

Halyard



Halyard Nitril-Handschuhe PUREZERO HG3 weiß #CLN3031SM

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

Farbe: Weiß; Größe: S / VE: 1000STK

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

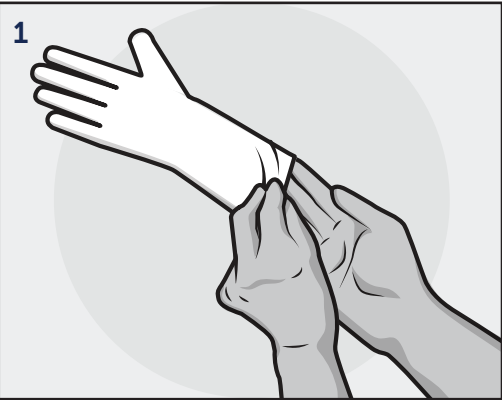
Farbe: Weiß; Größe: XL / VE: 1000STK

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



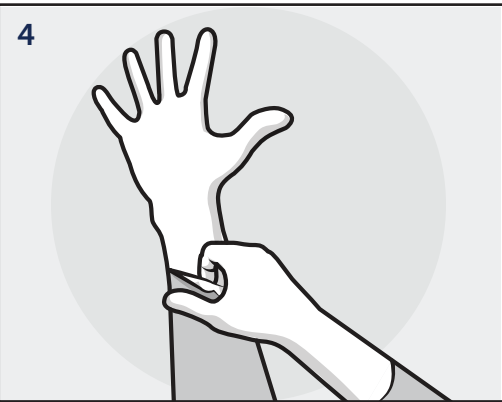
Grasp the beaded cuff of one glove and carefully pull over the opposite hand.



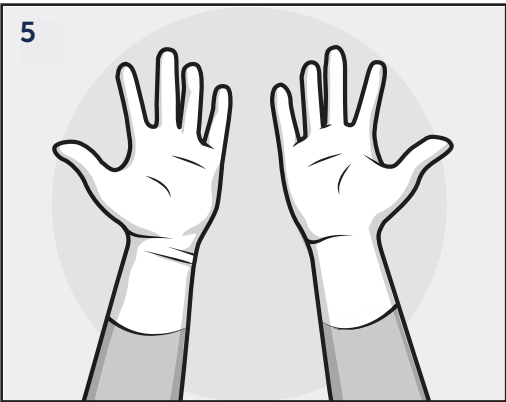
Gently ease the glove up over the hand and wrist.



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

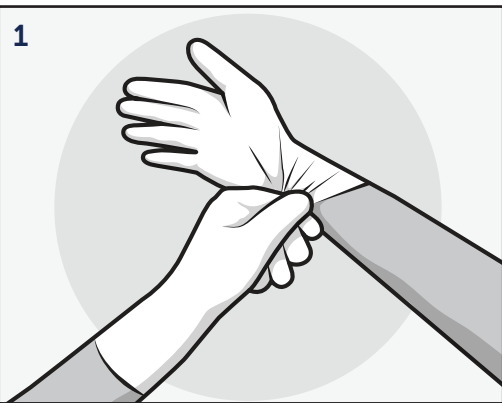


Gently ease the glove up over the hand and wrist.

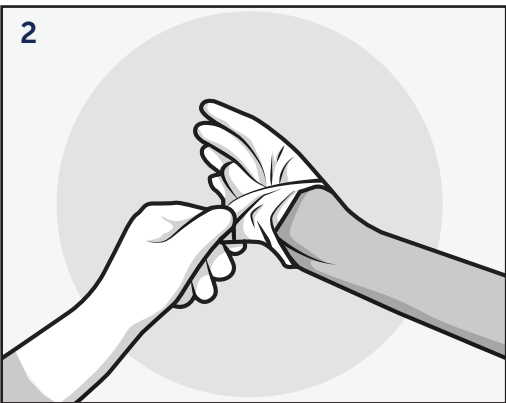


You are now ready to perform your task.

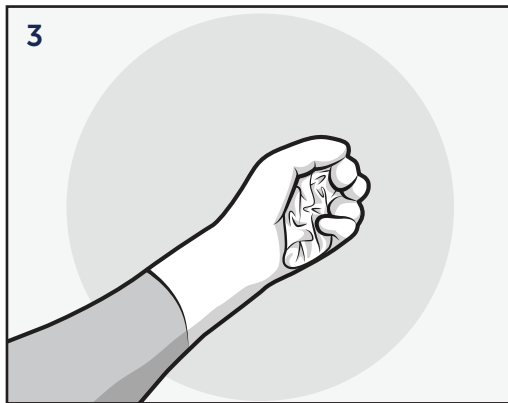
DOFFING GLOVES



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



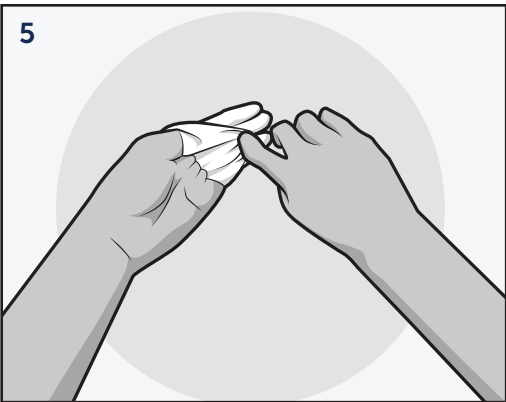
Carefully pull the glove off your hand, turning it inside-out.



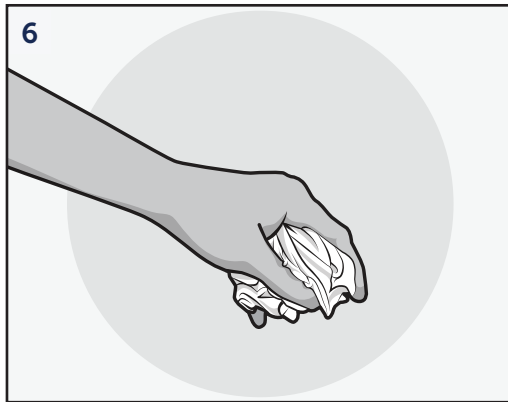
Ball the glove up and hold in your other gloved hand.



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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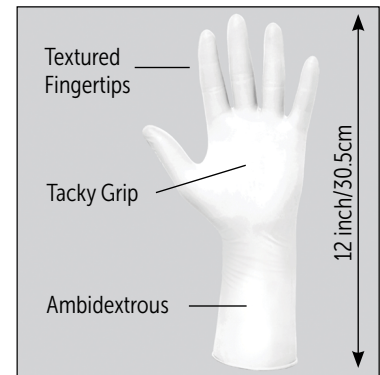
TECHNICAL DATA SHEET



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

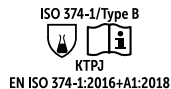
HALYARD* PUREZERO* Nitrile Gloves shall be stored in conditions where the product is kept dry (away from moisture), away from direct sunlight, away from sources of heat, and away from radioactive sources.

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

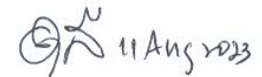
	Anions Results				Cations Results			
	Chloride	Nitrate	Sulfate	Sodium	Ammonium	Potassium	Magnesium	Calcium
Units :	Cl ⁻	NO ₃ ⁻	SO ₄ ⁻²	Na ⁺	NH ₄ ⁺	K ⁺	Mg ⁺²	Ca ⁺²
µg/g glove	25.912	4.810	1.325	1.754	1.286	1.749	1.274	42.222
Inspection Result :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept

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

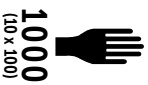


PUREZERO* HG3

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) 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 1.0 Level 2 CI	ISO 374-5:2016 VIRUS	ISO 374-1/Type B KTP3
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EN ISO 374-1:2016+A1:2018

104816981

CLN3031MD



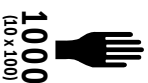
3 06 80651 48169 7

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) ホワイテニトリルグローブ
- (KO) 흰색 니트릴 장갑
- (ZH) HG3 白色丁腈手套

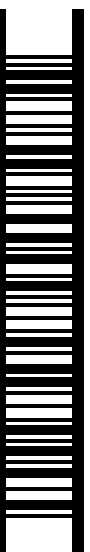


AQL 1.0 Level 2 CI	ISO 374-5:2016 VIRUS	ISO 374-1/Type B KTP3
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EN ISO 374-1:2016+A1:2018

104816981

CLN3031MD



3 06 80651 48169 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			CE 2797 (PPE Cat. III)	UK CA 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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Place Label Here

06-HM-089-0-02

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
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

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	DISSIPATIVE	INSULATOR	TEST METHOD (ASTM D 257)	OTHER	
	WIDTH	MAX	MIN	LENGTH	MAX	MIN									NO	RIGHT	LEFT						
SPEC	355±5	360	350	405±10	415	395	0.05±0.01	0.05	0.04	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
1	353			410			0.05										1	10	11				
2	354			411			0.05										2	11	11				
3	353			410			0.05										3	11	10				
4	354			410			0.05										4	10	11				
5	353			411			0.05										5	11	10				
6	354			410			0.05										6	10	11				
7	353			411			0.05										7	11	10				
8	354			410			0.05										8	10	11				
9	353			411			0.05										9	11	10				
10	354	OK		411	OK		0.05	OK		OK	OK	OK	OK	OK	OK	OK	10	11	11				
11	353			410			0.05										11	10	10				
12	354			410			0.05										12	11	11				
13	353			411			0.05										13	10	10				
14	354			411			0.05										14	11	11				
15	353			410			0.05										15	10	10				
16	354			411			0.05										16	11	11				
17	353			410			0.05										17	10	11				
18	354			411			0.05										18	11	10				
19	353			410			0.05										19	11	10				
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32																	32						

REMARKS : ACCEPT ☒ REJECT ☐

Prepared By : *[Signature]*
Final disposition : OK
Accept / Reject : ACCEPT

Verified By : *[Signature]*
Final Disposition : OK
Accept / Reject : ACCEPT



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 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													SAMPLE NO			PROPERTIES OF MATERIAL						
NO	DIMENSION CHECK						THICKNESS	MAX	MIN	VISUAL	REMARKS	EASY TO OPEN	SEAL STRENGTH	PRT / GUSSET	OHM/SQ SEAL			CONDUCTIVE	DISSIPATIVE	INSULATOR	TEST METHOD (ASTM D 257)	OTHER
	WIDTH	MAX	MIN	LENGTH	MAX	MIN									NO	RIGHT	LEFT					
1	355			410			0.047			OK	OK	OK	OK		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
14 Hulu Langat, 43100 Selangor, MY.

Tel : +603-90213985 / 6 / 7 Fax : +603-90213982/4 Email: sales@tipcorp.com

FORM QC-21

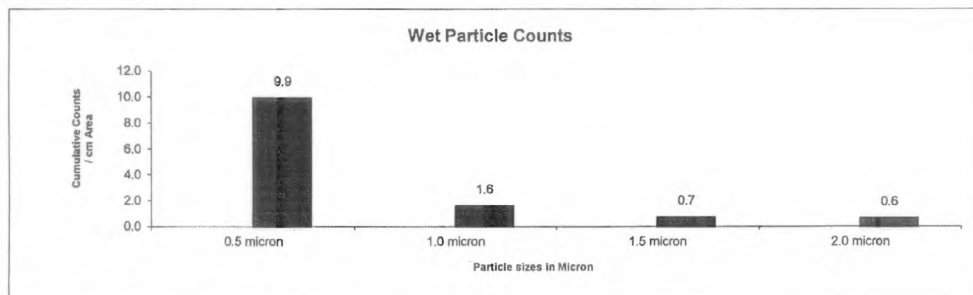
LPC Test Report

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

Lot 2288, Jalan P4/8, Bandar Teknologi Kajang,
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				
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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	50PCS
Qty per carton	500PCS	500PCS
Carton size	T10	T10
PN vs Actual	06-HM-042-0-00	06-HM-042-0-00
Label In vs Out	OK	OK

Verified By : HAJAR

Final Disposition : OK

Accept / Reject : Accept

CASE LINER COC



TIP CORPORATION SDN BHD

Lot 2288, Jalan P4/8, Bandar Teknologi Kajang,
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

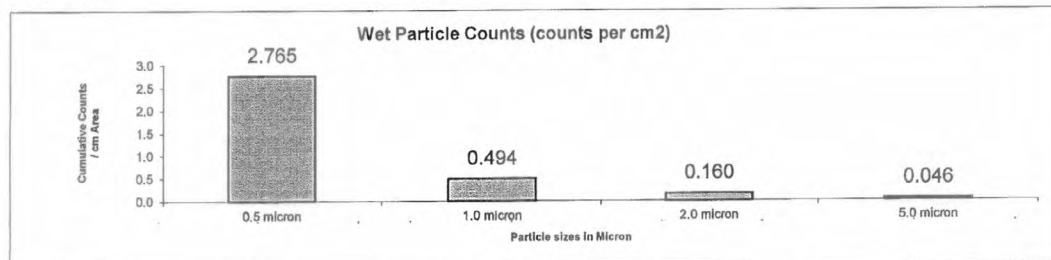
Total Washed Area 8775 cm²

(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



...making excellence a habit.™

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](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

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](#).

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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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Further clarifications regarding the scope of this certificate and the applicability of ISO 14001:2015 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.



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.

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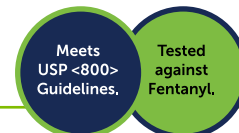
COPY-04632

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/cm²/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/cm²/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
Didecyldimethylammonium 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, appearing to read 'Caitlin Senter'.

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

A handwritten signature in black ink, appearing to read '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,

Gustavo Fiallos
Director Global Quality Operations, Owens & Minor

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