



pure<sup>11</sup>-Nr.: 1130172, Marke:

## Eigenschaften

## Empfohlene Reinraumklassen

ISO

GMP

## Material

- 

## Verpackung

- Box

## Produktvarianten

---

**pure<sup>11</sup>-Nr.: 1130172,**

---

**pure<sup>11</sup>-Nr.: 1130172WHL, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512LG**

Farbe: Weiß; Größe: L / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1130172WHM, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512MD**

Farbe: Weiß; Größe: M / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1130172WHS, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512SM**

Farbe: Weiß; Größe: S / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1130172WHXL, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512XL**

Farbe: Weiß; Größe: XL / VE: 1000STK

---

**pure<sup>11</sup>-Nr.: 1130172WHXS, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512XS**

Farbe: Weiß; Größe: XS / VE: 1000STK

---



# HALYARD\* **PUREZERO\*** HG5 WHITE NITRILE CLEANROOM GLOVES

DATA PACK



For the Cleanroom Environment  
For Industrial Use Only

# HALYARD\* **PUREZERO\*** HG5 WHITE NITRILE CLEANROOM GLOVES

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

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# TECHNICAL DATA SHEET

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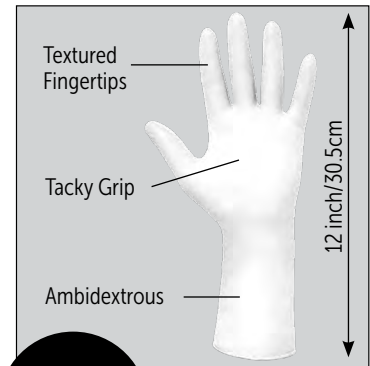
# HALYARD\* PUREZERO\* HG5 WHITE NITRILE GLOVES (12")

For the Cleanroom Environment  
For Industrial Use Only

## TECHNICAL DATA SHEET

### Description

HALYARD\* **PUREZERO\*** HG5 White Nitrile Cleanroom Gloves are 12" long and 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 5 or higher and Grade B/C/D cleanrooms. Because HALYARD\* **PUREZERO\*** HG5 White Nitrile Cleanroom Gloves have an **accelerator-free**<sup>1</sup> formulation, there is a reduced risk of allergies and skin irritation associated with accelerator chemicals in other nitrile gloves.



Meets  
USP <800>  
Guidelines.

### Cleanliness Properties

Max Particle Count (>0.5 µm) <1500 Particles/cm<sup>2</sup> IEST RP-CC005



Manufactured at OUR OWN  
Safeskin Facility in Thailand.

### Physical Properties

AQL	1.0
Non-Sterile	✓
Ambidextrous	✓
Tacky Grip	✓
Textured Fingertips	✓
Accelerator-Free <sup>1</sup>	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Static Dissipative in Use <sup>2</sup>	✓
Tensile Strength	24 MPa (Target)
Ultimate Elongation	600%
Shelf Life	3 Years

### Glove Dimensions

	X-SMALL	SMALL	MEDIUM	LARGE	X-LARGE	XX-LARGE
Glove Length (inch/cm)	12"/30.5	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	94.8
Width of Palm (mm)	70	80	95	110	120	130
Finger Tip Thickness	0.15mm (5.9mil)	0.15mm (5.9mil)	0.15mm (5.9mil)	0.15mm (5.9mil)	0.15mm (5.9mil)	0.15mm (5.9mil)
Palm Thickness	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)	0.13 mm (5 mil)
Cuff Thickness	0.10 mm (4 mil)	0.10 mm (4 mil)	0.10 mm (4 mil)	0.10 mm (4 mil)	0.10 mm (4 mil)	0.10 mm (4 mil)



# HALYARD\* PUREZERO\* HG5 WHITE NITRILE GLOVES (12")

For the Cleanroom Environment  
For Industrial Use Only

## TECHNICAL DATA SHEET

### Packaging Data

XS - XL: 1000 gloves per case: 100 gloves per PE bag x10 PE bags per lined carton

2XL: 900 gloves per case: 90 gloves per PE bag x10 PE bags per lined carton

Packaged in ISO Class 5 Cleanroom

### Quality & Regulatory Standards

Compliant to these regulatory standards:

ISO 9001  
ISO 13485

Compliant to these food handling regulatory standards:

FDA 21 CFR 177-2600  
FDA 21 CFR 180.22

Commission Regulation (EU) No 10/2011

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 Virus Protection

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

EN ISO 21420:2020 Dexterity Classification: Level 5

Compliant with the REACH regulation

Static Dissipative in Use

Tested per ANSI/ESD STM 15.1-2019

Meets USP <800> Guidelines

### Additional Glove Information

Recommended for use in ISO Class 5 or higher and Grade B/C/D cleanrooms.

Declaration of Conformity (DoC) and Certificates of Analysis (COA) for every production lot available on-line at [halyardhealth.com/information](http://halyardhealth.com/information)

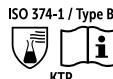
### Storage Instructions

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\* HG5 WHITE NITRILE GLOVES, NON-STERILE, AMBIDEXTROUS, TACKY

Size	Code
XS	CLN30512XS
SM	CLN30512SM
MD	CLN30512MD
LG	CLN30512LG
XL	CLN30512XL
2XL	CLN305122XL



For additional information  
or samples, contact your  
local distributor.

<sup>1</sup> Not formulated with these commonly used vulcanizing chemicals: Sulfur, Thiurams, Thioxoles, Guanidines and Carbamates.

<sup>2</sup> Tested against ANSI/ESD STM 15.1-2019

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

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

## CERTIFICATE OF ANALYSIS

Product Description : HALYARD\* PUREZERO\* HG5 White Nitrile Gloves

Catalog Numbers : CLN30512XS, CLN30512SM, CLN30512MD, CLN30512LG, CLN30512XL

OMH Code : 51745-80, 51746-80, 51747-80, 51748-80, 51749-80

Batches : SM22442AX to SM22732AX

Total Cases per Lot : 1,742

Date of Manufacture : Sep-22

Expiration Date : 2025-08-30

### Physical Test Data

	Visual Defects			Dimensions	Tensile (MPa)	Elongation (%)	Median Force at Break (N)
	Watertight	Minor	Negligible		Pre Aging	Pre Aging	Pre Aging
Sample Size :	1950	1452	1329	233	168	168	168
AQL Level :	1.0	2.5	4.0	4.0	4.0	4.0	4.0
Failures Allowed per AQL :	23	46	68	14	9	9	9
Failures :	0	0	2	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
	Averages:				39.70	570	13.88

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 <sup>2</sup>	Inspection Result
#/cm <sup>2</sup> :	1008	Accept

Particulate Level (≥0.5 microns) #/cm<sup>2</sup>

Test Method : IEST-RP-CC005.4

Review By :

*Juning AOT*  
18-09-2022  
( QA Sr. Manager )

# PACKAGE LABELS

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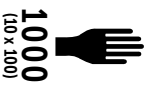


# PUREZERO\* HG5

## WHITE NITRILE GLOVES

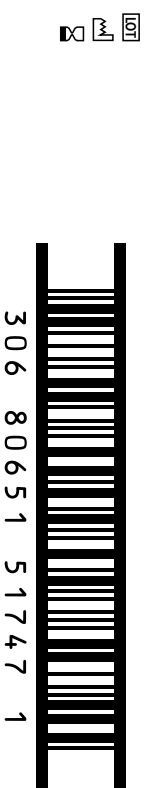


- (FR) Gants en nitrile blancs HG5
- (DE) HG5 Nitrilhandschuhe, weiß
- (BG) Бели нитрилни ръкавици HG5
- (ES) Guantes de nitrilo blancos HG5
- (CS) Bílé nitrilové rukavice HG5
- (DA) Hvide nitrilhandsker
- (ET) HG5 valged nitrilkiindad
- (EL) HG5 λευκά γάντια νιτριλίου
- (IT) Guanti in nitrile bianchi HG5
- (LV) HG5 balti nitrīla cimdi
- (LT) HG5 baltos nitrilinės pirštinės
- (HR) HG5 bijele nitrilne rukavice
- (HU) HG5 fehér nitrilkesztyű



AQL 1.0 Level 2 CI	ISO 374-5:2016 VIRUS	ISO 374-1 Type B KTP	EN ISO 374-1:2016+A1:2018
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105174781 **CLN30512MD**

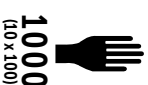


# PUREZERO\* HG5

## WHITE NITRILE GLOVES

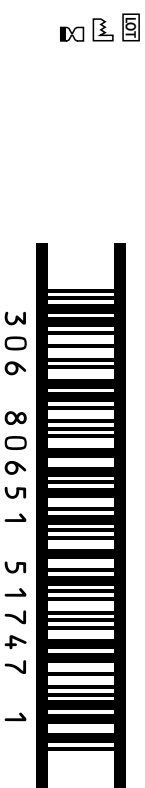


- (NL) HG5 Ingwanti tan-Nitril Bojod
- (NL) HG5 Witte nitril handschoenen
- (NO) HG5 hvite nitrilhansker
- (PL) HG5 Białe rękawice nitrilowe
- (PT) Luvas de nitrilo brancas HG5
- (RO) Manuși din nitril albe HG5
- (RU) Белые нитриловые перчатки HG5
- (SK) Biele nitrilové rukavice HG5
- (SL) HG5 Bele rokavice iz nitrila
- (SR) HG5 bele nitrilne rukavice
- (FI) HG5, valkoiiset nitrilkiisineet
- (SV) HG5 Vita nitrilhandskar
- (JA) ビュアゼロHG5 ホワイトニトリルグローブ
- (KO) HG5 흰색 니트릴 장갑
- (ZH) HG5 白色丁腈手套




AQL 1.0 Level 2 CI	ISO 374-5:2016 VIRUS	ISO 374-1 Type B KTP	EN ISO 374-1:2016+A1:2018
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105174781 **CLN30512MD**



# BAG LABEL



## PUREZERO\* HG5

### WHITE NITRILE GLOVES

For the Cleanroom Environment

For Industrial Use Only

12 in. / 30.5 cm

**FR** Gants en nitrile blancs HG5 • Pour l'environnement des salles blanches • Pour usage industriel uniquement • Sans accélérateur\* • Ambidextres

**DE** HG5 Nitrilhandschuhe, weiß • Für Reinraumumgebungen • Nur für den industriellen Gebrauch • Beschleunigerfrei\* • Beidhändig

**ES** Guantes de nitrilo blancos HG5 • Para entornos de sala blanca • Solo para uso industrial • Sin aceleradores\* • Ambidiestro

**IT** Guanti in nitrile bianchi HG5 • Per camera bianca • Solo per uso industriale • Privi di acceleranti\* • Ambidestri

**NL** HG5 Witte nitril handschoenen • Voor gebruik in kritieke schone ruimtes/cleanrooms • Alleen voor industrieel gebruik • Versnellervrij\* • Handspecifiek

**PT** Luvas de nitrilo brancas HG5 • Para ambiente de sala limpa • Exclusivamente para utilização industrial • Sem aceleradores\* • Ambidestras

**RU** Белые нитриловые перчатки HG5 • Для стерильных условий • Только для промышленного использования • Без химических присадок\* • Амбидекстральные










**JA** HG5 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** HG5 흰색 니트릴 장갑 • 클린룸 환경용 • 산업용으로만 사용 • 촉진제 없음\* • 양손형

**ZH** HG5 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) = CLN30512XS S (6.0 - 6.5) = CLN30512SM M (7.0 - 7.5) = CLN30512MD L (8.0 - 8.5) = CLN30512LG XL (9.0 - 10.0) = CLN30512XL	Ambidextrous							
AQL 1.0 Level 2 GI	ISO 374-5:2016  VIRUS	 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 1-844-425-9275 • halyardhealth.com

© ArcRoyal Unimitted Company, Virginia Road, Kells, Co Meath, Ireland

© O&M Halyard Belgium BV, Berkenlaan 8B, 1831 Machelem (Brab.), Belgium

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

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.

Sponsored in Australia by O&M Halyard Australia Pty Ltd., Tenancy 1, Level 1, Triniti 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

\*Registered Trademark or Trademark of O&M Halyard, Inc., or its affiliates. © 2018. All rights reserved. Patent and/or Pending Application. See www.halyardhealth.com/patents.

Place Label Here

06-HM-085-0-00

# PACKAGING CERTIFICATES

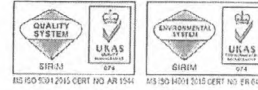
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## TIP CORPORATION SDN BHD (187530-A)

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



### 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	: <i>Orals</i>

#### 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

*Orals*  
TESTED BY: *Rubalyat*  
QC DEPARTMENT

*Orals*  
VERIFIED BY : QA EXECUTIVE



## TOP IN PERFORMANCE

# BAG COC

FORM CC-01 REV 5  
Date Implement: 05-04-2018  
REF NO: CC-61  
DATE: 12.07.2021

TIP CORPORATION SDN BHD

CUSTOMER / SUPPLIER: SARESKIN

SAMPLING PLAN: 0.65 Single Plan Normal Inspection S1

LOT NO: 61200

OUT GOING QUALITY INSPECTION REPORT

Lot Qty: 55

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

QUANTITY: 30,000 pcs

Accept / Reject: 13

Acc / Rej: 0/1

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

3,201 to 35,000 pcs

Acc / Rej: 0/1

32

35,001 to 500,000 pcs

Acc / Rej: 0/1

50

DIMENSION / PHYSICAL INSPECTION												PROPERTIES OF MATERIAL												
NO	DIMENSION CHECK				THICKNESS	MAX	MIN	0.05/-0.01	VISUAL	REMARKS	EASY TO OPEN	SEAL STRENGTH	PRT / GLSSET	SAMPLE NO		CONDUCTIVE	DISSSIPATIVE	INSULATOR	TEST METHOD	ASTM D 257	OTHER			
	WIDTH	MAX	MIN	LENGTH										MIN	MAX							OKNG	NO	RIGHT
1	353	360	350	405 +/- 30	415	395	0.05	OK	OK	OK	OK	OK	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			410	OK		0.05	OK	OK	OK	OK	OK	10	10	11									
11	353			410			0.05						11	10	10									
12	354			410			0.05						12	10	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									
20	354			411			0.05						20	10	11									
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29													29											
30													30											
31													31											
32													32											

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

REMARKS: **REJECT**

FORM: QC-07 REV 10  
Date Reviewed : 30.11.2017



## TIP CORPORATION SDN BHD (187530-A)

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



### 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 :

<b>Safeskin Thailand</b>	
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

OUT GOING QUALITY INSPECTION REPORT  
 LOT NO : 61448

SAMPLING PLAN 0.65 single Plan Normal Inspection S3  
 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

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

QUANTITY : 48,000 pcs

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

NO	DIMENSION / PHYSICAL INSPECTION										VISUAL	REMARKS	EASY TO OPEN	SEAL STRENGTH	PRT / GUSSET	SAMPLE NO			PROPERTIES OF MATERIAL
	WIDTH	MAX	MIN	LENGTH	MAX	MIN	THICKNESS	MAX	MIN	OK/NG						NO	RIGHT	LEFT	
SPEC	355+/-5	360	350	405+/-10	415	395	0.045+/-0.01	0.055	0.035	OK	OK	OK	OK	NO	RIGHT	LEFT	Remarks :		
1	355			410			0.047							1	11	10	2 side seal-seal width 10mm min		
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	For Incoming visual :		
11	355			409			0.048							11	10	10	Bag no torn , damaged - Accept		
12	354			410			0.047							12	11	11	Reject for the bag is broken		
13	355			409			0.048							13	10	10	Equipment for Inspection : -		
14	354			410			0.047							14	11	11	Dimension - Measuring Tape		
15	355			409			0.048							15	10	11	Thickness - Thickness Checker		
16	355	OK		410	OK		0.047	OK		OK	OK	OK		16	11	10	Surface Resistivity - SRM		
17	354			409			0.048							17	11	11	SUMMARY OF OUTGOING QC		
18	355			410			0.047							18	10	10	INSPECTION RESULT :		
19	354			409			0.048							19	11	11	Visual : OK MVTR- N/A		
20	354			410			0.047							20	11	10	Sticky : NO Easy to open: OK		
21	355			409			0.047							21	10	11	LPC : OK Mixed: NO		
22	354			410			0.048							22	11	10	Seal Strength : OK Water Leak Test N/A		
23	355			409			0.047							23	10	11	Printing per spec: N/A		
24	354			409			0.048							24	11	10	Surface Resistivity: N/A		
25	354			410			0.047							25	10	11			
26	355			410			0.048							26	11	10	PACKING CONDITION INSPECTION		
27	354			409			0.048							27	10	11	SPEC ACTUAL		
28	355			410			0.047							28	10	10	Qty per bag		
29	354			409			0.048							29	11	11	Qty per carton		
30	355			410			0.047							30	10	10	Carton size		
31	354			409			0.048							31	10	11	PN vs Actual		
32	354			410			0.048							32	11	11	Label In vs Out		

REMARKS : ACCEPT  REJECT

Prepared By : CA  
 Final disposition : OK  
 Accept / Reject : ACCEPT

Verified By : [Signature]  
 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

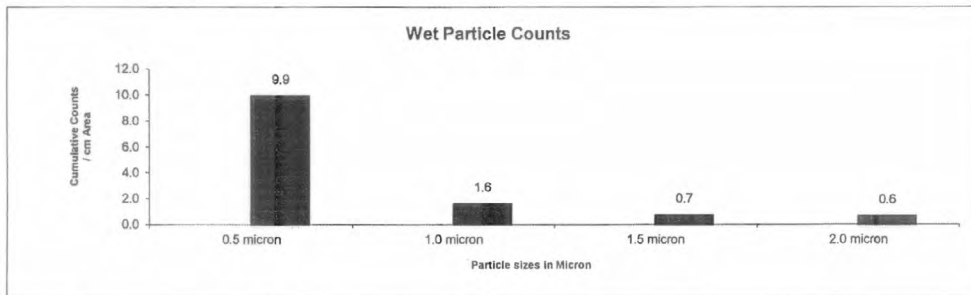
Blank Particle Counts ( Cumulative )					
	Blank Cts 1 Counts/ml	Blank Cts 2 Counts/ml	Blank Ct 3 Counts/ml	Average Blank ( A ) Counts/ml	
0.5 micron	20.0	19.0	17.0	18.7	
1.0 micron	3.0	4.0	2.0	3.0	
1.5 micron	2.0	4.0	2.0	2.7	
2.0 micron	1.0	2.0	4.0	2.3	
				Total counts	26.666667

Wash Sample Particle Counts ( Cumulative )					
	Washed Cts 1 Counts/ml	Washed Cts 2 Counts/ml	Washed Cts 3 Counts/ml	Average Washed ( B ) Counts/ml	
0.5 micron	80.0	95.0	100.0	91.7	
1.0 micron	13.0	14.0	17.0	14.7	
1.5 micron	9.0	8.0	7.0	8.0	
2.0 micron	5.0	7.0	9.0	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	<u>Total Area of Plastic</u> ( E ) Total Area for wash 2947 cm <sup>2</sup>
1.0 micron	11.7	
1.5 micron	5.3	
2.0 micron	4.7	

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



Total Particle : 12.8492252

SPEC:  $\geq 0.5\mu \leq 100$  COUNTS/CM<sup>2</sup>

Tested By : **MARIAM**  
 Date : 10.8.2021

Verified By : *[Signature]*  
 Date : 10/8/2021

# CASE LINER COC

FORM: QC-07 REV 10

Date Reviewed : 30.11.2017



## 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



### 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	: P8108087
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] ENGINEER



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

OUT GOING QUALITY INSPECTION REPORT

CUSTOMER / SUPPLIER : SAFESKIN MEDICAL

LOT NO : K61449

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

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

QUANTITY : 20,000 PCS

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

NO	DIMENSION / PHYSICAL INSPECTION										SURFACE RESISTIVITY DATA (EQUIPMENT - SRM110)			PROPERTIES OF MATERIAL								
	DIMENSION CHECK										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	THICKNESS	MAX	MIN	OK/NG						NO	INSIDE					
SPEC	350±5mm	355mm	345mm	700±10mm	710mm	690mm	0.04±0.01mm	0.05mm	0.03mm	OK				150mm±10MM								
1	351			702			0.05							151	1							
2	351			701			0.04							152	2							
3	350			702			0.04							152	3							
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				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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29															29							
30															30							
31															31							
32															32							



For incoming visual :  
 Bag no torn, damaged - Accept  
 Reject for the bag is broken

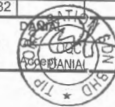
Equipment for inspection : -  
 Dimension - Measuring Tape  
 Thickness - Thickness Checker  
 Surface Resistivity - SRM

SUMMARY OF OUTGOING QC INSPECTION RESULT :  
 Visual : OK MVTR : -  
 Sticky : NO Easy to open : OK  
 LPC : OK Mixed : NO  
 Seal Strength : OK Water Leak Test : -  
 Printing per spec : -  
 Surface Resistivity : -

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

REMARKS : ACCEPT  REJECT

Prepared By :  
 Final disposition :  
 Accept / Reject :



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  
Machine: KCCS-6

#### Blank Particle Counts (Cumulative)

	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	
				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	
				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

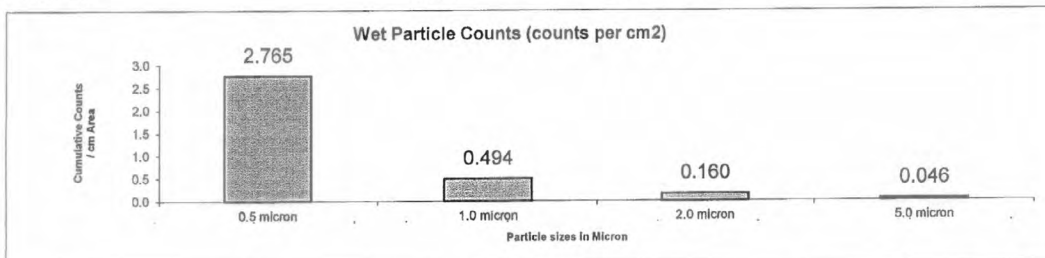
Total Washed Area 8775 cm<sup>2</sup>

#### (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 / cm<sup>2</sup> (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/CM<sup>2</sup>

Tested By: SUHAIDA

Date: 06.08.2021

Verified By:

Date: 06.08.2021

# SAFETY DATA SHEET

---



**1. IDENTIFICATION**Product Name: *HALYARD\* PUREZERO\* HG5 Nitrile Gloves***Product Number:** Various

Date Prepared:	5/17/2023
Manufacturer:	O&M Halyard, Inc. 1 Edison Dr. Alpharetta, Georgia 30005
Telephone: MEDICAL EMERGENCY: TRANSPORTATION EMERGENCY: INFORMATION:	Call 911 or your local Emergency Room or Poison Control Services Chemtrec 1-800-424-9300 or 1-703-527-3887 (collect calls accepted) 1-844-HALYARD

**Product Use:** Protective gloves.**2. HAZARDS IDENTIFICATION**

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

**GHS Labeling:** No GHS labeling required.**3. COMPOSITION/INFORMATION ON INGREDIENTS**

<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.

**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.

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## 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.

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**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.

<b>16. OTHER INFORMATION</b>
------------------------------

**Date Prepared:** 5/17/2023

**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](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

Sincerely,

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

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

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

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# 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

Effective Date: 2021-08-12

Latest Revision Date: 2021-07-16

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](#). Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://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.

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.

# 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](#).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://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.

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



## 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

Effective Date: 2022-10-27

Latest Revision Date: 2022-10-27

Expiry Date: 2025-10-26

Page: 1 of 1



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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](#).

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

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.



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](mailto: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.

COPY-04632



May 9<sup>th</sup>, 2023

RE: HALYARD\* PUREZERO\* HG5 Nitrile Gloves

Dear Valued Customer,

This letter is in response to your recent inquiry regarding food contact testing of HALYARD\* PUREZERO\* HG5 Nitrile Gloves.

The following gloves have been tested against the Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, 21 CFR 177.2600 for "Rubber Articles Intended for Repeated Use" of Part 177 - Indirect Food Additives: Polymers. And 21 CFR 180.22 of "Food and Drugs" Part 180 - FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY: Acrylonitrile copolymers.

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

To simulate aqueous foods (distilled water) and fatty foods (n-Hexane), the results below reflect testing in accordance with 21 CFR 177.2600 for "Rubber Articles Intended for Repeated Use" of Part 177 - Indirect Food Additives: Polymers for (e) and (f):

Products	Extraction Times	Extraction Solvent	Extractable Content (mg/in <sup>2</sup> )	Requirement (mg/in <sup>2</sup> )	Pass/Fail
HALYARD* PUREZERO* HG5 White Nitrile Gloves	First 7 Hours	Distilled Water	1.4	20	Pass
	Next 2 Hours		0.1	1	Pass
	First 7 Hours	n-Hexane	1.6	175	Pass
	Next 2 Hours		0.4	4	Pass
HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves	First 7 Hours	Distilled Water	1.1	20	Pass
	Next 2 Hours		0.2	1	Pass
	First 7 Hours	n-Hexane	0.9	175	Pass
	Next 2 Hours		0.4	4	Pass

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

COPY-04650

Based on extraction conditions of 40°C for 2 hours, the results below reflect testing in accordance with 21 CFR 180.22 of "Food and Drugs" Part 180 - FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY: Acrylonitrile copolymers.

Products	Solvent	Acrylonitrile (ppm)	0.2 ppm Low Spike
HALYARD* PUREZERO* HG5 White Nitrile Gloves	Water	<0.26	*
	n-Heptane	<0.05	**
HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves	Water	<0.26	*
	n-Heptane	<0.05	**
*Recovery of Acrylonitrile Monomer spike at approximately 64.3%			
**Recovery of Acrylonitrile Monomer spike at approximately 88.8%			

Based on extraction conditions of 40°C for 2 hours, the results below reflect testing in accordance with Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

Products	Extraction Solvent	Food Simulant Abbreviation	Mean Global Migration (mg/dm <sup>2</sup> )	Requirement (mg/dm <sup>2</sup> )	Pass/Fail
HALYARD* PUREZERO* HG5 White Nitrile Gloves	Acetic Acid, 3%	Food Simulant B	2.77	≤10	Pass
	Ethanol, 20%	Food Simulant C	4.9		Pass
	Sunflower Oil	Food Simulant D2	3.45		Pass
HALYARD* PUREZERO* HG5 Blue SGX* Nitrile Gloves	Acetic Acid, 3%	Food Simulant B	4.63	≤10	Pass
	Ethanol, 20%	Food Simulant C	3.01		Pass
	Sunflower Oil	Food Simulant D2	2.86		Pass

\*\*Not Detectable: The test result is below the detectable level or quantification limit of the test method and/or equipment.

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](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

Sincerely,

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

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

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

COPY-04650

# PUREZERO\*

## HG5 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\*** HG5 Cleanroom Gloves are **now tested against 2 chemotherapy drugs and 21 chemicals**.

### CHEMOTHERAPY DRUG RESISTANCE GUIDE<sup>4</sup>

Chemotherapy Agent (Concentration in mg/ml)	PUREZERO* HG5 White Nitrile Gloves 12"		PUREZERO* HG5 Blue SGX* Nitrile Gloves 12"	
	Minimum Breakthrough Time (minutes)	Permeation Rate ( $\mu\text{g}/\text{cm}^2/\text{min}$ )	Minimum Breakthrough Time (minutes)	Permeation Rate ( $\mu\text{g}/\text{cm}^2/\text{min}$ )
Carmustine (BCNU) (3.3)	67.3	0.29	68.7	0.12
Thiotepa (1.0)	>240	N/A	>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 $\mu\text{g}/\text{cm}^2/\text{min}$ ) 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.

\*Tested per ASTM D6978, Standard Practice Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. The testing conditions used are intended to approximate the worst case conditions for use. Testing was conducted on a single layer glove material.

#### 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 ( $\mu\text{g}/\text{cm}^2/\text{min}$ ).

# HG5 Nitrile Cleanroom Gloves

## CHEMICAL RESISTANCE GUIDE<sup>5</sup>

Chemical (Concentration %)	PUREZERO* HG5 White Nitrile Gloves 12"		PUREZERO* HG5 Blue SGX* Nitrile Gloves 12"	
	Minimum Breakthrough Time (minutes)	Permeation Rate (µg/cm <sup>2</sup> /min)	Minimum Breakthrough Time (minutes)	Permeation Rate (µg/cm <sup>2</sup> /min)
Acetic Acid (99)	15	2.9E+03	10.1	3.2E+04
Acrylamide (40)	>480***	0.03	>480***	<1.0
Ammonium Hydroxide (25)	60.8	5.5	26.4	4.2
1-Butanol (99)	55.8	1.7E+01	357.6	0.9
Chloroform (70)	0	N/A	0	N/A
Citric Acid (30)	>480	<1.0	>480	<1.0
Citric Acid (70)	>480	<1.0	>480	<1.0
Cyclohexane (99)	60.6	2.9E+01	>480***	<1.0
Dimethyl Sulfoxide (99)	10.2	N/A	0	N/A
Ethanol (70)	43.3	11.4	29.1	2.0E+01
Ethanol (99)	20.3	7.6E+01	17.5	7.0E+01
Ethidium Bromide (1)	>480	<1.0	>480	<1.0
Hydrochloric Acid (30)	341.1	17.0	>480	<1.0
Isopropyl Alcohol (70)	145.2	3.0	>480***	<1.0
Isopropyl Alcohol (99)	98.5	3.3	>480***	<1.0
Methanol (99)	9.3	N/A	1.2	4.8E+01
Nitric Acid (65)	10.0	3.2E+02	3.1	3.2E+04
Phosphoric Acid (70)	>480	<1.0	>480	<1.0
Sodium Hydroxide (50)	>480	<1.0	>480	<1.0
Sodium Hypochlorite (10-13)	>480	<1.0	>480	<1.0
Sulfuric Acid (50)	>480	<1.0	>480	<1.0

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

<10	Permeation breakthrough is poor - avoid use with this chemical.
11 - 479	Glove is suitable under careful control of its use.
>480	Permeation breakthrough is excellent.

The following gloves are applicable to this chart:

HALYARD\* PUREZERO\* HG5 White Nitrile Gloves

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

\*\*\* Though detected at trace amounts, the permeation did not hit the required rate of 1.0 µg/cm<sup>2</sup>/min to be deemed as Standardized Breakthrough per EN 16523-01:2015.

DISCLAIMER: The permeation breakthrough times presented in this chart were evaluated using the Test Method EN 16523-1.

\* Permeation Time (minutes) and Permeation Rate (µg/cm<sup>2</sup>/min) using Test Method EN 16523-1

Contact your Sales Representative for additional chemical and chemotherapy drug testing information.



November 13<sup>th</sup>, 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**

<b>Glove Description</b>	<b>Code</b>
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* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923260
HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923265
HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923270
HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923275
HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923280
HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923285
HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923290
HALYARD* <b>PUREZERO*</b> HG3 Blue Sterile Nitrile Gloves	CLN923210

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

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

**HALYARD\* **PUREZERO\*** Nitrile Exam Gloves**

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



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

**HALYARD\* **PUREZERO\*** Nitrile Gloves**

<b>Glove Description</b>	<b>Code</b>
HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves	LFS1117XS
HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves	LFS1117SM
HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves	LFS1117MD
HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves	LFS1117LG
HALYARD* <b>PUREZERO*</b> MARIN* Nitrile Gloves	LFS1117XL
HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves	LFS3117XS
HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves	LFS3117SM
HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves	LFS3117MD
HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves	LFS3117LG
HALYARD* <b>PUREZERO*</b> LIMON* Nitrile Gloves	LFS3117XL
HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves	LFS5117XS
HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves	LFS5117SM
HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves	LFS5117MD
HALYARD* <b>PUREZERO*</b> ULTRA VIOLET* Nitrile Gloves	LFS5117LG
HALYARD* <b>PUREZERO*</b> 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<sup>4</sup> to 10<sup>11</sup> 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](mailto: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](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

*–This statement is valid unsigned –*



March 14<sup>th</sup>, 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](mailto: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<sup>-1</sup> to 50cm<sup>-1</sup> via FT-IR (Fourier Transform Infrared Anaysis). 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 3<sup>rd</sup> 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 Anaysis (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](mailto:PIQ@hyh.com) or call us directly at (844) 425-9273.

Sincerely

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COPY-04662



A handwritten signature in black ink that reads 'Caitlin Senter'.

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

A handwritten signature in black ink that reads '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:**

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



<b>PUREZERO* HG5 White Nitrile Gloves</b>
<b>CODE</b>
CLN30512XS
CLN30512SM
CLN30512MD
CLN30512LG
CLN30512XL
<b>PUREZERO* HG5 Blue SGX* Nitrile Gloves</b>
<b>CODE</b>
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](mailto: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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