumumgebung,
nur zur industriellen Verwendung

TECHNISCHES DATENBLATT

Beschreibung

Die sterilen hellblauen HALYARD* **PURE**ZERO* HG3 Reinraumhandschuhe aus Nitril dienen dem Gebrauch in kritischen Reinraumumgebungen, wie beispielsweise bei der Herstellung pharmazeutischer und biotechnologischer Erzeugnisse im Reinraum und beim sterilen Compounding. Diese handspezifischen Handschuhe werden einem Reinheitsverfahren unterzogen (mehrfach in deionisiertem Wasser gewaschen), um eine konsistente Kontrolle geringfügiger Partikel, extrahierbarer Substanzen und des Endotoxin-Niveaus zu gewährleisten und werden für den Gebrauch in Reinraumumgebungen der ISO-Klasse 3 oder darüber empfohlen. Da die sterilen HALYARD* **PURE**ZERO* HG3 Reinraumhandschuhe aus einem Nitrilpolymer **ohne Beschleunige**r gefertigt werden, besteht ein geringeres Allergie- und Hautirritationsrisiko als bei beschleunigerhaltigen Nitrilhandschuhen.

Maße der Handschuhe

	6,0	6,5	7,0	7,5	8,0	8,5	9,0	10,0
Handschuhlänge (cm):	30,5	30,5	30,5	30,5	30,5	30,5	30,5	30,5
Breite Handfläche (mm)	80	87	94	98	109	114	120	128
Länge Mittelfinger (cm)	7,32	7,69	8,12	8,53	8,73	9,17	9,37	9,78
Dicke Fingerspitze	0,10 mm	0,10 mm	0,10 mm	0,10 mm	0,10 mm	0,10 mm	0,10 mm	0,10 mm
Dicke Handfläche	0,08 mm	0,08 mm	0,08 mm	0,08 mm	0,08 mm	0,08 mm	0,08 mm	0,08 mm
Dicke Handschuhbund	0,07 mm	0,07 mm	0,07 mm	0,07 mm	0,07 mm	0,07 mm	0,07 mm	0,07 mm

Physikalische Eigenschaften

AQL	1,5
Steril	✓
Handspezifische Paare	✓
Glatte Oberflächenbeschaffenheit	✓
Texturierte Fingerspitzen	✓
Beschleunigerfrei	✓
Latexfrei	✓

Puderfrei	✓
Silikonfrei	✓
Reißfestigkeit*	20 MPa (Zielwert)
Maximale Dehnung*	600%
Sterilitätssicherheitsgrad (SAL)	10^{-6}
Haltbarkeit	3 Jahre

*Geprüft gemäß ASTM D6319, EN 455-2

HALYARD

Sterile HALYARD* **PURE**ZERO* HG3 Nitrilhandschuhe, hellblau,

für die kritische Reinraumumgebung,
nur zur industriellen Verwendung

TECHNISCHES DATENBLATT

Reinheit

Max. Partikelzahl	>0,5µm / cm^2 <1200	IEST RP-CC005
Max. Endotoxin-Niveau	<20 EU	
Ionengehalt (Extrahierbare Ionen)	Max. Gehalt (ug/g)	IEST RP-CC005
Calcium	50	
Chlorid	35	
Magnesium	5	
Nitrat	20	
Kalium	5	
Natrium	10	
Sulfat	10	
Zink	25	
Ammonium	5	

Verpackung

Dreischichtige Verpackung (Polyhülle und Polybeutel plus auskleidende Schutzhülle im Karton)

300 Paare pro Kiste: 1 Handschuhpaar/Polytasche & Hülle X 30 versiegelte Hüllen pro PE-Beutel x 10 PE-Beutel pro ausgekleidetem Karton

Im Reinraum der ISO-Klasse 5 verpackt

Qualitäts- und Regulierungsstandards

Entspricht diesen regulatorischen Normen:
- ISO 9001
- ISO 13485

Entspricht diesen regulatorischen Normen zum Umgang mit Lebensmitteln:
- FDA 21 CFR 177-2600
- Verordnung (EU) 10/2011 der Kommission
- Japanisches Lebensmittelhygienegesetz

Akkreditiert gemäß FDA 21 CFR Abschnitt 820

CE 2797 PSA-Kategorie III gemäß EU-Verordnung 2016/425 EWG
- EN ISO 374-5:2016 Virusschutz
- EN ISO 374-1:2016/Typ C K - Geringer Chemikalienschutz
- EN 420:2003 +A1:2009

CE 2797 (PPE Cat. III) ISO 374-5:2016 VIRUS ISO 374-1:2016/Type C K-Low Chemical

Weitere Informationen

Empfohlen für den Gebrauch in Reinräumen der ISO-Klasse 3 oder darüber

Hergestellt in Thailand

Konformitätserklärung und Analysenzertifikate sowie Bestrahlungszertifikate für jede Charge abrufbar unter: .halyardhealth.com/information

Hergestellt in unserer Produktionsstätte Safeskin Medical & Scientific (Thailand) Ltd.

Bestellinformation

Sterile HALYARD* PUREZERO* HG3 Nitrilhandschuhe, hellblau, handspezifisch, glatte Oberflächenbeschaffenheit

6,0	CLN923260
6,5	CLN923265
7,0	CLN923270
7,5	CLN923275
8,0	CLN923280
8,5	CLN923285
9,0	CLN923290
10,0	CLN923210

Weitere Informationen oder Muster erhalten Sie über Ihren lokalen Vertriebshändler oder unter **www.halyardhealth.de**

Dieses Datenblatt wurde auf Grundlage der aktuellsten Informationen erstellt. Im Interesse kontinuierlicher Verbesserungen können Produktmerkmale ohne vorherige Ankündigung geändert werden.

EU Type Examination Certificate

This is to certify that:

O&M Halyard Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate Number: CE 725273

In respect of:

Nitrile Protective Gloves for Personal Protection
Model: CLN 923280 (Sterile)

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

First Issued: 2020-11-06
Latest Issue: 2020-11-06

Effective Date: 2020-11-06
Expiry Date: 2025-11-06

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 725273

Product Specification

Range: HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK

Models:
CLN923260
CLN923265
CLN923270
CLN923275
CLN923280
CLN923285
CLN923290
CLN923210

Classification: Protective gloves for use against chemical and micro-organism hazards.

Description: A five fingered, hand specific, single use powder free, non-sterile, gamma irradiated glove with textured finger surface and beaded cuff. Gloves available coloured light blue.

PPE Category: Complex

Product sizes: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0

Applicable Standards: The following Harmonized European Standards:

EN 420:2003+A1:2009 Protective gloves. General requirements.

EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN 374-2:2019. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

EN 374-4:2019 Determination of resistance to degradation by chemicals.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks.

EN 16523-1:2015. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

ISO 16604:2004 Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by blood-borne pathogens.

First Issued: 2020-11-06
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Effective Date: 2020-11-06
Expiry Date: 2025-11-06

EU Type Examination Certificate

No. CE 725273

Product Specification

Performance

General requirements for gloves to EN 420:2003+A1:2009

Characteristic	Level
Dexterity	5

Terminology and performance requirements for micro-organism Risks EN ISO 374-5:2016

Characteristic	Level
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Resistance to chemical permeation to EN ISO 374-1:2016

Tested to the chemicals below to EN 16523-1:2015

Resistance to Degradation to chemical protection EN 374-4:2019

Tested to the chemicals below

Chemical	Permeation Level	Mean Degradation %
70% Isopropyl Alcohol	-	33.3
40% Sodium Hydroxide (K)	6	-69.1
50% Sulphuric Acid	6	-37.4
30% Hydrochloric Acid	6	39.2
1% Ethidium Bromide	6	-4.2

First Issued: 2020-11-06
Latest Issue: 2020-11-06

Effective Date: 2020-11-06
Expiry Date: 2025-11-06

EU Type Examination Certificate

No. CE 725273

Certificate Administration Details

Technical File Reference: No. 012-03 R01 Halyard Sterile Cleanroom Gloves

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
November 2020	First issue models: CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210.	2797:20:3154548

Note: The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE:

The validity of the Certificate is also dependent on the maintenance of the EC quality of production by monitoring system, Module C2, as referenced on BSI Certificate CE 708082.

First Issued: 2020-11-06
Latest Issue: 2020-11-06

Effective Date: 2020-11-06
Expiry Date: 2025-11-06

February 8th, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding the chemotherapy drugs tested on HALYARD* PUREZERO* HG3 Nitrile Gloves.

The results below reflect a comprehensive list of chemotherapy drugs tested on HALYARD* PUREZERO* HG3 Nitrile Gloves with indicated breakthrough time in accordance with ASTM D6978, *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*.

HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves (Sterile and Non-Sterile)

	Chemotherapy Drug and Concentration	Min. Breakthrough Time (Minutes)
1	Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
2	Cyclophosphamide (Cytoxan) (20.0 mg/ml)	No breakthrough up to 240 minutes
3	Dacarbazine (10.0 mg/ml)	No breakthrough up to 240 minutes
4	Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
5	Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
6	Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
7	Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
8	Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
9	Paclitaxel (6.0 mg/ml)	No breakthrough up to 240 minutes
10	Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
11	Carmustine (3.3 mg/ml)	Breakthrough detected at 87.9 minutes
12	ThioTEPA (10.0 mg.ml)	Breakthrough detected at 109.1 minutes

HALYARD* PUREZERO* HG3 White Nitrile Gloves (Sterile and Non-Sterile)

	Chemotherapy Drug and Concentration	Min. Breakthrough Time (Minutes)
1	Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
2	Cyclophosphamide (Cytoxan) (20.0 mg/ml)	No breakthrough up to 240 minutes
3	Dacarbazine (10.0 mg/ml)	No breakthrough up to 240 minutes
4	Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
5	Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
6	Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
7	Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
8	Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
9	Paclitaxel (6.0 mg/ml)	No breakthrough up to 240 minutes
10	Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
11	Carmustine (3.3 mg/ml)	Breakthrough detected at 99.0 minutes
12	ThioTEPA (10.0 mg.ml)	Breakthrough detected at 179.8 minutes

HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

	Chemotherapy Drug and Concentration	Min. Breakthrough Time (Minutes)
1	Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
2	Cyclophosphamide (Cytoxan) (20.0 mg/ml)	No breakthrough up to 240 minutes
3	Dacarbazine (10.0 mg/ml)	No breakthrough up to 240 minutes
4	Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
5	Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
6	Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
7	Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
8	Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
9	Paclitaxel (6.0 mg/ml)	No breakthrough up to 240 minutes
10	Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
11	Carmustine (3.3 mg/ml)	WARNING: Breakthrough detected at 18.1 minutes
12	ThioTEPA (10.0 mg.ml)	Breakthrough detected at 89.3 minutes

CAUTION: The testing conditions used are intended to approximate the worst-case conditions for clinical use. Testing was conducted on a single layer glove material. It is the user's responsibility to demonstrate the applicability of these gloves for their intended use with chemotherapy drugs.

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Associate Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

May 21st, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding isopropyl alcohol chemical permeation testing on HALYARD* PUREZERO* HG3 Sterile Nitrile Gloves.

The results below reflect the chemical permeation test results of HALYARD* PUREZERO* HG3 Sterile Nitrile Gloves against isopropyl alcohol (70%) with indicated breakthrough time in accordance with **EN 16523-1**, *Determination of Material Resistance to Permeation by Chemicals – Permeation by Liquid Chemicals under Conditions of Continuous Contact.*

Product Family	Product Codes	Chemical Tested	Min. Breakthrough Time (Minutes)
PUREZERO* HG3 Sterile Light Blue	CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210	Isopropyl Alcohol (70%)	194.0
PUREZERO* HG3 Sterile White	CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323285, CLN323290, CLN323210		185.0

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Associate Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

July 14th, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding EN 1149 testing on **HALYARD* PUREZERO* HG3 Nitrile Gloves.**

The data provided on the following pages reflect the test results of **HALYARD* PUREZERO* HG3 Nitrile Gloves** for electrostatic properties in accordance with **EN 1149-1:2006** *"Protective Clothing - Electrostatic Properties - Part 1: Test Method for Measurement of Surface Resistivity"* and **EN 1149-3:2004 (Method 2)** *"Protective Clothing - Electrostatic Properties - Part 3: Test Method for Measurement of Charge Decay".*

The tests were performed at Intertek Testing Services in the UK with a report issuance of 05.07.2021.

Description of the Tested Gloves:
SAMPLE A - HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves

SAMPLE B - HALYARD* PUREZERO* HG3 White Nitrile Gloves

SAMPLE C - HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves

SAMPLE D - HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

SAMPLE E - HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves

SAMPLE A - HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample A

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	1.1×10^{12}	2.2×10^{13}
Face	1.7×10^{12}	3.4×10^{13}
Face	1.9×10^{12}	3.8×10^{13}
Face	1.0×10^{12}	2.0×10^{13}
Face	1.4×10^{12}	2.8×10^{13}
Mean	1.4×10^{12}	2.7×10^{13}
Reverse	1.3×10^{12}	2.6×10^{13}
Reverse	1.9×10^{12}	3.8×10^{13}
Reverse	2.4×10^{12}	4.8×10^{13}
Reverse	2.1×10^{12}	4.2×10^{13}
Reverse	1.8×10^{12}	3.6×10^{13}
Mean	1.9×10^{12}	3.7×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	21.50
2	0.00	20.15
3	0.00	>30.00
Mean	0.00	≥23.88

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE B - HALYARD* PUREZERO* HG3 White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample B

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	5.3×10^{11}	1.0×10^{13}
Face	5.1×10^{11}	1.0×10^{13}
Face	5.9×10^{11}	1.2×10^{13}
Face	5.9×10^{11}	1.2×10^{13}
Face	6.4×10^{11}	1.3×10^{13}
Mean	5.7×10^{11}	1.1×10^{13}
Reverse	7.6×10^{11}	1.5×10^{13}
Reverse	7.4×10^{11}	1.5×10^{13}
Reverse	6.8×10^{11}	1.3×10^{13}
Reverse	6.4×10^{11}	1.3×10^{13}
Reverse	6.6×10^{11}	1.3×10^{13}
Mean	6.9×10^{11}	1.4×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.01	12.50
2	0.01	6.96
3	0.00	8.86
Mean	0.01	9.42

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE C - HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample C

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	2.4×10^{12}	4.8×10^{13}
Face	2.1×10^{12}	4.2×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	2.6×10^{12}	5.1×10^{13}
Face	2.5×10^{12}	5.0×10^{13}
Mean	2.3×10^{12}	4.5×10^{13}
Reverse	1.7×10^{12}	3.4×10^{13}
Reverse	2.1×10^{12}	4.2×10^{13}
Reverse	2.8×10^{12}	5.5×10^{13}
Reverse	2.0×10^{12}	4.0×10^{13}
Reverse	2.4×10^{12}	4.8×10^{13}
Mean	2.2×10^{12}	4.3×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	>30.00
2	0.00	>30.00
3	0.00	>30.00
Mean	0.00	>30.00

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE D - HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample D

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	1.2×10^{12}	2.4×10^{13}
Face	1.4×10^{12}	2.8×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	1.1×10^{12}	2.2×10^{13}
Mean	1.4×10^{12}	2.8×10^{13}
Reverse	1.0×10^{12}	2.0×10^{13}
Reverse	1.6×10^{12}	3.2×10^{13}
Reverse	1.1×10^{12}	2.2×10^{13}
Reverse	1.5×10^{12}	3.0×10^{13}
Reverse	1.9×10^{12}	3.8×10^{13}
Mean	1.4×10^{12}	2.7×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	9.37
2	0.00	7.85
3	0.00	13.05
Mean	0.00	10.09

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE E - HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample E

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	5.6×10^{11}	1.1×10^{13}
Face	5.0×10^{11}	9.9×10^{12}
Face	5.5×10^{11}	1.1×10^{13}
Face	5.3×10^{11}	1.0×10^{13}
Face	5.1×10^{11}	1.0×10^{13}
Mean	5.3×10^{11}	1.0×10^{13}
Reverse	7.0×10^{11}	1.4×10^{13}
Reverse	6.8×10^{11}	1.3×10^{13}
Reverse	6.7×10^{11}	1.3×10^{13}
Reverse	6.4×10^{11}	1.3×10^{13}
Reverse	7.2×10^{11}	1.4×10^{13}
Mean	6.8×10^{11}	1.3×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.02	6.09
2	0.01	5.57
3	0.00	7.74
Mean	0.00	6.47

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

1. IDENTIFICATION

Product Name: ***HALYARD* PUREZERO* HG3 Nitrile Gloves***

Product Number: Various

Date Prepared:	6/24/2021
Manufacturer:	O&M Halyard, Inc. 1 Edison Dr. Alpharetta, Georgia 30005
Telephone: MEDICAL EMERGENCY: TRANSPORTATION EMERGENCY: INFORMATION:	 Call 911 or your local Emergency Room or Poison Control Services Chemtrec 1-800-424-9300 or 1-703-527-3887 (collect calls accepted) 1-844-HALYARD

Product Use: Protective gloves.

2. HAZARDS IDENTIFICATION

GHS Classification: Not Hazardous. These products are manufactured articles or articles as this term is defined in the OSHA Hazard Communication Standard (20CFR 1910.1200), EU REACH, Canadian WHMIS, Australia WHS and the GHS. These products are out of the scope of the GHS and no SDS or labeling are required.

GHS Labeling: No GHS labeling required.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No./ EINECS-No	*%*	*GHS Classification:*
Non-Hazardous Ingredients	Mixture	100	Not Hazardous

4. FIRST AID MEASURES

Inhalation: No first aid needed.

Skin contact: No first aid needed. These products are intended to be used in contact with the skin.

Eye contact: No first aid needed.

Ingestion: Not a relevant route of exposure.

Most Important symptoms and effects, both acute and delayed: No adverse effects.

Indication of any immediate medical attention and special treatment needed: None required.

5. FIRE-FIGHTING MEASURES

Suitable (and unsuitable) Extinguishing Media: Use media suitable for surrounding materials.

Specific Hazards Arising from the Chemical: These products can melt in a fire. Molten material may flow or drip and spread the fire.

Hazardous Combustion Products: Combustion may produce toxic and irritating gases and vapors.

Special Protective Equipment and Precautions for Fire-fighters: None required.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: None required.

Environmental Precautions: None required.

Methods and Materials for Containment and Cleaning Up: No special precautions required. Pick up and dispose of in an appropriate container.

7. HANDLING AND STORAGE

Precautions for Safe Handling: No special handling is required.

Conditions for Safe Storage, including any Incompatibilities: Store away from heat and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)

Chemical Name	Exposure limit(s)
Non-Hazardous Ingredients	None established

Appropriate Engineering Controls: None required.

Individual Protection Measures, such as Personal Protective Equipment:

Respiratory Protection: None required.

Protective Gloves: None required.

Eye Protection: None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor	Solid Gloves, blue or white
Odor Threshold:	Not applicable
Boiling point/range	Not applicable
Melting point/range	Not determined
Relative Density (water=1)	Not determined
Vapor pressure	Not applicable
Vapor density (air=1)	Not applicable
Solubility	Insoluble
pH	Not applicable
Partition coefficient (n-octanol/water):	Not applicable
Evaporation Rate (Butyl acetate=1)	Not applicable
Viscosity:	Not applicable
Volatile Organic Carbon Compounds (VOC) (g/L)	Not applicable
Flashpoint:	None.
Flammable Limits in Air % by Volume:	LEL (Lower):Not applicable UEL (Upper): Not applicable
Autoignition temperature:	Not determined.
Decomposition temperature:	Not determined
Flammability (solid, gas):	Not a flammable solid

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.

Chemical Stability: Stable at ambient temperature and pressure.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: Avoid heat and flames.

Incompatible Materials: None known.

Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides and unidentified hydrocarbon fragments.

11. TOXICOLOGICAL INFORMATION

Symptoms/Effects of Overexposure: These gloves are manufactured articles. Their use will not result in exposure to any hazardous materials.

Inhalation: Not applicable.

Skin contact: None. Intended for skin contact. These products contain no natural latex.

Eye contact: None expected.

Ingestion: Not applicable.

Chronic toxicity: None expected.

Carcinogenicity Data: None of the components of this product is listed as a carcinogen by IARC, NTP, US OSHA or the EU CLP Annex VI.

Reproductive Toxicity: None known.

Numerical Measures of Toxicity:
Not acutely toxic.

12. ECOLOGICAL INFORMATION

Ecotoxicity: These gloves are manufactured articles. Their use will not result in adverse environmental effects.

Persistence and Degradability: Not degradable.

Bioaccumulative Potential: Not bioaccumulative.

Mobility in Soil: Not mobile.

Other Adverse Effects: None currently known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all state, local and federal regulations. If unused, the product may be disposed of as a non-hazardous material.

14. TRANSPORT INFORMATION

US DOT Shipping Description: Not regulated

IATA Shipping Description (Air): Not regulated

IMDG Shipping Description (Vessel): Not regulated

15. REGULATORY INFORMATION

US Regulations

EPA Toxic Substances Control Act (TSCA): These gloves are articles and exempt from the TSCA regulations.

SARA 302 Listed Chemicals: None.

SARA 311/312 Hazard Categories: Not applicable to articles

SARA 313 This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under the SARA Section 313 (40 CFR 372): Not applicable to articles.

16. OTHER INFORMATION

Date Prepared: 6/24/2021

HMIS Rating: Health 0 Fire 1 Physical Hazard 0

The information contained herein is true and correct to the best of O&M Halyard, Inc's knowledge. However, no warranty, expressed or implied, is made. Nothing herein should be interpreted as a recommendation to infringe existing patents or violate any laws or regulations. Final determination of the suitability of the material is the sole responsibility of the user.

February 8th, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding the chemotherapy drugs tested on HALYARD* PUREZERO* HG3 Nitrile Gloves.

The results below reflect a comprehensive list of chemotherapy drugs tested on HALYARD* PUREZERO* HG3 Nitrile Gloves with indicated breakthrough time in accordance with ASTM D6978, *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*.

HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves (Sterile and Non-Sterile)

	Chemotherapy Drug and Concentration	Min. Breakthrough Time (Minutes)
1	Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
2	Cyclophosphamide (Cytoxan) (20.0 mg/ml)	No breakthrough up to 240 minutes
3	Dacarbazine (10.0 mg/ml)	No breakthrough up to 240 minutes
4	Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
5	Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
6	Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
7	Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
8	Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
9	Paclitaxel (6.0 mg/ml)	No breakthrough up to 240 minutes
10	Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
11	Carmustine (3.3 mg/ml)	Breakthrough detected at 87.9 minutes
12	ThioTEPA (10.0 mg.ml)	Breakthrough detected at 109.1 minutes

HALYARD* PUREZERO* HG3 White Nitrile Gloves (Sterile and Non-Sterile)

	Chemotherapy Drug and Concentration	Min. Breakthrough Time (Minutes)
1	Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
2	Cyclophosphamide (Cytoxan) (20.0 mg/ml)	No breakthrough up to 240 minutes
3	Dacarbazine (10.0 mg/ml)	No breakthrough up to 240 minutes
4	Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
5	Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
6	Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
7	Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
8	Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
9	Paclitaxel (6.0 mg/ml)	No breakthrough up to 240 minutes
10	Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
11	Carmustine (3.3 mg/ml)	Breakthrough detected at 99.0 minutes
12	ThioTEPA (10.0 mg.ml)	Breakthrough detected at 179.8 minutes

HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

	Chemotherapy Drug and Concentration	Min. Breakthrough Time (Minutes)
1	Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
2	Cyclophosphamide (Cytoxan) (20.0 mg/ml)	No breakthrough up to 240 minutes
3	Dacarbazine (10.0 mg/ml)	No breakthrough up to 240 minutes
4	Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
5	Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
6	Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
7	Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
8	Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
9	Paclitaxel (6.0 mg/ml)	No breakthrough up to 240 minutes
10	Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
11	Carmustine (3.3 mg/ml)	WARNING: Breakthrough detected at 18.1 minutes
12	ThioTEPA (10.0 mg.ml)	Breakthrough detected at 89.3 minutes

CAUTION: The testing conditions used are intended to approximate the worst-case conditions for clinical use. Testing was conducted on a single layer glove material. It is the user's responsibility to demonstrate the applicability of these gloves for their intended use with chemotherapy drugs.

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Associate Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

August 31st, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding ESD testing of **HALYARD* PUREZERO* HG3 Nitrile Gloves.**

The following HALYARD* PUREZERO* HG3 Nitrile Glove families have been tested against **ANSI/ESD SP15.1-2011 "In-Use Resistance Testing of Gloves and Finger Cots"**:

HALYARD* PUREZERO* HG3 White Nitrile Gloves
HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves
HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

Based on the ANSI/ESD SP15.1-2011 test results from an external laboratory at conditions of 12% RH and 23°C, all five HALYARD* PUREZERO* HG3 Nitrile Glove product families listed above are within the dissipative classification range (Resistance = 10^4 to 10^{11} ohms) as defined by ANSI/ESD standards. Therefore, **HALYARD* PUREZERO* HG3 Nitrile Gloves** are considered to be static dissipative in-use.

Please note that this is based on a standardized test method in a laboratory environment, and the resistance test results and classification do not fully characterize the glove for all electrostatic properties. Other electrostatic properties, such as charge accumulation, and specific process conditions may need to be assessed based on your particular application prior to use.

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

July 14th, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding EN 1149 testing on **HALYARD* PUREZERO* HG3 Nitrile Gloves.**

The data provided on the following pages reflect the test results of **HALYARD* PUREZERO* HG3 Nitrile Gloves** for electrostatic properties in accordance with **EN 1149-1:2006** *"Protective Clothing - Electrostatic Properties - Part 1: Test Method for Measurement of Surface Resistivity"* and **EN 1149-3:2004 (Method 2)** *"Protective Clothing - Electrostatic Properties - Part 3: Test Method for Measurement of Charge Decay".*

The tests were performed at Intertek Testing Services in the UK with a report issuance of 05.07.2021.

Description of the Tested Gloves:
SAMPLE A - HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves

SAMPLE B - HALYARD* PUREZERO* HG3 White Nitrile Gloves

SAMPLE C - HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves

SAMPLE D - HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

SAMPLE E - HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves

SAMPLE A - HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample A

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	1.1×10^{12}	2.2×10^{13}
Face	1.7×10^{12}	3.4×10^{13}
Face	1.9×10^{12}	3.8×10^{13}
Face	1.0×10^{12}	2.0×10^{13}
Face	1.4×10^{12}	2.8×10^{13}
Mean	1.4×10^{12}	2.7×10^{13}
Reverse	1.3×10^{12}	2.6×10^{13}
Reverse	1.9×10^{12}	3.8×10^{13}
Reverse	2.4×10^{12}	4.8×10^{13}
Reverse	2.1×10^{12}	4.2×10^{13}
Reverse	1.8×10^{12}	3.6×10^{13}
Mean	1.9×10^{12}	3.7×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	21.50
2	0.00	20.15
3	0.00	>30.00
Mean	0.00	≥23.88

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE B - HALYARD* PUREZERO* HG3 White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample B

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	5.3×10^{11}	1.0×10^{13}
Face	5.1×10^{11}	1.0×10^{13}
Face	5.9×10^{11}	1.2×10^{13}
Face	5.9×10^{11}	1.2×10^{13}
Face	6.4×10^{11}	1.3×10^{13}
Mean	5.7×10^{11}	1.1×10^{13}
Reverse	7.6×10^{11}	1.5×10^{13}
Reverse	7.4×10^{11}	1.5×10^{13}
Reverse	6.8×10^{11}	1.3×10^{13}
Reverse	6.4×10^{11}	1.3×10^{13}
Reverse	6.6×10^{11}	1.3×10^{13}
Mean	6.9×10^{11}	1.4×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.01	12.50
2	0.01	6.96
3	0.00	8.86
Mean	0.01	9.42

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE C - HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample C

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	2.4×10^{12}	4.8×10^{13}
Face	2.1×10^{12}	4.2×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	2.6×10^{12}	5.1×10^{13}
Face	2.5×10^{12}	5.0×10^{13}
Mean	2.3×10^{12}	4.5×10^{13}
Reverse	1.7×10^{12}	3.4×10^{13}
Reverse	2.1×10^{12}	4.2×10^{13}
Reverse	2.8×10^{12}	5.5×10^{13}
Reverse	2.0×10^{12}	4.0×10^{13}
Reverse	2.4×10^{12}	4.8×10^{13}
Mean	2.2×10^{12}	4.3×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	>30.00
2	0.00	>30.00
3	0.00	>30.00
Mean	0.00	>30.00

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE D - HALYARD* PUREZERO* SMOOTH HG3 White Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample D

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	1.2×10^{12}	2.4×10^{13}
Face	1.4×10^{12}	2.8×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	1.8×10^{12}	3.6×10^{13}
Face	1.1×10^{12}	2.2×10^{13}
Mean	1.4×10^{12}	2.8×10^{13}
Reverse	1.0×10^{12}	2.0×10^{13}
Reverse	1.6×10^{12}	3.2×10^{13}
Reverse	1.1×10^{12}	2.2×10^{13}
Reverse	1.5×10^{12}	3.0×10^{13}
Reverse	1.9×10^{12}	3.8×10^{13}
Mean	1.4×10^{12}	2.7×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.00	9.37
2	0.00	7.85
3	0.00	13.05
Mean	0.00	10.09

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

SAMPLE E - HALYARD* PUREZERO* HG3 Light Blue Nitrile Gloves

Surface Resistivity Test (EN 1149-1: 2006)
Sample E

Determination of Surface Resistivity

The surface resistivity of 5 areas across the sample was determined according to the method specified in BS EN 1149-1: 2006

Surface	Surface Resistance (Ω)	Surface Resistivity (Ω)
Face	5.6×10^{11}	1.1×10^{13}
Face	5.0×10^{11}	9.9×10^{12}
Face	5.5×10^{11}	1.1×10^{13}
Face	5.3×10^{11}	1.0×10^{13}
Face	5.1×10^{11}	1.0×10^{13}
Mean	5.3×10^{11}	1.0×10^{13}
Reverse	7.0×10^{11}	1.4×10^{13}
Reverse	6.8×10^{11}	1.3×10^{13}
Reverse	6.7×10^{11}	1.3×10^{13}
Reverse	6.4×10^{11}	1.3×10^{13}
Reverse	7.2×10^{11}	1.4×10^{13}
Mean	6.8×10^{11}	1.3×10^{13}

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Induction Decay Test (EN 1149-3: 2004 Method 2)

Determination of Induction Decay Time

	Shielding Factor (S)	Half Decay Time t_{50} (Secs)
1	0.02	6.09
2	0.01	5.57
3	0.00	7.74
Mean	0.00	6.47

Note: The fabric was not subjected to a pre-wash due to being intended for single use only.

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

EU Type Examination Certificate

This is to certify that:

O&M Halyard Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate Number: CE 725273

In respect of:

Nitrile Protective Gloves for Personal Protection
Model: CLN 923280 (Sterile)

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

First Issued: 2020-11-06
Latest Issue: 2020-11-06

Effective Date: 2020-11-06
Expiry Date: 2025-11-06

PRODUCTS
RvA C 646

...making excellence a habit.™

EU Type Examination Certificate

No. CE 725273

Product Specification

Range: HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK

Models:
CLN923260
CLN923265
CLN923270
CLN923275
CLN923280
CLN923285
CLN923290
CLN923210

Classification: Protective gloves for use against chemical and micro-organism hazards.

Description: A five fingered, hand specific, single use powder free, non-sterile, gamma irradiated glove with textured finger surface and beaded cuff. Gloves available coloured light blue.

PPE Category: Complex

Product sizes: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0

Applicable Standards: The following Harmonized European Standards:

EN 420:2003+A1:2009 Protective gloves. General requirements.

EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN 374-2:2019. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

EN 374-4:2019 Determination of resistance to degradation by chemicals.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks.

EN 16523-1:2015. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

ISO 16604:2004 Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by blood-borne pathogens.

First Issued: 2020-11-06
Latest Issue: 2020-11-06

Effective Date: 2020-11-06
Expiry Date: 2025-11-06

EU Type Examination Certificate

No. CE 725273

Product Specification

Performance

General requirements for gloves to EN 420:2003+A1:2009

Characteristic	Level
Dexterity	5

Terminology and performance requirements for micro-organism Risks EN ISO 374-5:2016

Characteristic	Level
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Resistance to chemical permeation to EN ISO 374-1:2016

Tested to the chemicals below to EN 16523-1:2015

Resistance to Degradation to chemical protection EN 374-4:2019

Tested to the chemicals below

Chemical	Permeation Level	Mean Degradation %
70% Isopropyl Alcohol	-	33.3
40% Sodium Hydroxide (K)	6	-69.1
50% Sulphuric Acid	6	-37.4
30% Hydrochloric Acid	6	39.2
1% Ethidium Bromide	6	-4.2

First Issued: 2020-11-06
Latest Issue: 2020-11-06

Effective Date: 2020-11-06
Expiry Date: 2025-11-06

EU Type Examination Certificate

No. CE 725273

Certificate Administration Details

Technical File Reference: No. 012-03 R01 Halyard Sterile Cleanroom Gloves

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
November 2020	First issue models: CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210.	2797:20:3154548

Note: The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE:

The validity of the Certificate is also dependent on the maintenance of the EC quality of production by monitoring system, Module C2, as referenced on BSI Certificate CE 708082.

First Issued: 2020-11-06
Latest Issue: 2020-11-06

Effective Date: 2020-11-06
Expiry Date: 2025-11-06

TITLE: HALYARD* PUREZERO* HG3 Nitrile Gloves

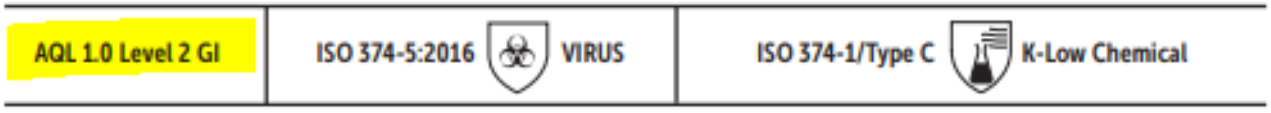
PRODUCT UPDATE: AQL (Acceptable Quality Limit) improvement from AQL 1.5 to AQL 1.0

WHAT YOU NEED TO KNOW: For the lot release inspection of HALYARD* PUREZERO* HG3 Nitrile Gloves, the outgoing inspection acceptable quality level has been improved from AQL 1.5 to AQL 1.0 for freedom from holes/pinhole testing. All of the HALYARD* PUREZERO* HG3 Nitrile Gloves have passed the criteria for water tightness (pinholes) per the applicable ASTM and or EN test method/standards. There are no changes to the formulation, manufacturing process, or process specifications/parameters.

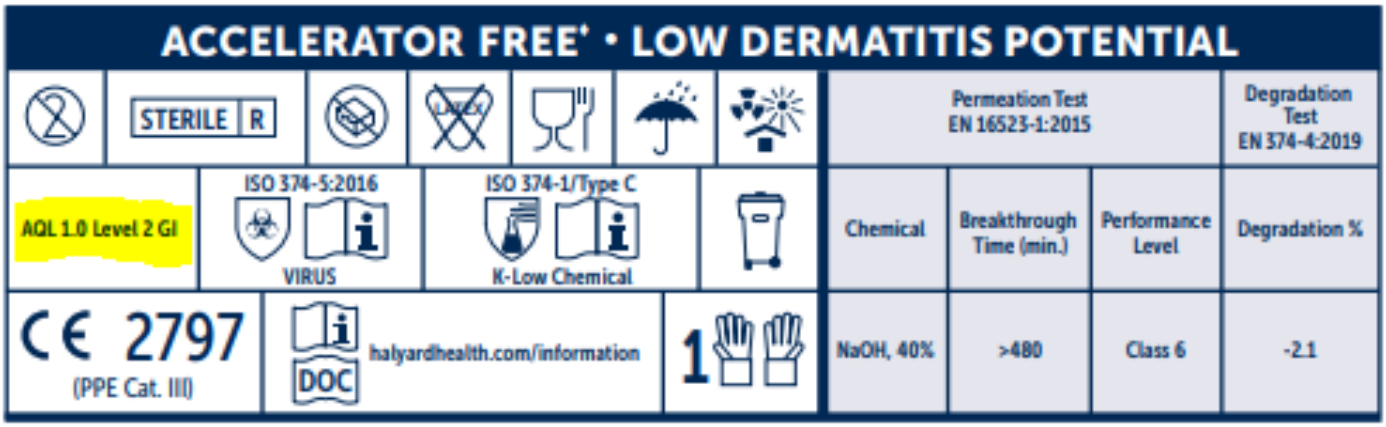
WHEN IS THIS CHANGING: These changes will be displayed on the product when it enters the market in January 2022.

WHERE TO FIND THIS CHANGE ON THE PACKAGING:

CASE LABEL:



BAG/POUCH LABEL:



IFU:

ORDERING INFORMATION:

Product Name	Size	Code
HALYARD* PURERZERO* HG3 Light Blue Nitrile Gloves	XS	CLN9031XS
HALYARD* PURERZERO* HG3 Light Blue Nitrile Gloves	S	CLN9031SM
HALYARD* PURERZERO* HG3 Light Blue Nitrile Gloves	M	CLN9031MD
HALYARD* PURERZERO* HG3 Light Blue Nitrile Gloves	L	CLN9031LG
HALYARD* PURERZERO* HG3 Light Blue Nitrile Gloves	XL	CLN9031XL
HALYARD* PUREZERO* HG3 White Nitrile Gloves	XS	CLN3031XS
HALYARD* PUREZERO* HG3 White Nitrile Gloves	S	CLN3031SM
HALYARD* PUREZERO* HG3 White Nitrile Gloves	M	CLN3031MD
HALYARD* PUREZERO* HG3 White Nitrile Gloves	L	CLN3031LG
HALYARD* PUREZERO* HG3 White Nitrile Gloves	XL	CLN3031XL
HALYARD* PUREZERO* HG3 SMOOTH White Nitrile Gloves	XS	CLN3231XS
HALYARD* PUREZERO* HG3 SMOOTH White Nitrile Gloves	S	CLN3231SM
HALYARD* PUREZERO* HG3 SMOOTH White Nitrile Gloves	M	CLN3231MD
HALYARD* PUREZERO* HG3 SMOOTH White Nitrile Gloves	L	CLN3231LG
HALYARD* PUREZERO* HG3 SMOOTH White Nitrile Gloves	XL	CLN3231XL
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	6.0	CLN923260
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	6.5	CLN923265
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	7.0	CLN923270
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	7.5	CLN923275
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	8.0	CLN923280
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	8.5	CLN923285
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	9.0	CLN923290
HALYARD* PUREZERO* HG3 Sterile Light Blue Nitrile Gloves	10.0	CLN923210
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	6.0	CLN323260
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	6.5	CLN323265
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	7.0	CLN323270
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	7.5	CLN323275
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	8.0	CLN323280
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	8.5	CLN323285
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	9.0	CLN323290
HALYARD* PUREZERO* HG3 Sterile White Nitrile Gloves	10.0	CLN323210

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Shannon Smith

Shannon Smith
Associate Product Manager
Global Products
O&M Halyard, Inc.

Steven Dowdley
Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

October 5th, 2021

RE: HALYARD* PUREZERO* HG3 Light Blue Sterile Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding chemical permeation testing on HALYARD* PUREZERO* HG3 Light Blue Sterile Nitrile Gloves.

The results below reflect a comphrensive list of chemicals tested against HALYARD* PUREZERO* HG3 Light Blue Sterile Nitrile Gloves with indicated breakthrough time in accordance with EN 16523-1, *Determination of Material Resistance to Permeation by Chemicals – Permeation by Liquid Chemicals under Conditions of Continuous Contact.*

Chemical	Concentration (%)	Minimum Breakthrough Time (min.)
1-Butanol	99	**192.1**
Acrylamide	40	No breakthrough detected up to **480** minutes
Citric Acid Monohydrate	30	No breakthrough detected up to **480** minutes
Cyclohexane	99.7	**52.5**
Dimethylformamide	99	**0.0**
Dimethyl Sulfoxide	99	**5.5**
Ethanol	70	**27.6**
Ethidium Bromide	1	No breakthrough detected up to **480** minutes
Formaldehyde	37	No breakthrough detected up to **480** minutes
Glutaraldehyde	50	No breakthrough detected up to **480** minutes
Hydrazine Monohydrate	55	No breakthrough detected up to **480** minutes
Hydrochloric Acid	30	No breakthrough detected up to **480** minutes
Hydrogen Peroxide	30	**36.0**
Isopropyl Alcohol	70	**194.0**
Methanol	99	**1.2**
Peracetic Acid	5	No breakthrough detected up to **480** minutes
Sodium Hydroxide	50	No breakthrough detected up to **480** minutes
Sodium Hypochlorite	10-13%	No breakthrough detected up to **480** minutes
Spor-Klenz	-	No breakthrough detected up to **480** minutes
Sulfuric Acid	50	No breakthrough detected up to **480** minutes

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Thank you for your interest in HALYARD* products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

May 21st, 2021

RE: HALYARD* PUREZERO* HG3 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding isopropyl alcohol chemical permeation testing on HALYARD* PUREZERO* HG3 Sterile Nitrile Gloves.

The results below reflect the chemical permeation test results of HALYARD* PUREZERO* HG3 Sterile Nitrile Gloves against isopropyl alcohol (70%) with indicated breakthrough time in accordance with **EN 16523-1**, *Determination of Material Resistance to Permeation by Chemicals – Permeation by Liquid Chemicals under Conditions of Continuous Contact.*

Product Family	Product Codes	Chemical Tested	Min. Breakthrough Time (Minutes)
PUREZERO* HG3 Sterile Light Blue	CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210	Isopropyl Alcohol (70%)	194.0
PUREZERO* HG3 Sterile White	CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323285, CLN323290, CLN323210		185.0

Thank you for your interest in Halyard products. If you have any questions or need additional information, please do not hesitate to contact us at PIQ@hyh.com or call us directly at (844) 425-9273.

Sincerely,

Steven Dowdley
Associate Director of Regulatory Affairs
Global Products
O&M Halyard, Inc.

Ryan Solan
R&D Senior Engineer
Global Research and Development
O&M Halyard, Inc.

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the :

Manufacturer:

O&M HALYARD, Inc.
9120 Lockwood Blvd
Mechanicsville, VA. 23116

EU Authorized Representative:

Arc Royal
Virginia Road Kells, Co
Meath, Ireland

Technical File TF12-03 for Sterile Protective Gloves

Product Code	Product Description	Color
CLN323260	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323265	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323270	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323275	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323280	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323285	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323290	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN323210	HALYARD PUREZERO HG3 STERILE WHITE NITRILE GLOVES HAND SPECIFIC PAIR SLICK	WHITE
CLN923260	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923265	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923270	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923275	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923280	LYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923285	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923290	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE
CLN923210	HALYARD PUREZERO HG3 STERILE LIGHT BLUE NITRILE GLOVE HAND SPECIFIC PAIR SLICK	LIGHT BLUE

The object of the declaration is in conformity with PPE Regulation 2016/425. Conformity is declared with the following standards :

Standards:
EN 420:2003+A1:2009 Protective Gloves. General requirements
EN ISO 374-1:2016 Protective Gloves Against dangerous chemicals and microorganisms. Terminology and performance requirements for chemical risks.
EN ISO 374-2:2019 Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.
EN ISO 374-4:2019. Protective gloves against chemicals and micro-organisms. Determination of resistance by chemicals
EN ISO 374-5:2016. Protective gloves against chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.
EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

This declaration confirms that the notified body, BSI Group Netherlands, Notified Body Number 2797 (John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands) performed the EU type-examination (Module B) and issued the EU type-examination certificate CE 725270 and CE 725273. Protective gloves are classified as Category III under the PPE Regulation 2016/425 and Protective gloves are in conformance to type based on internal production control plus supervised product checks at random intervals (Module C2) under CE 708082.

Authorized Signature :

Steven Dowdley
Associate Director Regulatory Affairs
O&M HALYARD, Inc.
9120 lockwood blvd , Mechanicsville, VA, 23116
Date : 23 Nov 2020

Note: EU DECLARATION OF CONFORMITY - this declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: http://www.halyardhealth.com/information