

Halyard



Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN3031LG

pure¹¹-Nr.: 1105011, Marke: Halyard

Eigenschaften

- Marke: Halyard
- Handschuhtyp: Dünnsfilm
- Länge in cm: 30,5 cm
- Chemikalienbeständigkeit - Typ: Typ C
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Zytostatikageeignet
- Lebensmittelkonformität
- Silikonfrei
- Vulkanisationsbeschleunigerfrei
- Verpackungsform: Beutel
- AQL (Acceptable Quality Level)-Wert: 0,65
- Chemikalienbeständig gegen Isopropanol (100%): Level 3 (60-120min)
- Chemikalienbeständig gegen Isopropanol (70%): Level 3 (60-120min)
- Länge in Inches: 12 In
- Latexfrei
- Materialzusammensetzung: Reinmaterial
- Oberflächenbeschaffenheit: griffig

Empfohlene

Reinraumklassen

ISO 3|4|5|6|7|8|9

GMP C|D



- Reißfestigkeit EN 455-2 ASTM in MPa: 20-30
- Schutz vor Blut und Körpersekreten ISO 16604:2004
- Passform Hand: beidhändig
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,16 mm

Material

- Nitril

Verpackung

- 1000STK

Produktvarianten

pure¹¹-Nr.: 1105011WHL, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN3031LG

Farbe: Weiß; Größe: L / VE: 1000STK

pure¹¹-Nr.: 1105011WHM, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN3031MD

Farbe: Weiß; Größe: M / VE: 1000STK

pure¹¹-Nr.: 1105011WHS, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN3031SM

Farbe: Weiß; Größe: S / VE: 1000STK

pure¹¹-Nr.: 1105011WHXL, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN3031XL

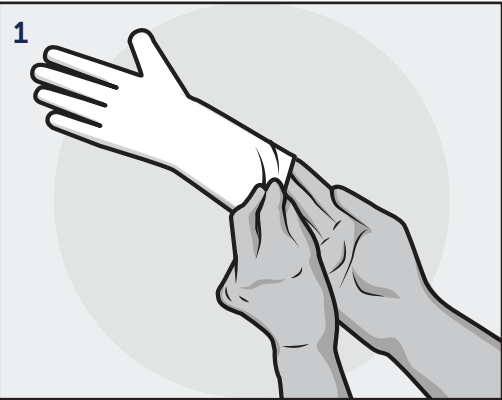
Farbe: Weiß; Größe: XL / VE: 1000STK

pure¹¹-Nr.: 1105011WHXS, Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN3031XS

Farbe: Weiß; Größe: XS / VE: 1000STK

GUIDE TO DONNING AND DOFFING OF NON-STERILE CLEANROOM GLOVES

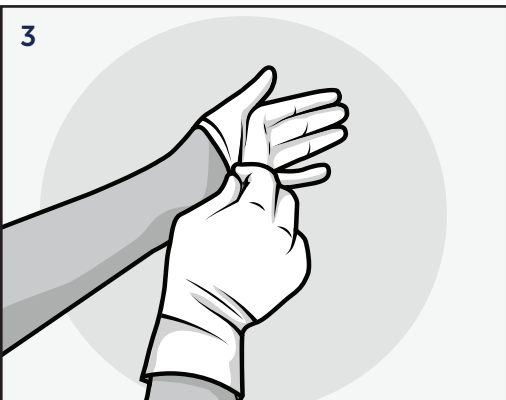
DONNING GLOVES



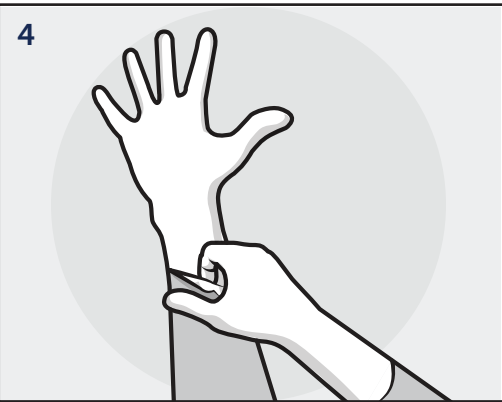
Grasp the beaded cuff of one glove and carefully pull over the opposite hand.



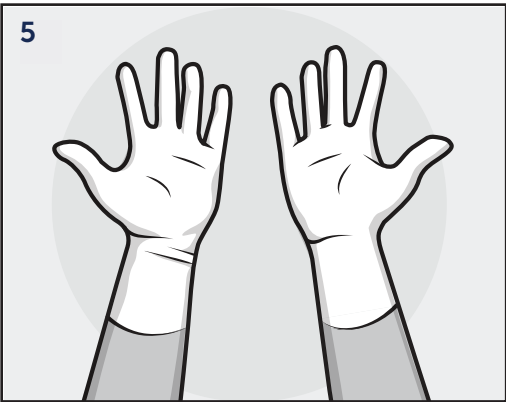
Gently ease the glove up over the hand and wrist.



Grasp the second glove at the edge of the beaded cuff.

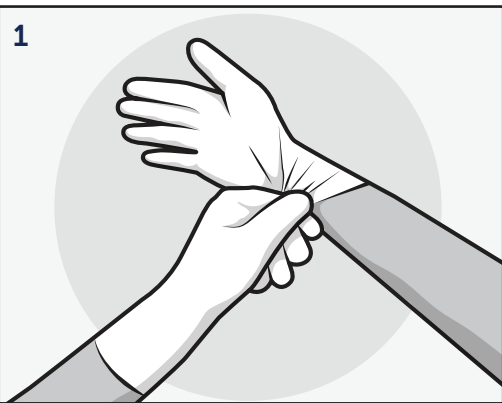


Gently ease the glove up over the hand and wrist.

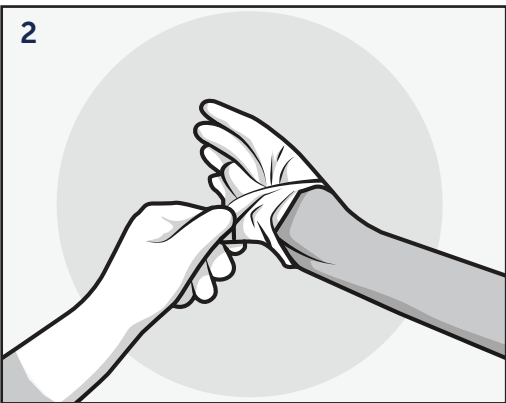


You are now ready to perform your task.

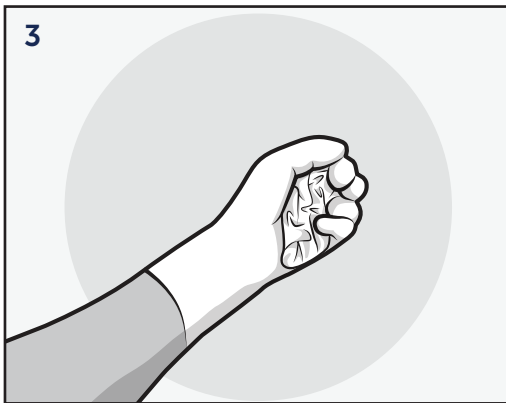
DOFFING GLOVES



Grasp the exterior of one glove with your other gloved hand.



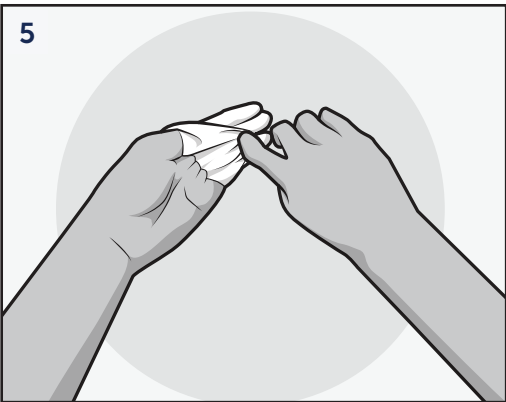
Carefully pull the glove off your hand, turning it inside-out.



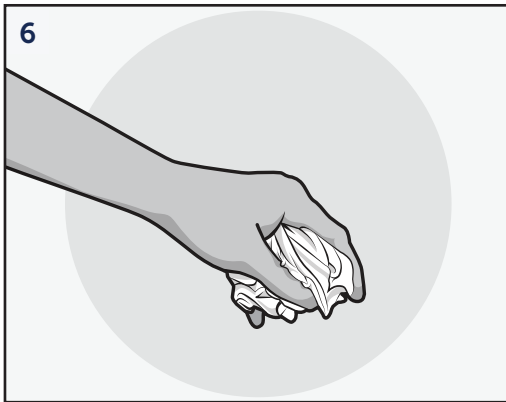
Ball the glove up and hold in your other gloved hand.



Slide your ungloved fingers into the opening of the other glove.



Carefully pull the glove off your hand, turning it inside-out and wrapping it around the doffed glove in your palm.



Discard appropriately.

For more information, contact your HALYARD* representative or distributor, or visit www.purezerogloves.com



HALYARD* **PUREZERO*** HG3 WHITE NON-STERILE CLEANROOM GLOVES

DATA PACK



For the Cleanroom Environment
For Industrial Use Only

HALYARD* **PUREZERO*** HG3 WHITE NON-STERILE CLEANROOM GLOVES DATA PACK

All documents depicted here are FOR EXAMPLE ONLY. For specific documents related to lot numbers, please visit www.halyardhealth.com/information, or ask your Distributor or HALYARD* Representative.

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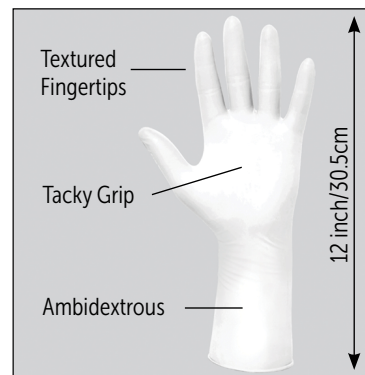
TECHNICAL DATA SHEET



TECHNICAL DATA SHEET

Description

HALYARD* **PUREZERO*** HG3 White Nitrile Cleanroom Gloves are designed for semiconductor, pharmaceutical and medical device manufacturing applications. These gloves are clean processed (washed repeatedly in deionized water) to ensure consistent control of low particles and extractables and are recommended for use in ISO Class 3 or higher and Grade B/C/D cleanrooms. Because HALYARD* **PUREZERO*** White Nitrile Gloves have an **accelerator-free**¹ formulation, 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.

Cleanliness Properties

| | | |
|---|--------------------------------|---------------|
| Max Particle Count (>0.5 µm) | <950 Particles/cm ² | IEST RP-CC005 |
| 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 | 1.0 |
| Non-Sterile | ✓ |
| Ambidextrous | ✓ |
| Tacky Grip | ✓ |
| Textured Fingertips | ✓ |
| Accelerator-Free ¹ | ✓ |
| Latex-Free | ✓ |
| Powder-Free | ✓ |
| Silicone-Free | ✓ |
| Static Dissipative in Use | ✓ |
| Tensile Strength ² | 35 MPa (Target) |
| Ultimate Elongation ² | 600% |
| Shelf Life | 3 Years |

Glove Dimensions

| | X-SMALL | SMALL | MEDIUM | LARGE | X-LARGE |
|---------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Glove Length (inch/cm) | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 | 12"/30.5 |
| Middle Finger Length (mm) | 71 | 78.5 | 80.5 | 88.1 | 91.6 |
| Width of Palm (mm) | 70 | 80 | 95 | 110 | 120 |
| Finger Tip Thickness | 0.16 mm (6.2 mil) | 0.16 mm (6.2 mil) | 0.16 mm (6.2 mil) | 0.16 mm (6.2 mil) | 0.16 mm (6.2 mil) |
| Palm Thickness | 0.13 mm (5.1 mil) | 0.13 mm (5.1 mil) | 0.13 mm (5.1 mil) | 0.13 mm (5.1 mil) | 0.13 mm (5.1 mil) |
| Cuff Thickness | 0.10 mm (3.9 mil) | 0.10 mm (3.9 mil) | 0.10 mm (3.9 mil) | 0.10 mm (3.9 mil) | 0.10 mm (3.9 mil) |

TECHNICAL DATA SHEET

Packaging Data

Double bag, plus case liner
1000 gloves per case: 100 gloves per PE 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

Additional Glove Information

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

Tested against 29 chemicals, 14 chemotherapy drugs and Fentanyl.

Made in Thailand

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

Storage Instructions

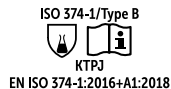
HALYARD* PUREZERO* Nitrile Gloves shall be stored in conditions where the product is kept dry (away from moisture), away from direct sunlight, away from sources of heat, and away from radioactive sources.

Ordering Information

HALYARD* PUREZERO* HG3 WHITE NITRILE GLOVES, NON-STERILE, AMBIDEXTROUS, TACKY

| Size | Code |
|------|-----------|
| XS | CLN3031XS |
| SM | CLN3031SM |
| MD | CLN3031MD |
| LG | CLN3031LG |
| XL | CLN3031XL |

CE 2797
(PPE Cat. III)



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, Thioxoles, 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.

CERTIFICATE OF ANALYSIS



Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla 90120 Thailand

CERTIFICATE OF ANALYSIS

Product Description : HALYARD* PUREZERO* HG3 White Nitrile Gloves

Catalog Numbers : CLN3031XS, CLN3031SM, CLN3031MD, CLN3031LG, CLN3031XL

OMH Code : 48167-81, 48168-81, 48169-81, 48170-81, 48171-81

Batches : SM318223X to SM321223X
SM318223V to SM321223V

Total Cases per Lot : 4,511
Date of Manufacture : Jul-23
Expiration Date : 2026-06-30

Physical Test Data

| | Watertight | Visual Defects | | Dimensions | Tensile (MPa) | Elongation (%) | Median Force at Break (N) |
|----------------------------|------------|----------------|------------|------------|---------------|----------------|---------------------------|
| | | Minor | Negligible | | Pre Aging | Pre Aging | Pre Aging |
| Sample Size : | 3555 | 3555 | 3440 | 403 | 286 | 286 | 286 |
| AQL Level : | 1.0 | 2.5 | 4.0 | 4.0 | 4.0 | 4.0 | 4.0 |
| Failures Allowed per AQL : | 54 | 130 | 192 | 31 | 22 | 22 | 22 |
| Failures : | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Inspection Results : | Accept | Accept | Accept | Accept | Accept | Accept | Accept |
| Averages: | | | | | 43.12 | 620 | 15.09 |

Test Methods : Water tight test ASTM D 5151, EN 455-1, Elongation and Tensile ASTM D 412, ASTM D 6319, Median Force at Break EN 455-2, Dimension ASTM D 6319, EN 455-2

Particle Test Data

| Particle | Total Particles/cm ² | Inspection Result |
|--|---------------------------------|-------------------|
| #/cm ² : | 830 | Accept |
| Particulate Level (≥0.5 microns) #/cm ² | | |

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data

| | Anions Results | | | | Cations Results | | | |
|---------------------|-----------------|------------------------------|-------------------------------|-----------------|------------------------------|----------------|------------------|------------------|
| | Chloride | Nitrate | Sulfate | Sodium | Ammonium | Potassium | Magnesium | Calcium |
| Units : | Cl ⁻ | NO ₃ ⁻ | SO ₄ ⁻² | Na ⁺ | NH ₄ ⁺ | K ⁺ | Mg ⁺² | Ca ⁺² |
| µg/g glove | 25.912 | 4.810 | 1.325 | 1.754 | 1.286 | 1.749 | 1.274 | 42.222 |
| Inspection Result : | Accept | Accept | Accept | Accept | Accept | Accept | Accept | Accept |

Trace Element Results

| | Zinc |
|---------------------|--------|
| | Zn |
| Units : | |
| µg/g glove | 3.48 |
| Inspection Result : | Accept |

Test Method : IEST-RP-CC005.4

Review By :


(QA Sr. Manager)

FORM-28013/7

PACKAGE LABELS

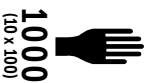


PUREZERO* HG3

WHITE NITRILE GLOVES



- (FR) Gants en nitrile blancs HG3
- (DE) HG3 Nitrilhandschuhe, weiß
- (BG) Бели нитрилни ръкавици HG3
- (ES) Guantes de nitrilo blancos HG3
- (CS) Bílé nitrilové rukavice HG3
- (DA) HG3 Hvide nitrilhandsker
- (ET) HG3 valged nitrilkindad
- (EL) HG3 Λευκά γάντια νιτριλίου
- (IT) Guanti in nitrile bianchi HG3
- (LV) HG3 balti nitrīla cimdi
- (LT) HG3 baltos nitrilinės pirštinės
- (HR) HG3 bijele nitrilne rukavice
- (HU) HG3 fehér nitrilkesztyű



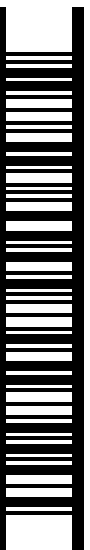
AQL L10 Level 2 Cl



104816981

REF

CLN3031MD



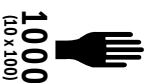
3 0 6 8 0 6 5 1 4 8 1 6 9 7

PUREZERO* HG3

WHITE NITRILE GLOVES



- (MT) HG3 Ingwanti tan-Nitril Bojod
- (NL) HG3 Witte nitril handschoenen
- (NO) HG3 hvite nitrilhandsker
- (PL) HG3 Białe rękawice nitylowe
- (PT) Luvas de nitrilo brancas HG3
- (RO) Mănuși din nitril albe HG3
- (RU) Белые нитриловые перчатки HG3
- (SK) Biele nitrilové rukavice HG3
- (SL) HG3 Bele rokavice iz nitrila
- (FI) HG3, valkoiset nitrilikäsineet
- (SV) HG3 Vita nitrilhandskar
- (JA) HG3 ホワイトニトリルグローブ
- (KO) HG3 흰색 니트릴 장갑
- (ZH) HG3 白色丁腈手套



AQL L10 Level 2 Cl



104816981

REF

CLN3031MD



3 0 6 8 0 6 5 1 4 8 1 6 9 7

CASE LABEL

BAG LABEL



PUREZERO* HG3

WHITE NITRILE GLOVES

For the Cleanroom Environment

For Industrial Use Only

12 in. / 30.5 cm

(FR) Gants en nitrile blancs HG3 • Pour l'environnement des salles blanches • Pour usage industriel uniquement • Sans accélérateur* • Ambidextres

(DE) HG3 Nitrilhandschuhe, weiß • Für Reinraumumgebungen • Nur für den industriellen Gebrauch • Beschleunigerfrei* • Beidhändig

(ES) Guantes de nitrilo blancos HG3 • Para entornos de sala blanca • Solo para uso industrial • Sin aceleradores* • Ambidiestro

(IT) Guanti in nitrile bianchi HG3 • Per camera bianca • Solo per uso industriale • Privi di acceleranti* • Basso potenziale di dermatite • Ambidestri

(NL) HG3 Witte nitril handschoenen • Voor gebruik in kritieke schone ruimtes/cleanrooms • Alleen voor industrieel gebruik • Versneller vrij* • Symmetrisch

(PT) Luvas de nitrilo brancas HG3 • Para ambiente de sala limpa • Exclusivamente para utilização industrial • Sem aceleradores* • Baixo potencial de dermatite • Ambidestras

(RU) Белые нитриловые перчатки HG3 • Для стерильных условий • Только для промышленного использования • Без химических присадок* • Амбидекстральные

(JA) ピュアゼロ HG3 ホワイトニトリルグローブ • クリーンルーム環境対応 • 工業用途のみ • 加硫促進剤不使用* • 左右兼用

(KO) HG3 흰색 니트릴 장갑 • 클린룸 환경용 • 산업용으로만 사용 • 촉진제 없음* • 양손형

(ZH) HG3 白色丁腈手套 • 适用于洁净室环境 • 仅限工业使用 • 无催化剂* • 左右手通用

Manufactured at our SAFESKIN® Facility

ACCELERATOR FREE*

| | | | | | | | | |
|--|--------------------|--|---|---|--|---|--|---|
| XS (5.5) = CLN3031XS S (6.0 - 6.5) = CLN3031SM M (7.0 - 7.5) = CLN3031MD L (8.0 - 8.5) = CLN3031LG XL (9.0 - 10.0) = CLN3031XL | Ambidextrous |  |  |  |  |  |  |  |
| | AQL 1.0 Level 2 GI |   halyardhealth.com/information | | |  2797 <small>(PPE Cat. III)</small> |  0086 | 100  | |

* Not formulated with the following vulcanizing chemicals and accelerators: Sulfur, Thiurams, Thiazoles, Guanidines, Carbamates

Product of Thailand

O&M Halyard, Inc., 9120 Lockwood Blvd., Mechanicsville, VA 23116 • In USA, please call 1-844-425-9273 • halyardhealth.com

© O&M Halyard Belgium BV, Berkenlaan 88, 1831 Machelen (Brab.), Belgium

Product certified to the Regulation (EU) 2016/425 by Notified Body 2797 BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, and to the Regulation (EU) 2016/425 on personal protective equipment, as amended to apply in Great Britain by Approved Body BSI Assurance UK Ltd (0086) Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP.

UK RP • RLD Quality Limited Centenary House, Peninsula Park, Rydon Lane, Exeter, EX2 7XE, United Kingdom

Sponsored in Australia by O&M Halyard Australia Pty Ltd., Tenancy 1, Level 1, Trinit 3, 39 Delhi Road, North Ryde NSW 2113

販売元 O&M Halyard Japan合同会社 東京都港区芝公園2-6-3 芝公園フロントタワー12階

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06-HM-089-0-02

Place Label Here

PACKAGING CERTIFICATES





TIP CORPORATION SDN BHD

Lot 608, Jalan Sungai Sop, Batu 14,
43100 Hulu Langat, Selangor, Malaysia.
Tel: +603-9021 3985
E-mail: sales@tipcorp.com Website: www.tipcorp.com

FORM: QC-07 REV 10
Date Reviewed : 30.11.2017



CERTIFICATE OF CONFORMANCE

THIS IS TO CERTIFY THAT THE FOLLOWING PRODUCT CONFORM/PASS THE SPECIFICATION LISTED BELOW:-

CUSTOMER : SAFESKIN
DESCRIPTION : C/R EASY TEAR LDPE -PRT -355X405X0.05MM
QUANTITY : 20,000 PCS
LOT NO : 61200
PART NO : 06-HM-039-0-00
P.O NO. & DATE : 4561162599
TEST DATE : 12.07.2021
OUR INVOICE NO: TPL16374
PALLET REFERENCE
NUMBER (IF ANY):
PACKING LIST NUMBER : TPL16374
DATE OF MANUFACTURING :
DATE OF EXPIRED :

| Safeskin Thailand | |
|-------------------|---------------|
| D/O No. | : TPL16374 |
| IQA Batch | : P2107139 |
| Date | : 16-JUL-2021 |
| Signature By | : [Signature] |

SURFACE RESISTIVITY TEST - (Reference ASTM D257, ANSI / ESD S541 & ANSI / ESD STM 11.11)

- ☐ DISSIPATIVE : $\geq 1 \times 10^5$ AND $< 1 \times 10^{12}$ OHMS/SQ
- ☐ CONDUCTIVE : $< 1 \times 10^5$ OHMS/SQ
- ☒ VISUAL TEST
- ☒ DIMENSION CHECK (WIDTH, LENGTH & THICKNESS)
- ☐ WATER LEAK TEST
- ☒ LPC TEST
- ☒ SEAL/PEEL STRENGTH TEST
- ☒ PRINTING
- ☐ AMIDE & SILICON FREE
- ☐ CENTRE SEAL / WITH PERFORATION LINE
- ☐ NO CENTRE SEAL / WITHOUT PERFORATION

TESTED BY: Rubaiyat
QC DEPARTMENT

VERIFIED BY: [Signature]
QA EXECUTIVE



TOP IN PERFORMANCE

BAG COC



TIP CORPORATION SDN BHD

FORM QC-01 REV 5

Date Implement : 05.04.2018

REF NO : QC-01

DATE : 12.07.2021

IN COMING QUALITY INSPECTION REPORT
CUSTOMER / SUPPLIER : SAFESKIN

LOT NO : 61200

OUT GOING QUALITY INSPECTION REPORT

SAMPLING PLAN 0.65 single Plan Normal Inspection S2

Lot Qty : 55

Accept / Reject

501 to 3,200pcs : 13

Acc / Rej : 0/1

3,201 to 35,000pcs : 20

Acc / Rej : 0/1

35,001 to 500,000pcs : 32

Acc / Rej : 0/1

500,001 pcs and over : 50

Acc / Rej : 0/1

TEM : CIR EASY TEAR LDPE -PRT -355X405X0.05MM

QUANTITY : 20,300 pcs

PART NO : 06-HM-039-0-00

| DIMENSION / PHYSICAL INSPECTION | | | | | | | | | | | | | SAMPLE NO | | | PROPERTIES OF MATERIAL | | |
|---------------------------------|-----------------|-----|-----|---------|-----|-----|------------|------|------|--------|---------|--------------|---------------|---------------|-----------|------------------------|------|--|
| NO | DIMENSION CHECK | | | | | | THICKNESS | MAX | MIN | VISUAL | REMARKS | EASY TO OPEN | SEAL STRENGTH | PRT / GLUSSET | SAMPLE NO | | | CONDUCTIVE |
| | WIDTH | MAX | MIN | LENGTH | MAX | MIN | | | | | | | | | CHIM | SEAL | LEFT | |
| SPEC | 355+/5 | 360 | 350 | 405+/30 | 415 | 395 | 0.05+/0.01 | 0.05 | 0.04 | OK | OK | OK | OK | OK | 1 | 10 | 11 | DISSIPATIVE |
| 1 | 353 | | | 410 | | | 0.05 | | | | | | | | 2 | 11 | 11 | INSULATOR |
| 2 | 354 | | | 411 | | | 0.05 | | | | | | | | 3 | 11 | 10 | TEST METHOD |
| 3 | 353 | | | 410 | | | 0.05 | | | | | | | | 4 | 10 | 11 | (ASTM D 257) |
| 4 | 354 | | | 410 | | | 0.05 | | | | | | | | 5 | 11 | 10 | OTHER |
| 5 | 353 | | | 411 | | | 0.05 | | | | | | | | 6 | 10 | 11 | Remarks |
| 6 | 354 | | | 410 | | | 0.05 | | | | | | | | 7 | 11 | 10 | |
| 7 | 353 | | | 411 | | | 0.05 | | | | | | | | 8 | 10 | 11 | |
| 8 | 354 | | | 410 | | | 0.05 | | | | | | | | 9 | 11 | 10 | For Incoming visual : |
| 9 | 353 | | | 411 | | | 0.05 | | | | | | | | 10 | 11 | 11 | Bag no torn, damaged - Accept |
| 10 | 354 | OK | | 411 | OK | | 0.05 | OK | | OK | OK | OK | OK | | 11 | 10 | 10 | Reject for the bag is broken |
| 11 | 353 | | | 410 | | | 0.05 | | | | | | | | 12 | 11 | 11 | |
| 12 | 354 | | | 410 | | | 0.05 | | | | | | | | 13 | 10 | 10 | Equipment for inspection : |
| 13 | 353 | | | 411 | | | 0.05 | | | | | | | | 14 | 11 | 11 | Dimension - Measuring Tape |
| 14 | 354 | | | 411 | | | 0.05 | | | | | | | | 15 | 10 | 10 | Thickness - Thickness Checker |
| 15 | 353 | | | 410 | | | 0.05 | | | | | | | | 16 | 11 | 11 | Surface Resistivity - SRM |
| 16 | 354 | | | 411 | | | 0.05 | | | | | | | | 17 | 10 | 11 | SUMMARY OF OUTGOING QC |
| 17 | 353 | | | 410 | | | 0.05 | | | | | | | | 18 | 11 | 10 | INSPECTION RESULT : |
| 18 | 354 | | | 411 | | | 0.05 | | | | | | | | 19 | 11 | 10 | Visual : OK MVTR: N/A |
| 19 | 353 | | | 410 | | | 0.05 | | | | | | | | 20 | 10 | 11 | Sticky : NO Easy to open OK |
| 20 | 354 | | | 411 | | | 0.05 | | | | | | | | 21 | | | LPC : OK Mixed: NO |
| 21 | | | | | | | | | | | | | | | 22 | | | Seal Strength : OK Water Leak Test N/A |
| 22 | | | | | | | | | | | | | | | 23 | | | Printing per spec: OK |
| 23 | | | | | | | | | | | | | | | 24 | | | Surface Resistivity: N/A |
| 24 | | | | | | | | | | | | | | | 25 | | | |
| 25 | | | | | | | | | | | | | | | 26 | | | |
| 26 | | | | | | | | | | | | | | | 27 | | | |
| 27 | | | | | | | | | | | | | | | 28 | | | |
| 28 | | | | | | | | | | | | | | | 29 | | | |
| 29 | | | | | | | | | | | | | | | 30 | | | |
| 30 | | | | | | | | | | | | | | | 31 | | | |
| 31 | | | | | | | | | | | | | | | 32 | | | |
| 32 | | | | | | | | | | | | | | | | | | |

REMARKS :

ACCEPT ☐

REJECT ☐

Prepared By : *Cm*

Final disposition : OK

Accept / Reject : ACCEPT

Verified By : *JS*

Final Disposition : OK

Accept / Reject : ACCEPT

BAG 2 COC



TIP CORPORATION SDN BHD

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E-mail: sales@tipcorp.com Website: www.tipcorp.com

FORM: QC-07 REV 10

Date Reviewed : 30.11.2017



CERTIFICATE OF CONFORMANCE

THIS IS TO CERTIFY THAT THE FOLLOWING PRODUCT CONFORM/PASS THE SPECIFICATION LISTED BELOW:-

CUSTOMER : SAFESKIN
DESCRIPTION : C/R EASY TEAR LDPE BAG -355X405X0.045MM
QUANTITY : 48,000 PCS
LOT NO : 61448
PART NO : 06-HM-041-0-00
P.O NO. & DATE : 4561164448
TEST DATE : 10.08.2021
OUR INVOICE NO: TPL16679
PALLET REFERENCE
NUMBER (IF ANY):
PACKING LIST NUMBER : TPL16679
DATE OF MANUFACTURING :
DATE OF EXPIRED :

| Safeskin Thailand | |
|-------------------|---------------|
| D/O No. | : TPL 16679 |
| IQA Batch | : P 2108109 |
| Date | : 14-AUG-2021 |
| Signature By | : (Signature) |

SURFACE RESISTIVITY TEST – (Reference ASTM D257, ANSI / ESD S541 & ANSI / ESD STM 11.11)

- ☐ DISSIPATIVE : $\geq 1 \times 10^5$ AND $< 1 \times 10^{12}$ OHMS/SQ
- ☐ CONDUCTIVE : $< 1 \times 10^5$ OHMS/SQ
- ☒ VISUAL TEST
- ☒ DIMENSION CHECK (WIDTH, LENGTH & THICKNESS)
- ☐ WATER LEAK TEST
- ☒ LPC TEST
- ☒ SEAL/PEEL STRENGTH TEST
- ☐ PRINTING
- ☒ AMIDE & SILICON FREE
- ☐ CENTRE SEAL / WITH PERFORATION LINE
- ☐ NO CENTRE SEAL / WITHOUT PERFORATION

TESTED BY: *Rubalyat*
QC DEPARTMENT

VERIFIED BY: *(Signature)* EXECUTIVE



TOP IN PERFORMANCE

BAG 2 COC



TIP CORPORATION SDN BHD

FORM : QC-01 REV 9
Date Implement : 05.04.2018
REF NO : QC-01
DATE : 10.08.2021

☐ IN COMING QUALITY INSPECTION REPORT
CUSTOMER / SUPPLIER : SAFESKIN

LOT NO 61448 ☒ OUT GOING QUALITY INSPECTION REPORT

ITEM : C/R EASY TEAR LDPE BAG -355X405X0.045MM

QUANTITY 48,000 pcs

SAMPLING PLAN 0.85 single Plan Normal Inspection S3
Lot Qty SS
501 to 3,200pcs 13
3,201 to 35,000pcs 20
35,001 to 500,000pcs 32
500,001 pcs and over 50

Accept / Reject
Acc / Rej : 0/1
Acc / Rej : 0/1
Acc / Rej : 0/1
Acc / Rej : 0/1

PART NO: 06-HM-041-0-00

| DIMENSION / PHYSICAL INSPECTION | | | | | | | | | | | | | SURFACE RESISTIVITY TEST (EQUIPMENT : SRM10) | | | PROPERTIES OF MATERIAL | | | | | | | |
|---------------------------------|-----------------|-----|-----|--------|-----|-----|-----------|-----|-----|--------------|---------|--------------|--|--------------|-----------|------------------------|------|-------------------------------------|--------------------------------------|------------------------------------|---|--------------------------------|--|
| NO | DIMENSION CHECK | | | | | | THICKNESS | MAX | MIN | VISUAL OK/NG | REMARKS | EASY TO OPEN | SEAL STRENGTH | PRT / GUSSET | SAMPLE NO | | | CONDUCTIVE <input type="checkbox"/> | DISSIPATIVE <input type="checkbox"/> | INSULATOR <input type="checkbox"/> | TEST METHOD (ASTM D 257) <input type="checkbox"/> | OTHER <input type="checkbox"/> | |
| | WIDTH | MAX | MIN | LENGTH | MAX | MIN | | | | | | | | | OHM/SQ | RIGHT | LEFT | | | | | | |
| 1 | 355 | | | 410 | | | 0.047 | | | OK | OK | OK | OK | | NO | 1 | 11 | 10 | | | | | |
| 2 | 354 | | | 409 | | | 0.047 | | | | | | | | 2 | 10 | 10 | | | | | | |
| 3 | 355 | | | 410 | | | 0.048 | | | | | | | | 3 | 10 | 11 | | | | | | |
| 4 | 354 | | | 410 | | | 0.047 | | | | | | | | 4 | 11 | 10 | | | | | | |
| 5 | 355 | | | 409 | | | 0.048 | | | | | | | | 5 | 10 | 10 | | | | | | |
| 6 | 354 | | | 410 | | | 0.047 | | | | | | | | 6 | 11 | 11 | | | | | | |
| 7 | 355 | | | 409 | | | 0.048 | | | | | | | | 7 | 11 | 10 | | | | | | |
| 8 | 354 | | | 410 | | | 0.047 | | | | | | | | 8 | 10 | 11 | | | | | | |
| 9 | 355 | | | 409 | | | 0.048 | | | | | | | | 9 | 11 | 10 | | | | | | |
| 10 | 354 | | | 410 | | | 0.047 | | | | | | | | 10 | 11 | 11 | | | | | | |
| 11 | 355 | | | 409 | | | 0.048 | | | | | | | | 11 | 10 | 10 | | | | | | |
| 12 | 354 | | | 410 | | | 0.047 | | | | | | | | 12 | 11 | 11 | | | | | | |
| 13 | 355 | | | 409 | | | 0.048 | | | | | | | | 13 | 10 | 10 | | | | | | |
| 14 | 354 | | | 410 | | | 0.047 | | | | | | | | 14 | 11 | 11 | | | | | | |
| 15 | 355 | | | 409 | | | 0.048 | | | | | | | | 15 | 10 | 11 | | | | | | |
| 16 | 355 | OK | | 410 | OK | | 0.047 | OK | | OK | OK | OK | OK | | 16 | 11 | 10 | | | | | | |
| 17 | 354 | | | 409 | | | 0.048 | | | | | | | | 17 | 11 | 11 | | | | | | |
| 18 | 355 | | | 410 | | | 0.047 | | | | | | | | 18 | 10 | 10 | | | | | | |
| 19 | 354 | | | 409 | | | 0.048 | | | | | | | | 19 | 11 | 11 | | | | | | |
| 20 | 354 | | | 410 | | | 0.047 | | | | | | | | 20 | 11 | 10 | | | | | | |
| 21 | 355 | | | 409 | | | 0.047 | | | | | | | | 21 | 10 | 11 | | | | | | |
| 22 | 354 | | | 410 | | | 0.048 | | | | | | | | 22 | 11 | 10 | | | | | | |
| 23 | 355 | | | 409 | | | 0.047 | | | | | | | | 23 | 10 | 11 | | | | | | |
| 24 | 354 | | | 409 | | | 0.048 | | | | | | | | 24 | 11 | 10 | | | | | | |
| 25 | 354 | | | 410 | | | 0.047 | | | | | | | | 25 | 10 | 11 | | | | | | |
| 26 | 355 | | | 410 | | | 0.048 | | | | | | | | 26 | 11 | 10 | | | | | | |
| 27 | 354 | | | 409 | | | 0.048 | | | | | | | | 27 | 10 | 11 | | | | | | |
| 28 | 355 | | | 410 | | | 0.047 | | | | | | | | 28 | 10 | 10 | | | | | | |
| 29 | 354 | | | 409 | | | 0.048 | | | | | | | | 29 | 11 | 11 | | | | | | |
| 30 | 355 | | | 410 | | | 0.047 | | | | | | | | 30 | 10 | 10 | | | | | | |
| 31 | 354 | | | 409 | | | 0.048 | | | | | | | | 31 | 10 | 11 | | | | | | |
| 32 | 354 | | | 410 | | | 0.048 | | | | | | | | 32 | 11 | 11 | | | | | | |

REMARKS : ACCEPT ☒ REJECT ☐

Prepared By : *Cm*
Final disposition : OK
Accept / Reject : ACCEPT

Verified By : *HA*
Final Disposition : OK
Accept / Reject : ACCEPT

BAG 2 COC



TIP Corporation Sdn. Bhd.
Lot 608, Jalan Sg Sop, Off Jalan Sg Tekali, Batu
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FORM QC-21

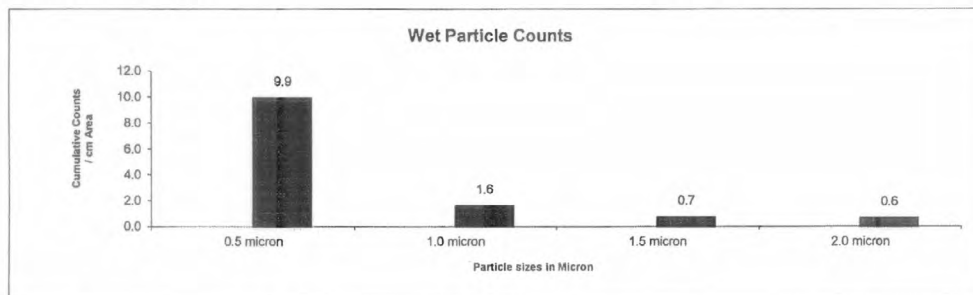
LPC Test Report

| | | |
|--------------------------------------|-------------------------------|----------------------------------|
| Item | : C/R EASY TEAR LDPE I Lot No | : 61448 |
| Testing Date | : 10.8.2021 | size : 355 X 405 X 0.05MM |
| Customer | : SAFESKIN | OUTGOING |
| Blank Particle Counts (Cumulative) | | 06-HM-041-0-00 |
| | Blank Cts 1 Counts/ml | Blank Cts 2 Counts/ml |
| 0.5 micron | 20.0 | 19.0 |
| 1.0 micron | 3.0 | 4.0 |
| 1.5 micron | 2.0 | 4.0 |
| 2.0 micron | 1.0 | 2.0 |
| | | Blank Ct 3 Counts/ml |
| | | 17.0 |
| | | Average Blank (A) Counts/ml |
| | | 18.7 |
| | | 3.0 |
| | | 2.7 |
| | | 4.0 |
| | | 2.3 Total counts |
| | | 26.666667 |

| | | | |
|--|---------------------------|---------------------------|-----------------------------------|
| Wash Sample Particle Counts (Cumulative) | | | |
| | Washed Cts 1 Counts/ml | Washed Cts 2 Counts/ml | Washed Cts 3 Counts/ml |
| 0.5 micron | 80.0 | 95.0 | 100.0 |
| 1.0 micron | 13.0 | 14.0 | 17.0 |
| 1.5 micron | 9.0 | 8.0 | 7.0 |
| 2.0 micron | 5.0 | 7.0 | 9.0 |
| | | | Average Washed (B) Counts/ml |
| | | | 91.7 |
| | | | 14.7 |
| | | | 8.0 |
| | | | 7.0 Total counts |
| | | | 121.33333 |

| | | | |
|--|------|-----------------------------|------------------------------------|
| Wet Particle Counts | | (C) | Total Vol. for Washed Sample (D) |
| Ave. Washed - Ave. Blank (C = B - A) | | | Washed Volume (ml) 400 ml |
| 0.5 micron | 73.0 | | |
| 1.0 micron | 11.7 | | |
| 1.5 micron | 5.3 | | |
| 2.0 micron | 4.7 | | |
| | | Total Area of Plastic (E) | |
| | | Total Area for wash | 2947 cm ² |

| | | |
|--|-----------|--|
| Total Particle Counts in Washed Volume (F) | | Total Wet Part Cts / cm ² (G) |
| (F = C x D) | | (G = F / E) |
| 0.5 micron | 29200 | 9.9083814 |
| 1.0 micron | 4666.6667 | 1.5835313 |
| 1.5 micron | 2133.3333 | 0.7239 |
| 2.0 micron | 1866.6667 | 0.6334125 |



Total Particle : 12.8492252

SPEC: $\geq 0.5\mu \leq 100$ COUNTS/CM²

Tested By : **MARIAM**
Date : 10.8.2021

Verified By :
Date : 10/8/2021

CASE LINER COC



TIP CORPORATION SDN BHD

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Semenyih, 43500 Selangor, Malaysia.
Tel: +603-8723 7889
E-mail: sales@tipcorp.com Website: www.tipcorp.com
SST No: W24-1808-21017734

FORM: QC-07 REV 10

Date Reviewed : 30.11.2017

Reg No 109091010224
1187330-A1



CERTIFICATE OF CONFORMANCE

THIS IS TO CERTIFY THAT THE FOLLOWING PRODUCT CONFORM/PASS THE SPECIFICATION LISTED BELOW:-

CUSTOMER : SAFESKIN

DESCRIPTION : CLEANROOM LDPE BAG WITH GUSSET 350 X 700 X 0.04mm + G150mm

QUANTITY : 20,000 PCS

LOT NO : K61449

PART NO : 06-HM-042-0-00

P.O NO. & DATE : 4561163570

TEST DATE : 06.08.2021

OUR INVOICE NO: TPL16653

PALLET REFERENCE
NUMBER (IF ANY): -

PACKING LIST NUMBER : TPL16653

DATE OF MANUFACTURING : N/A

DATE OF EXPIRED : N/A

Safeskin Thailand

D/O No. : TPL16653
IQA Batch : P3108087
Date : 11-AUG-2021
Signature By : [Signature]

SURFACE RESISTIVITY TEST – (Reference ASTM D257, ANSI / ESD S541 & ANSI / ESD STM 11.11)

- ☐ DISSIPATIVE : $\geq 1 \times 10^5$ AND $< 1 \times 10^{12}$ OHMS/SQ
- ☐ CONDUCTIVE : $< 1 \times 10^5$ OHMS/SQ
- ☒ VISUAL TEST
- ☒ DIMENSION CHECK (WIDTH, LENGTH & THICKNESS)
- ☐ WATER LEAK TEST
- ☒ LPC TEST
- ☒ SEAL/PEEL-STRENGTH TEST
- ☐ PRINTING
- ☒ AMIDE & SILICON FREE
- ☐ CENTRE SEAL / WITH PERFORATION LINE
- ☐ NO CENTRE SEAL / WITHOUT PERFORATION


TESTED BY: [Signature]

VERIFIED BY: [Signature]



TOP IN PERFORMANCE

CASE LINER COC



TIP CORPORATION SDN BHD

FORM : QC-01 REV 9
 Date Implement : 05.04.2018
 REF NO : QC-01
 DATE : 06.08.2021

☐ IN COMING QUALITY INSPECTION REPORT

CUSTOMER / SUPPLIER : **SAFESKIN MEDICAL**

ITEM : **CLEANROOM LDPE BAG 350 X 700 X 0.04mm + G150mm**

PART NO: 06-HM-042-0-00

☒ OUT GOING QUALITY INSPECTION REPORT

LOT NO : **K61449**


QUANTITY : **20,000 PCS**

SAMPLING PLAN 0.65 single Plan Normal Inspection S3

| | | |
|----------------------|----|-----------------|
| Lot Qty | 55 | Accept / Reject |
| 501 to 3,200pcs | 13 | Acc / Rej : 0/1 |
| 3,201 to 35,000pcs | 20 | Acc / Rej : 0/1 |
| 35,001 to 500,000pcs | 32 | Acc / Rej : 0/1 |
| 500,001 pcs and over | 50 | Acc / Rej : 0/1 |

| DIMENSION / PHYSICAL INSPECTION | | | | | | | | | | | | | | | SURFACE RESISTIVITY DATA (EQUIPMENT - SRM110) | | | PROPERTIES OF MATERIAL | |
|---------------------------------|-----------------|-------|-------|----------|-------|-------|-------------|--------|--------|--------|---------|--------------|---------------|--------------|---|--------|----|------------------------|--------|
| NO | DIMENSION CHECK | | | | | | | | | VISUAL | REMARKS | EASY TO OPEN | SEAL STRENGTH | PRT / GUSSET | SAMPLE NO | | | CONDUCTIVE | |
| | WIDTH | MAX | MIN | LENGTH | MAX | MIN | THICKNESS | MAX | MIN | | | | | | OK/NG | OHM/SQ | NO | | INSIDE |
| SPEC | 350±5mm | 355mm | 345mm | 700±10mm | 710mm | 690mm | 0.04±0.01mm | 0.05mm | 0.03mm | OK | | | | 150mm±10MM | | | | INSULATOR | |
| 1 | 351 | | | 702 | | | 0.05 | | | | | | | 151 | 1 | | | TEST METHOD | |
| 2 | 351 | | | 701 | | | 0.04 | | | | | | | 152 | 2 | | | (ASTM D 257) | |
| 3 | 350 | | | 702 | | | 0.04 | | | | | | | 152 | 3 | | | OTHER | |
| 4 | 350 | | | 702 | | | 0.04 | | | | | | | 150 | 4 | | | | |
| 5 | 351 | | | 701 | | | 0.05 | | | | | | | 152 | 5 | | | | |
| 6 | 350 | | | 702 | | | 0.04 | | | | | | | 152 | 6 | | | | |
| 7 | 351 | | | 702 | | | 0.04 | | | | | | | 152 | 7 | | | | |
| 8 | 351 | | | 701 | | | 0.04 | | | | | | | 150 | 8 | | | | |
| 9 | 350 | OK | OK | 702 | OK | OK | 0.05 | OK | OK | OK | | OK | OK | 152 | 9 | | | | |
| 10 | 350 | ↑ | ↑ | 702 | ↑ | ↑ | 0.04 | ↑ | ↑ | ↑ | | ↑ | ↑ | 150 | 10 | | | | |
| 11 | 351 | | | 701 | | | 0.04 | | | | | | | 152 | 11 | | | | |
| 12 | 350 | | | 702 | | | 0.04 | | | | | | | 152 | 12 | | | | |
| 13 | 351 | | | 702 | | | 0.05 | | | | | | | 152 | 13 | | | | |
| 14 | 351 | | | 701 | | | 0.04 | | | | | | | 152 | 14 | | | | |
| 15 | 350 | | | 702 | | | 0.05 | | | | | | | 150 | 15 | | | | |
| 16 | 350 | | | 702 | | | 0.04 | | | | | | | 152 | 16 | | | | |
| 17 | 351 | | | 701 | | | 0.04 | | | | | | | 150 | 17 | | | | |
| 18 | 350 | | | 702 | | | 0.04 | | | | | | | 152 | 18 | | | | |
| 19 | 351 | | | 702 | | | 0.05 | | | | | | | 152 | 19 | | | | |
| 20 | 351 | | | 702 | | | 0.04 | | | | | | | 151 | 20 | | | | |
| 21 | | | | | | | | | | | | | | | 21 | | | | |
| 22 | | | | | | | | | | | | | | | 22 | | | | |
| 23 | | | | | | | | | | | | | | | 23 | | | | |
| 24 | | | | | | | | | | | | | | | 24 | | | | |
| 25 | | | | | | | | | | | | | | | 25 | | | | |
| 26 | | | | | | | | | | | | | | | 26 | | | | |
| 27 | | | | | | | | | | | | | | | 27 | | | | |
| 28 | | | | | | | | | | | | | | | 28 | | | | |
| 29 | | | | | | | | | | | | | | | 29 | | | | |
| 30 | | | | | | | | | | | | | | | 30 | | | | |
| 31 | | | | | | | | | | | | | | | 31 | | | | |
| 32 | | | | | | | | | | | | | | | 32 | | | | |

REMARKS : ☒ ACCEPT ☐ REJECT

Prepared By : 

Final Disposition : **OK**

Accept / Reject : **Accept**

PACKING CONDITION INSPECTION

| SPEC | ACTUAL |
|-----------------|----------------|
| Qty per bag | 50PCS |
| Qty per carton | 500PCS |
| Carton size | T10 |
| PN vs Actual | 06-HM-042-0-00 |
| Label In vs Out | OK |

Verified By : **HAJAR**

Final Disposition : **OK**

Accept / Reject : **Accept**

CASE LINER COC



TIP CORPORATION SDN BHD

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Semenyih, 43500 Selangor, Malaysia.
Tel: +603-8723 7889
E-mail: sales@tipcorp.com Website: www.tipcorp.com
SST No: W24-1808-21017734



FORM QC-21

LPC Test Report

Item: C/R LDPE BAG

Lot No: K61449

Testing Date: 06.08.2021

Size: 650X700X0.04MM

Customer: SAFESKIN

Method: BY SHAKER

Blank Particle Counts (Cumulative)

Machine: KCCS-6

| | Blank Cts 1 | Blank Cts 2 | Blank Ct 3 | Average Blank (A) | |
|------------|-------------|-------------|------------|-------------------|-----|
| | Counts | Counts | Counts | Counts | |
| 0.5 micron | 4.0 | 2.0 | 0.0 | 2.0 | |
| 1.0 micron | 1.0 | 0.0 | 0.0 | 0.3 | |
| 2.0 micron | 0.0 | 0.0 | 0.0 | 0.0 | |
| 5.0 micron | 0.0 | 0.0 | 0.0 | 0.0 Total counts | 2.3 |

Wash Sample Particle Counts (Cumulative)

| | Washed Cts 1 | Washed Cts 2 | Washed Cts 3 | Average Washed (B) | |
|------------|--------------|--------------|--------------|--------------------|-------|
| | Counts | Counts | Counts | Counts | |
| 0.5 micron | 124.0 | 134.0 | 112.0 | 123.3 | |
| 1.0 micron | 21.0 | 26.0 | 19.0 | 22.0 | |
| 2.0 micron | 8.0 | 5.0 | 8.0 | 7.0 | |
| 5.0 micron | 2.0 | 2.0 | 2.0 | 2.0 Total counts | 154.3 |

(C) Wet Particle Counts

Ave. Washed - Ave. Blank (C = B - A)

| | |
|------------|-------|
| 0.5 micron | 121.3 |
| 1.0 micron | 21.7 |
| 2.0 micron | 7.0 |
| 5.0 micron | 2.0 |

(D) Total Vol. for Washed Sample

Washed Volume (ml) 1000 ml

(E) Sampling size 5 ml

(F) Total Area of Plastic

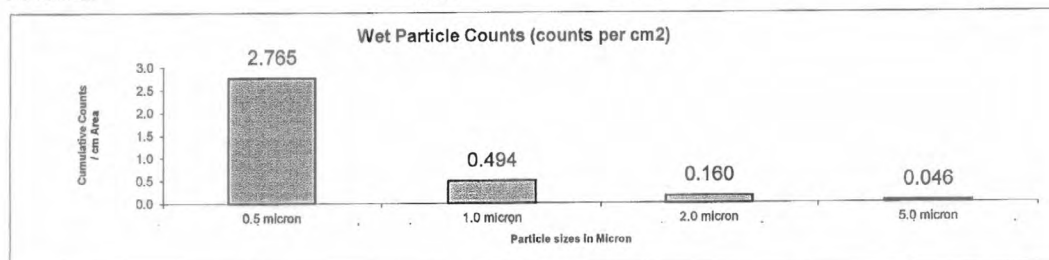
Total Washed Area 8775 cm²

(G) Particle counts per ml (G = C / E)

| | |
|------------|--------|
| 0.5 micron | 24.267 |
| 1.0 micron | 4.333 |
| 2.0 micron | 1.400 |
| 5.0 micron | 0.400 |

(H) Total Wet Part Cts / cm² (H = G X D / F)

| | |
|------------|-------|
| 0.5 micron | 2.765 |
| 1.0 micron | 0.494 |
| 2.0 micron | 0.160 |
| 5.0 micron | 0.046 |



Total Particle (≥0.5): 3.464 (PASSED)

SPEC: ≥ 0.5u ≤ 100 COUNTS/CM²

Tested By: SUHAIDA

Date: 06.08.2021

Verified By:

Date: 06.08.2021

SAFETY DATA SHEET





SAFETY DATA SHEET

HALYARD* PUREZERO* HG3 Nitrile Gloves

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 (29CFR 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

| <i>Chemical Name</i> | <i>CAS-No./ EINECS-No</i> | <i>%</i> | <i>GHS Classification:</i> |
|---------------------------|-------------------------------|----------|----------------------------|
| 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.



SAFETY DATA SHEET

HALYARD PUREZERO* HG3 Nitrile Gloves*

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.



SAFETY DATA SHEET

HALYARD* PUREZERO* HG3 Nitrile Gloves

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.



SAFETY DATA SHEET

HALYARD* PUREZERO* HG3 Nitrile Gloves

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.



July 11, 2023

RE: HALYARD* PUREZERO* HG3 and HG5 Cleanroom Nitrile Gloves

O&M Halyard, Inc. confirms that our Halyard **PUREZERO*** HG3 and Halyard **PUREZERO** HG5 Nitrile Cleanroom Glove families are fully compliant with the related requirements of the European Union Regulation (EC) 1907/2006 concerning Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH).

O&M Halyard, Inc. hereby confirms that our Halyard **PUREZERO*** HG3 and Halyard **PUREZERO** HG5 Nitrile Cleanroom Gloves either do not contain the presence of greater than 0.1% of substances identified on the SVHC Candidate list according to Article 33 of the REACH Regulation and/or do not contain any of the listed substances.

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,

A handwritten signature in black ink, appearing to read 'Caitlin Senter'.

Caitlin Senter

Director

Global Regulatory Affairs

O&M Halyard, Inc.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Safeskin Medical & Scientific
(Thailand) Ltd.
200 Moo 8, Kanchanavanich Road,
Tambol Prik, Amphur Sadao,
Songkhla
90120
Thailand

Holds Certificate Number:

FM 697757

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design and Development, Production and Distribution of Industrial Gloves-Sterile and Non-Sterile Examination Gloves.

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2018-08-12

Latest Revision Date: 2021-07-16

Effective Date: 2021-08-12

Expiry Date: 2024-08-11

Page: 1 of 2



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An electronic certificate can be authenticated [online](https://www.bsi-global.com/ClientDirectory).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

ISO 9001:2015 (continued)

Certificate No: **FM 697757**

Location

Safeskin Medical & Scientific
(Thailand) Ltd.
200 Moo 8, Kanchanavanich Road,
Tambol Prik, Amphur Sadao,
Songkhla
90120
Thailand

Registered Activities

Design and Development, Production and Distribution of
Industrial Gloves-Sterile and Non-Sterile Examination Gloves.

Including the following support function:
Owens & Minor Halyard Incorporation, 5405 Windward
Parkway, Alpharetta, GA, USA : Design and Development of
Industrial Gloves-Sterile and Non-Sterile Examination Gloves.



Original Registration Date: 2018-08-12

Latest Revision Date: 2021-07-16

Effective Date: 2021-08-12

Expiry Date: 2024-08-11

Page: 2 of 2

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Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 735497

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of sterile and non-sterile medical examination gloves.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-11-25

Latest Revision Date: 2023-01-05

Effective Date: 2023-01-09

Expiry Date: 2026-01-08



Page: 1 of 2

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ISO 13485:2016 (continued)

Certificate No: **MD 735497**

| Location | Registered Activities |
|--|--|
| O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA | Headquarter management activities. |
| O & M Halyard, Inc. 1 Edison Drive Alpharetta Georgia 30005 USA | The design and development of sterile and non-sterile medical examination gloves. |
| Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand | Design, development, manufacture and distribution of sterile and non-sterile medical examination gloves. |

Original Registration Date: 2020-11-25
Latest Revision Date: 2023-01-05

Effective Date: 2023-01-09
Expiry Date: 2026-01-08

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#)



Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

Safeskin Medical & Scientific
(Thailand) Ltd.
200 Moo 8, Kanchanavanich Road,
Tambol Prik, Amphur Sadao,
Songkhla
90120
Thailand

Holds Certificate Number:

EMS 772160

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

The Manufacturing of Medical and Scientific Gloves.

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2022-10-27

Latest Revision Date: 2022-10-27

Effective Date: 2022-10-27

Expiry Date: 2025-10-26

Page: 1 of 1



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



May 4, 2023

RE: **HALYARD* PUREZERO* HG3 and HG5 Nitrile Gloves**

Dear Valued Customer,

This letter is in response to your recent accelerator-free inquiry for the **HALYARD* PUREZERO* HG3 and HG5 Nitrile Gloves**.

The following gloves are accelerator-free and are not formulated with the following vulcanizing chemicals and accelerators: Sulfur, Thiurams, Thioxoles, Guanidines, Carbamates.[†]

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

HALYARD* PUREZERO* HG5 White Nitrile Gloves
HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves

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
O&M Halyard, Inc.

[†] The chemicals and accelerators shown is not a comprehensive list.

*Registered Trademark or Trademark of O&M Halyard or its affiliates.

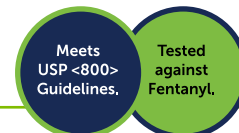
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HG3 Nitrile Cleanroom Gloves

ADDED PROTECTION FROM THE RISK OF CHEMICAL EXPOSURE

It's critical to protect staff from exposure to potentially hazardous chemicals and chemotherapy drugs. In addition to providing a barrier to chemical splash, microorganisms and viruses, **PUREZERO* HG3 Cleanroom Gloves are now tested against 29 chemicals, 14 chemotherapy drugs and Fentanyl.**

CHEMOTHERAPY DRUG RESISTANCE GUIDE⁴



| Chemotherapy Agent (Concentration in mg/ml) | HALYARD* PUREZERO* HG3 White Nitrile Gloves | |
|---|---|---|
| | Minimum Breakthrough Detection Time (minutes) | Average Steady State Perm. Rate (µg/cm ² /min) |
| Carmustine (BCNU) (3.3) | 55.4 | 0.50 |
| Cisplatin (1.0) | >240 | N/A |
| Cyclophosphamide (20.0) | >240 | N/A |
| Dacarbazine (10.0) | >240 | N/A |
| Doxorubicin HCL (2.0) | >240 | N/A |
| Etoposide (20.0) | >240 | N/A |
| Fluorouracil (50.0) | >240 | N/A |
| Ifosfamide (50.0) | >240 | N/A |
| Methotrexate (25.0) | >240 | N/A |
| Mitomycin C (0.5) | >240 | N/A |
| Mitoxantrone (2.0) | >240 | N/A |
| Paclitaxel (6.0) | >240 | N/A |
| Thiotepa (10.0) | 48.8 | 0.23 |
| Vincristine (1.0) | >240 | N/A |
| Additional Tests | | |
| Fentanyl Citrate Injection, 100 mcg/2mL | >240 | N/A |

Use the rating system below to determine the chemotherapy compatibility for exposure:

| | |
|----------|--|
| <10 | Not recommended for use - breakthrough can occur in less than 10 minutes. |
| 11 - 239 | Use with caution - breakthrough can occur between 11 and 239 minutes. |
| >240 | Recommended for protection - no breakthrough up to 240 minutes. |
| N/A | The chemotherapy drug did not reach the minimum permeation rate (0.01 µg/cm ² /min) as defined within ASTM D6978. |

CAUTION: It's the user's responsibility to determine the applicability of these gloves for their intended use with chemotherapy drugs.

DEFINITION OF TERMS

Breakthrough time: The time required for the test chemical to be detected on the inside of the glove. Essentially, this is the amount of time that the glove can resist a chemical when the glove is fully immersed in the chemical.

Permeation: The process where chemicals, such as liquids, gases and vapors can pass through a glove film (or other PPE interfaces) without penetrating directly through a pinhole, tear or other visible opening.

Permeation rate: The flowrate of the chemical after the chemical breaks through the inside of the glove. It is measured in amount per surface area of the glove per time (µg/cm²/min).

HG3 Nitrile Cleanroom Gloves

CHEMICAL RESISTANCE GUIDE⁵

| Chemical (Concentration %) | HALYARD* PUREZERO HG3 White Nitrile Gloves | |
|--|---|---|
| | Minimum Breakthrough Detection Time (minutes) | Average Steady State Perm. Rate (µg/cm ² /min) |
| 1-Butanol (99) | 173.0 | 1.5 |
| Acetic Acid (30) | 388.9 | 4.5 |
| Acrylamide (40) | >480 | <1.0 |
| Benzalkonium Chloride (1) | >480 | <1.0 |
| Chloroform (70) | 0 | — |
| Citric Acid (30) | >480 | N/A |
| Citric Acid (70) | >480 | <1.0 |
| Cyclohexane (99) | 261.6 | 1.7 |
| Didecyltrimethylammonium Chloride (0.04) | >480 | <1.0 |
| Dimethylformamide (99) | 0 | N/A |
| Dimethyl Sulfoxide (99) | 10.1 | 3.6E+01 |
| Ethanol (70) | 42.2 | 12.5 |
| Ethanol (99) | 14.5 | 9.4E+01 |
| Ethidium Bromide (1) | >480 | <1.0 |
| Glycolic Acid (10) | >480 | <1.0 |
| Glutaraldehyde (50) | >480 | <1.0 |
| Hydrazine Monohydrate (55) | >480 | 0.1 |
| Hydrochloric Acid (30) | >480 | <1.0 |
| Isopropyl Alcohol (70) | 125.7 | 1.7 |
| Isopropyl Alcohol (99) | 102.2 | 4.3 |
| Methanol (99) | 4.2 | 4.5E+01 |
| Nitric Acid (65) | 16.0 | 2.0E+02 |
| Peracetic Acid (5) | >480 | <1.0 |
| Phosphoric Acid (70) | >480 | <1.0 |
| Sodium Hydroxide (50) | >480 | <1.0 |
| Sodium Hypochlorite (10-13) | >480 | <1.0 |
| Spor-Klenz (N/A) | >480 | <1.0 |
| Sulfuric Acid (50) | >480 | <1.0 |
| Sulfuric Acid (99) | 12.0 | N/A |

Use the rating system below to determine the chemical compatibility for exposure:

| | |
|----------|--|
| <10 | Not recommended for use - breakthrough can occur in less than 10 minutes. |
| 11 - 479 | Use with caution - breakthrough can occur between 11 and 479 minutes. |
| >480 | Permeation breakthrough is excellent. Permeation does not occur during the test (8 hours). |
| N/A | The chemical did not reach the minimum permeation rate (1 µg/cm ² /min) as defined within EN 16523-1. There is a possibility for trace amounts of the chemical to permeate through the glove. |
| — | The permeation rate was beyond the range of the detection instruments. The permeation of the chemical through the glove film may be too high for the detector to reach a steady-state reading. |

CAUTION: It's the user's responsibility to determine the applicability of these gloves for their intended use.



November 13th, 2023

RE: **ESD Testing for HALYARD* PUREZERO* Nitrile Gloves**

Dear Valued Customer,

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

The following **HALYARD* PUREZERO* Nitrile Glove** families have been tested against ANSI/ESD STM15.1:2019 "In-Use Resistance Testing of Gloves and Finger Cots":

HALYARD* PUREZERO* HG3 Cleanroom Nitrile Gloves

| <u>Glove Description</u> | <u>Code</u> |
|--|--------------------|
| HALYARD* PUREZERO* HG3 White Nitrile Gloves | CLN3031XS |
| HALYARD* PUREZERO* HG3 White Nitrile Gloves | CLN3031SM |
| HALYARD* PUREZERO* HG3 White Nitrile Gloves | CLN3031MD |
| HALYARD* PUREZERO* HG3 White Nitrile Gloves | CLN3031LG |
| HALYARD* PUREZERO* HG3 White Nitrile Gloves | CLN3031XL |
| HALYARD* PUREZERO* HG3 Blue Nitrile Gloves | CLN9031XS |
| HALYARD* PUREZERO* HG3 Blue Nitrile Gloves | CLN9031SM |
| HALYARD* PUREZERO* HG3 Blue Nitrile Gloves | CLN9031MD |
| HALYARD* PUREZERO* HG3 Blue Nitrile Gloves | CLN9031LG |
| HALYARD* PUREZERO* HG3 Blue Nitrile Gloves | CLN9031XL |
| HALYARD* PUREZERO* HG3 White SGX* Nitrile Gloves | CLN3231XS |
| HALYARD* PUREZERO* HG3 White SGX* Nitrile Gloves | CLN3231SM |
| HALYARD* PUREZERO* HG3 White SGX* Nitrile Gloves | CLN3231MD |
| HALYARD* PUREZERO* HG3 White SGX* Nitrile Gloves | CLN3231LG |
| HALYARD* PUREZERO* HG3 White SGX* Nitrile Gloves | CLN3231XL |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323260 |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323265 |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323270 |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323275 |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323280 |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323285 |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323290 |
| HALYARD* PUREZERO* HG3 White Sterile Nitrile Gloves | CLN323210 |

| | |
|---|-----------|
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923260 |
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923265 |
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923270 |
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923275 |
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923280 |
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923285 |
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923290 |
| HALYARD* PUREZERO* HG3 Blue Sterile Nitrile Gloves | CLN923210 |

HALYARD* **PUREZERO* HG5 Cleanroom Nitrile Gloves**

| <u>Glove Description</u> | <u>Code</u> |
|--|--------------------|
| HALYARD* PUREZERO* HG5 White Nitrile Gloves | CLN30512XS |
| HALYARD* PUREZERO* HG5 White Nitrile Gloves | CLN30512SM |
| HALYARD* PUREZERO* HG5 White Nitrile Gloves | CLN30512MD |
| HALYARD* PUREZERO* HG5 White Nitrile Gloves | CLN30512LG |
| HALYARD* PUREZERO* HG5 White Nitrile Gloves | CLN30512XL |
| HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves | CLN92512XS |
| HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves | CLN92512SM |
| HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves | CLN92512MD |
| HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves | CLN92512LG |
| HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves | CLN92512XL |

HALYARD* **PUREZERO* Nitrile Exam Gloves**

| <u>Glove Description</u> | <u>Code</u> |
|---|--------------------|
| HALYARD* PUREZERO* MARIN* Nitrile Exam Gloves | LFS111XS |
| HALYARD* PUREZERO* MARIN* Nitrile Exam Gloves | LFS111SM |
| HALYARD* PUREZERO* MARIN* Nitrile Exam Gloves | LFS111MD |
| HALYARD* PUREZERO* MARIN* Nitrile Exam Gloves | LFS111LG |
| HALYARD* PUREZERO* MARIN* Nitrile Exam Gloves | LFS111XL |
| HALYARD* PUREZERO* MARIN-XTRA* Nitrile Exam Gloves | LFS121XS |
| HALYARD* PUREZERO* MARIN-XTRA* Nitrile Exam Gloves | LFS121SM |
| HALYARD* PUREZERO* MARIN-XTRA* Nitrile Exam Gloves | LFS121MD |
| HALYARD* PUREZERO* MARIN-XTRA* Nitrile Exam Gloves | LFS121LG |
| HALYARD* PUREZERO* MARIN-XTRA* Nitrile Exam Gloves | LFS121XL |
| HALYARD* PUREZERO* LIMON* Nitrile Exam Gloves | LFS311XS |
| HALYARD* PUREZERO* LIMON* Nitrile Exam Gloves | LFS311SM |
| HALYARD* PUREZERO* LIMON* Nitrile Exam Gloves | LFS311MD |

| | |
|---|----------|
| HALYARD* PUREZERO* LIMON* Nitrile Exam Gloves | LFS311LG |
| HALYARD* PUREZERO* LIMON* Nitrile Exam Gloves | LFS311XL |
| HALYARD* PUREZERO* LIMON-XTRA* Nitrile Exam Gloves | LFS321XS |
| HALYARD* PUREZERO* LIMON-XTRA* Nitrile Exam Gloves | LFS321SM |
| HALYARD* PUREZERO* LIMON-XTRA* Nitrile Exam Gloves | LFS321MD |
| HALYARD* PUREZERO* LIMON-XTRA* Nitrile Exam Gloves | LFS321LG |
| HALYARD* PUREZERO* LIMON-XTRA* Nitrile Exam Gloves | LFS321XL |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves | LFS511XS |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves | LFS511SM |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves | LFS511MD |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves | LFS511LG |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Exam Gloves | LFS511XL |

HALYARD* **PUREZERO* Nitrile Gloves**

| <u>Glove Description</u> | <u>Code</u> |
|--|--------------------|
| HALYARD* PUREZERO* MARIN* Nitrile Gloves | LFS1117XS |
| HALYARD* PUREZERO* MARIN* Nitrile Gloves | LFS1117SM |
| HALYARD* PUREZERO* MARIN* Nitrile Gloves | LFS1117MD |
| HALYARD* PUREZERO* MARIN* Nitrile Gloves | LFS1117LG |
| HALYARD* PUREZERO* MARIN* Nitrile Gloves | LFS1117XL |
| HALYARD* PUREZERO* LIMON* Nitrile Gloves | LFS3117XS |
| HALYARD* PUREZERO* LIMON* Nitrile Gloves | LFS3117SM |
| HALYARD* PUREZERO* LIMON* Nitrile Gloves | LFS3117MD |
| HALYARD* PUREZERO* LIMON* Nitrile Gloves | LFS3117LG |
| HALYARD* PUREZERO* LIMON* Nitrile Gloves | LFS3117XL |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Gloves | LFS5117XS |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Gloves | LFS5117SM |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Gloves | LFS5117MD |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Gloves | LFS5117LG |
| HALYARD* PUREZERO* ULTRA VIOLET* Nitrile Gloves | LFS5117XL |

Based on the ANSI/ESD STM15.1:2019 test results from an external laboratory at conditions of 12% RH and 23°C, all **HALYARD* **PUREZERO*** 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*** 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,

Caitlin Senter
Director
Global Regulatory Affairs
O&M Halyard, Inc.

Ryan Solan
Manager
Global Research and Development
O&M Halyard, Inc.

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COPY-04825



RE: Compliance statement – HALYARD* **PUREZERO*** Nitrile Gloves

Please be advised that to the best of O&M Halyard knowledge, the **PUREZERO*** HG3 Nitrile Gloves and HALYARD* **PUREZERO*** HG5 Nitrile Gloves are produced entirely from materials of synthetic origin and therefore are free from human or any other animal derived materials including bovine products (Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE)).

- *Under various environmental protection and product safety regulations, directives, standards, and initiatives “intentionally introduced” means “deliberately utilized during the manufacture of the components and/or for the formulation of a material or component where its continued presence is desired in the final product to provide a specific property, appearance or quality.”*

This information is based on O&M Halyard, Inc.'s knowledge of these products at the time of publication.

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.

–This statement is valid unsigned –

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March 14th, 2023

RE: **HALYARD* PUREZERO* Nitrile Gloves**

Dear Valued Customer,

This letter is in response to your recent inquiry regarding storage conditions of **HALYARD* PUREZERO* Nitrile Gloves**.

As displayed by the indications on the packaging labeling, **HALYARD* PUREZERO* 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. To reduce the potential of accelerated aging, it is recommended to store the product at standard room temperature conditions, when possible.

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,



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



Theresa McCoy
Global Product Manager
Global Strategic Marketing
O&M Halyard, Inc.

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COPY-04606



September 24, 2023

RE: HALYARD* PUREZERO* HG3 and HG5 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding the presence of silicone for the **PUREZERO* HG3 White Nitrile Gloves**, **PUREZERO* HG3 White SGX* Nitrile Gloves**, **PUREZERO* HG3 Light Blue Nitrile Gloves**, **PUREZERO* HG3 Sterile Light Blue Nitrile Gloves**, **PUREZERO* HG3 Sterile White Nitrile Gloves**, **HALYARD* PUREZERO* HG5 White Nitrile Gloves**, and **HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves**.

According to ASTM E1252 Standard Practice for General Techniques for Obtaining Spectra for Qualitative Analysis, the results below reflect the detectable limits of silicone covering the spectral range from 4000cm^{-1} to 50cm^{-1} via FT-IR (Fourier Transform Infrared Analysis). The results below indicate that the **HALYARD* PUREZERO* HG3 NITRILE GLOVES** and **HALYARD* PUREZERO* HG5 NITRILE GLOVES** have no silicone detectable on the outside surface and inside surface of either gloves sampled per 3rd party testing.

The following product codes are applicable: **PUREZERO* HG3 White Nitrile Gloves**: CLN92512XS, CLN92512SM, CLN92512MD, CLN92512LG, CLN92512XL; **PUREZERO* HG3 Light Blue Nitrile Gloves**: CLN90511XS, CLN90511SM, CLN90511MD, CLN90511LG, CLN90511XL; **PUREZERO* HG3 White SGX* Nitrile Gloves**: CLN3031XS, CLN3031SM, CLN3031MD, CLN3031LG, CLN3031XL; **PUREZERO* HG3 Sterile White Nitrile Gloves**: CLN323260, CLN323265, CLN323270, CLN323275, CLN323280, CLN323290, CLN323210; **PUREZERO* HG3 Sterile Light Blue Nitrile Gloves**: CLN923260, CLN923265, CLN923270, CLN923275, CLN923280, CLN923285, CLN923290, CLN923210; **HALYARD* PUREZERO* HG5 White Nitrile Gloves**: CLN30512XS, CLN30512SM, CLN30512MD, CLN30512LG, and CLN30512XL; **HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves**: CLN92512XS, CLN92512SM, CLN92512MD, CLN92512LG, and CLN92512XL.

| Fourier Transform Infrared Analysis (FT-IR) Per ASTM E1252-98(21) | |
|--|---------------------|
| Gloves | Results |
| PUREZERO* HG3 and HG5 Nitrile Gloves | No silicon detected |

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

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COPY-04662



A handwritten signature in black ink, reading 'Caitlin Senter'.

Caitlin Senter
Director
Global Regulatory Affairs
O&M Halyard, Inc.

A handwritten signature in black ink, reading 'Nimia Maya'.

Nimia Maya
R&D Engineer II
Global Research and Development
O&M Halyard, Inc.

TITLE: HALYARD* **PUREZERO*** HG3 & HG5 Nitrile Gloves Packaging

UPDATE: Alternate packaging supplier for HALYARD* **PUREZERO*** HG3 and HG5 Nitrile Gloves

WHAT YOU NEED TO KNOW:

There will be an alternate supplier for the packaging (poly bag, poly pouch and poly wallet) used for **HALYARD* **PUREZERO*** HG3 and HG5 Nitrile Gloves**

WHAT YOU CAN EXPECT:

There is an alternate supplier being qualified to supply the poly bag, poly pouch and poly wallet used to package **HALYARD* **PUREZERO*** HG3 and HG5 Nitrile Gloves**. The alternate supplier, TAKO Astatic Technology SDN BHD, will supply the same packaging as our current supplier, Tip Corporation SDN BHD. All specifications for the packaging, including the material, composition, dimensions, thickness, and ink, will be identical to the current packaging. There will be no change to the appearance of the packaging or printing. There will be no change to the sterilization process or the sterility assurance level of the products. Additionally, there will be no changes to the product codes or product labeling.

TIMING OF CHANGE: There will be a rolling change for the alternate supplier's packaging that will enter our inventory as early as December 2023. Both packaging vendors could be used based on supply chain availability.



PRODUCTS IMPACTED BY THIS CHANGE:

| |
|--|
| PUREZERO* HG3 White Nitrile Gloves |
| CODE |
| CLN3031XS |
| CLN3031SM |
| CLN3031MD |
| CLN3031LG |
| CLN3031XL |
| PUREZERO* HG3 Light Blue Nitrile Gloves |
| CODE |
| CLN9031XS |
| CLN9031SM |
| CLN9031MD |
| CLN9031LG |
| CLN9031MD |
| PUREZERO* HG3 White SGX* Nitrile Gloves |
| CODE |
| CLN3231XS |
| CLN3231SM |
| CLN3231MD |
| CLN3231LG |
| CLN3231XL |
| PUREZERO* HG3 White Sterile Nitrile Gloves |
| CODE |
| CLN323260 |
| CLN323265 |
| CLN323270 |
| CLN323275 |
| CLN323280 |
| CLN323285 |
| CLN323290 |
| CLN323210 |
| PUREZERO* HG3 Light Blue Sterile Nitrile Gloves |
| CODE |
| CLN923260 |
| CLN923265 |
| CLN923270 |
| CLN923275 |
| CLN923280 |
| CLN923285 |
| CLN923290 |
| CLN923210 |

1 Edison Drive, Alpharetta, GA 30005 | 844.425.9273
owens-minor.com | halyardhealth.com | byramhealthcare.com



| |
|---|
| PUREZERO* HG5 White Nitrile Gloves |
| CODE |
| CLN30512XS |
| CLN30512SM |
| CLN30512MD |
| CLN30512LG |
| CLN30512XL |
| PUREZERO* HG5 Blue SGX* Nitrile Gloves |
| CODE |
| CLN92512XS |
| CLN92512SM |
| CLN92512MD |
| CLN92512LG |
| CLN92512XL |

Thank you for your interest in HALYARD* products. If you have any questions or need additional information including example certifications, please do not hesitate to contact us at PIQ@hyh.com, call us directly at 1-844-425-9273 or reach out to your O&M Halyard commercial representative or distributor.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gustavo Fiallos'.

Gustavo Fiallos
Director Global Quality Operations, Owens & Minor

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