

pure[11]-Nr.: 1130172, Marke:

Eigenschaften

Empfohlene Reinraumklassen

ISO

GMP

we care

pure[11] GmbH |
Bavariafilmplatz 7 | D-82031 Grünwald
T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

Material

-

Verpackung

- Box

Produktvarianten

pure[11]-Nr.: 1130172,

pure[11]-Nr.: 1130172WHL, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512LG

Farbe: Weiß; Größe: L / VE: 1000STK

pure[11]-Nr.: 1130172WHM, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512MD

Farbe: Weiß; Größe: M / VE: 1000STK

pure[11]-Nr.: 1130172WHS, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512SM

Farbe: Weiß; Größe: S / VE: 1000STK

pure[11]-Nr.: 1130172WHXL, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512XL

Farbe: Weiß; Größe: XL / VE: 1000STK

pure[11]-Nr.: 1130172WHXS, Halyard Nitril-Handschuhe PUREZERO HG5 weiß #CLN30512XS

Farbe: Weiß; Größe: XS / VE: 1000STK

HALYARD

HALYARD* **PURE**ZERO* HG5 WHITE NITRILE CLEANROOM GLOVES

DATA PACK



For the Cleanroom Environment
For Industrial Use Only

HALYARD* **PURE**ZERO* 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**, or ask your Distributor or HALYARD* Representative.

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HALYARD*

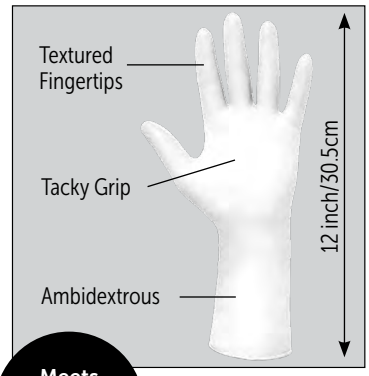
HALYARD* **PURE**ZERO* HG5 WHITE NITRILE GLOVES (12”)

For the Cleanroom Environment
For Industrial Use Only

TECHNICAL DATA SHEET

Description

HALYARD* **PURE**ZERO* 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* **PURE**ZERO* HG5 White Nitrile Cleanroom 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.



Meets USP <800> Guidelines.

Cleanliness Properties

Max Particle Count (>0.5 µm)	<1500 Particles/cm^2	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[1]	✓
Latex-Free	✓
Powder-Free	✓
Silicone-Free	✓
Static Dissipative in Use[2]	✓
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*

HALYARD* **PURE**ZERO* 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

CE 2797 (PPE Cat. III)

ISO 374-5:2016 VIRUS

ISO 374-1 / Type B KTP

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**

Storage Instructions

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

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.

1 Not formulated with these commonly used vulcanizing chemicals: Sulfur, Thiurams, Thiaxoles, Guanidines and Carbamates.
2 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.

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008789 COPY-05079 June 2024

Owens & Minor

HALYARD* is an Owens & Minor brand

CERTIFICATE OF ANALYSIS



Owens & Minor HALYARD

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			Tensile (MPa)	Elongation (%)	Median Force at Break (N)
	Watertight	Minor	Negligible	Dimensions	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/cm²	Inspection Result
	#/cm2:	1008	Accept

Particulate Level (≥0.5 microns) #/cm²

Test Method : IEST-RP-CC005.4

Review By : 18-Oct-2022

(QA Sr. Manager)

PACKAGE LABELS



CASE LABEL

PUREZERO* HG5
WHITE NITRILE GLOVES

M (7.0 – 7.5)

(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) HG5 Hvide nitrilhandsker
(ET) HG5 valged nitriilkindad
(EL) HG5 Λευκά γάντια νιτριλίου
(IT) Guanti in nitrile bianchi HG5
(LV) HG5 balti nitrila cimdi
(LT) HG5 baltos nitrilinės pirštinės
(HR) HG5 bijele nitrilne rukavice
(HU) HG5 fehér nitrilkesztyű

1000
(10 x 100)

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

105174781 (REF) **CLN30512MD**

LOT

306 80651 51747 1

PUREZERO* HG5
WHITE NITRILE GLOVES

M (7.0 – 7.5)

(MT) HG5 Ingwanti tan-Nitril Bojod
(NL) HG5 Witte nitril handschoenen
(NO) HG5 hvite nitrilhansker
(PL) HG5 Białe rękawice nitrylowe
(PT) Luvas de nitrilo brancas HG5
(RO) Mănuși 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, valkoiset nitriilikäsineet
(SV) HG5 Vita nitrilhandskar
(JA) ピュアゼロ 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

1000
(10 x 100)

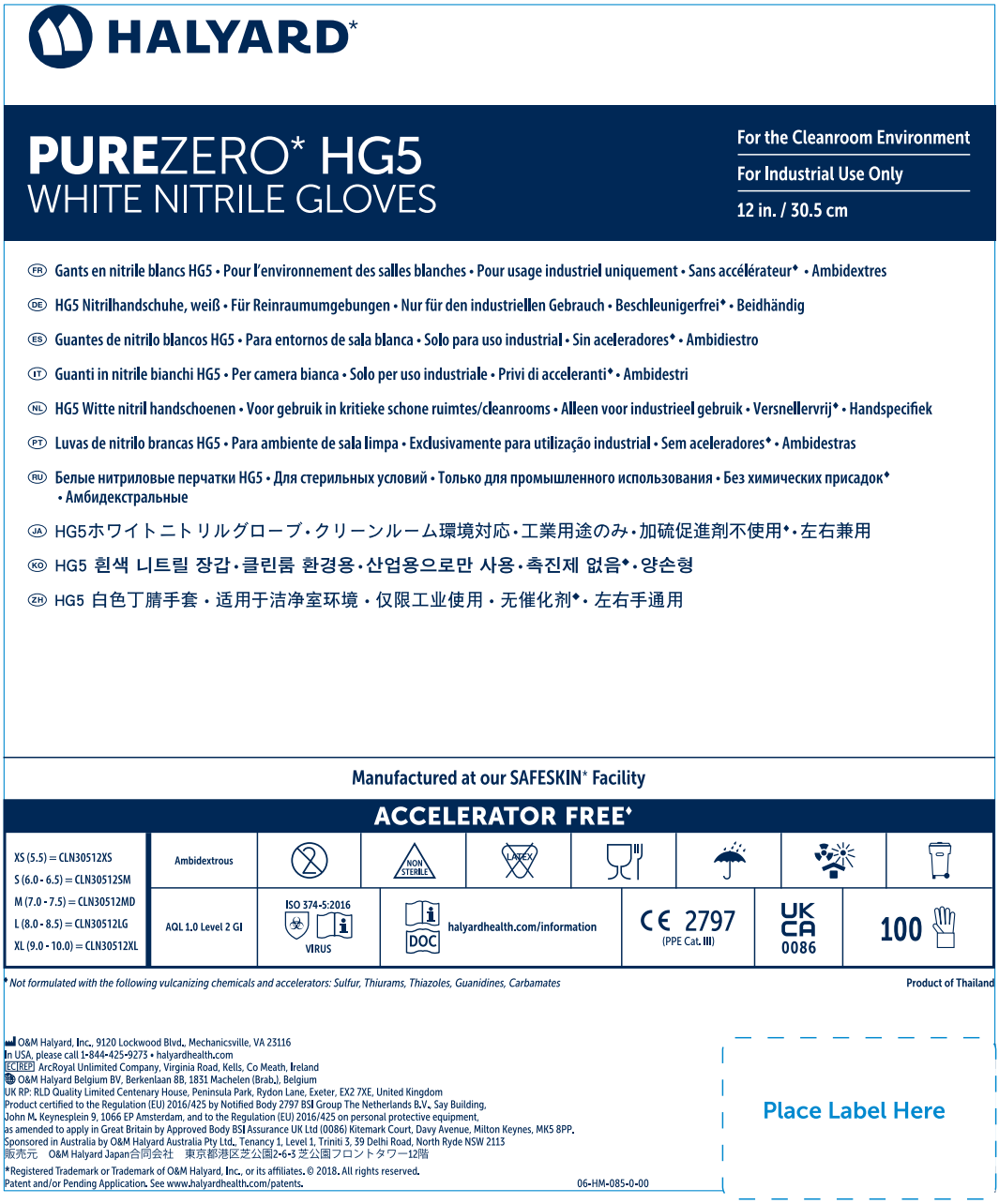
AQL 1.0 Level 2 GI	ISO 374-5:2016 VIRUS	ISO 374-1/Type B KTP EN ISO 374-1:2016+A1:2018

105174781 (REF) **CLN30512MD**

LOT

306 80651 51747 1

BAG LABEL


HALYARD*
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
NON STERILE
LATEX
AQL 1.0 Level 2 GI
ISO 374-5:2016
VIRUS
DOC
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
EC REP ArcRoyal Unlimited Company, Virginia Road, Kells, Co Meath, Ireland
O&M Halyard Belgium BV, Berkenlaan 8B, 1831 Machelen (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
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Patent and/or Pending Application. See www.halyardhealth.com/patents.
06-HM-085-0-00
Place Label Here

PACKAGING CERTIFICATES



BAG COC

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 -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 : Ohls

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

- ☐ DISSIPATIVE : ≥ 1 x 10^5 AND < 1 x 10^{12} OHMS/SQ
- ☐ CONDUCTIVE : < 1 X 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 : QA EXECUTIVE

TOP IN PERFORMANCE

TIP CORPORATION SDN BHD

FORM QC-01 REV 9
Date Implement : 05.04.2018
REF NO : QC -01
DATE 12.07.2021

[ ] IN COMING QUALITY INSPECTION REPORT [√] OUT GOING QUALITY INSPECTION REPORT

CUSTOMER / SUPPLIER: SAFESKIN
LOT NO: 61200
ITEM: C/R EASY TEAR LDPE -PRT -355X405X0.05MM
QUANTITY: 20,000 pcs
PART NO: 06-HM-039-0-00

SAMPLING PLAN 0.65 single Plan Normal Inspection S2

Lot Qtty	SS	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

NO	DIMENSION CHECK									VISUAL	REMARKS	EASY TO OPEN	SEAL STRENGTH	PRT / GUSSET
	WIDTH	MAX	MIN	LENGTH	MAX	MIN	THICKNESS	MAX	MIN	OK/NG				
SPEC	355+/-5	360	350	405+/-10	415	395	0.05+/-0.01	0.06	0.04	OK	OK	OK	OK	OK
1	353			410			0.05							
2	354			411			0.05							
3	353			410			0.05							
4	354			410			0.05							
5	353			411			0.05							
6	354			410			0.05							
7	353			411			0.05							
8	354			410			0.05							
9	353			411			0.05							
10	354	OK		411	OK		0.05	OK		OK	OK	OK	OK	OK
11	353			410			0.05							
12	354			410			0.05							
13	353			411			0.05							
14	354			411			0.05							
15	353			410			0.05							
16	354			411			0.05							
17	353			410			0.05							
18	354			411			0.05							
19	353			410			0.05							
20	354			411			0.05							
21														
22														
23														
24														
25														
26														
27														
28														
29														
30														
31														
32														

SURFACE RESISTIVITY DATA (EQUIPMENT : SRM110)

SAMPLE NO	RIGHT	LEFT
~~OHM/Sq~~ SEAL		
NO		
1	10	11
2	11	11
3	11	10
4	10	11
5	11	10
6	10	11
7	11	10
8	10	11
9	11	10
10	11	11
11	10	10
12	11	11
13	10	10
14	11	11
15	10	10
16	11	11
17	10	11
18	11	10
19	11	10
20	10	11
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31		
32		

PROPERTIES OF MATERIAL

- [ ] CONDUCTIVE
- [ ] DISSIPATIVE
- [ ] INSULATOR
- [ ] TEST METHOD (ASTM D 257)
- [ ] OTHER

Remarks

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- N/A
Sticky : NO Easy to open: OK
LPC : OK Mixed: NO
Seal Strength : OK Water Leak Test N/A
Printing per spec: OK
Surface Resistivity: N/A

PACKING CONDITION INSPECTION

	SPEC	ACTUAL
Qtty per bag		
Qtty per carton		
Carton size		
PN vs Actual		
Label In vs Out		

REMARKS : ACCEPT [ ] REJECT [ ]

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

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

BAG 2 COC

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

MS ISO 9001:2015 CERT NO: AR 1544 MS ISO 14001:2015 CERT NO: ER 0459

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):

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

PACKING LIST NUMBER :TPL16679

DATE OF MANUFACTURING :

DATE OF EXPIRED :

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

- ☐ DISSIPATIVE : ≥ 1 x 10^5 AND < 1 x 10^{12} OHMS/SQ
- ☐ CONDUCTIVE : < 1 X 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 : ~~QA~~ 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 ☑ OUT GOING QUALITY INSPECTION REPORT

CUSTOMER / SUPPLIER : SAFESKIN
LOT NO 61448
ITEM : C/R EASY TEAR LDPE BAG -355X405X0.045MM
QUANTITY 48,000 pcs
PART NO: 06-HM-041-0-00

SAMPLING PLAN 0.65 single Plan Normal Inspection S3

Lot Qtty	SS	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

NO	DIMENSION CHECK									VISUAL	REMARKS	EASY TO OPEN	SEAL STRENGTH	PRT / GUSSET
	WIDTH	MAX	MIN	LENGTH	MAX	MIN	THICKNESS	MAX	MIN	OK/NG				
SPEC	355+/-5	360	350	405+/-10	415	395	0.045+/-0.01	0.055	0.035	OK	OK	OK	OK	
1	355			410			0.047							
2	354			409			0.047							
3	355			410			0.048							
4	354			410			0.047							
5	355			409			0.048							
6	354			410			0.047							
7	355			409			0.048							
8	354			410			0.047							
9	355			409			0.048							
10	354			410			0.047							
11	355			409			0.048							
12	354			410			0.047							
13	355			409			0.048							
14	354			410			0.047							
15	355			409			0.048							
16	355	OK		410	OK		0.047	OK		OK	OK	OK	OK	
17	354			409			0.048							
18	355			410			0.047							
19	354			409			0.048							
20	354			410			0.047							
21	355			409			0.047							
22	354			410			0.048							
23	355			409			0.047							
24	354			409			0.048							
25	354			410			0.047							
26	355			410			0.048							
27	354			409			0.048							
28	355			410			0.047							
29	354			409			0.048							
30	355			410			0.047							
31	354			409			0.048							
32	354			410			0.048							

REMARKS : ACCEPT ■ REJECT ☐

SURFACE RESISTIVITY DATA (EQUIPMENT : SRM110)

SAMPLE NO ~~OHM/SQ~~ SEAL

NO	RIGHT	LEFT
1	11	10
2	10	10
3	10	11
4	11	10
5	10	10
6	11	11
7	11	10
8	10	11
9	11	10
10	11	11
11	10	10
12	11	11
13	10	10
14	11	11
15	10	11
16	11	10
17	11	11
18	10	10
19	11	11
20	11	10
21	10	11
22	11	10
23	10	11
24	11	10
25	10	11
26	11	10
27	10	11
28	10	10
29	11	11
30	10	10
31	10	11
32	11	11

PROPERTIES OF MATERIAL

CONDUCTIVE	☐
DISSIPATIVE	☐
INSULATOR	☐
TEST METHOD	☐
(ASTM D 257)	☐
OTHER	☐

Remarks :
2 side seal-seal width 10mm min

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- N/A
Sticky : NO Easy to open: OK
LPC : OK Mixed: NO
Seal Strength : OK Water Leak Test N/A
Printing per spec: N/A
Surface Resistivity: N/A

PACKING CONDITION INSPECTION

	SPEC	ACTUAL
Qtty per bag	10	10
Qtty per carton	11	11
Carton size	10	10
PN vs Actual	10	11
Label In vs Out	11	11

Prepared By :		Verified By :	
Final disposition :	OK	Final Disposition :	OK
Accept / Reject :	ACCEPT	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	
				06-HM-041-0-00	

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

0.5 micron	73.0
1.0 micron	11.7
1.5 micron	5.3
2.0 micron	4.7

Total Vol. for Washed Sample (D)
Washed Volume (ml) 400 ml

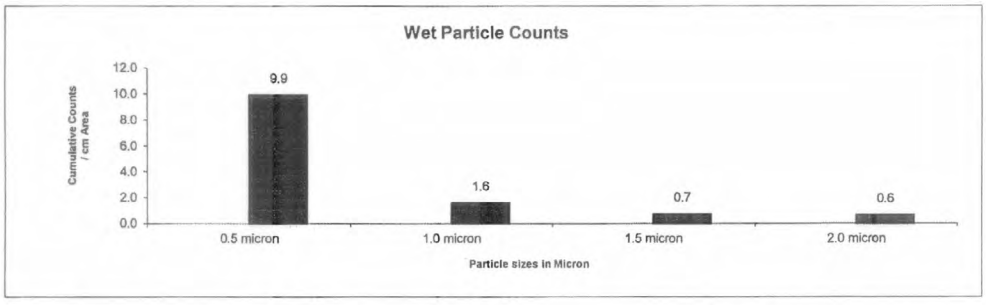
Total Area of Plastic (E)
Total Area for wash 2947 cm^2

Total Particle Counts in Washed Volume (F)
(F = C x D)

0.5 micron	29200
1.0 micron	4666.6667
1.5 micron	2133.3333
2.0 micron	1866.6667

Total Wet Part Cts / cm^2 (G)
(G = F / E)

0.5 micron	9.9083814
1.0 micron	1.5835313
1.5 micron	0.7239
2.0 micron	0.6334125



Total Particle : 12.8492252

SPEC: ≥ 0.5u ≤100 COUNTS/CM^2

Tested By : MARIAM
Date : 10.8.2021

Verified By :
Date : 10/8/2021

CASE LINER COC

FORM: QC-07 REV 10
Date Reviewed : 30.11.2017

TIP CORPORATION SDN BHD Reg No 199901010224 (467530-A)

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 : P2108087
Date : 11-AUG-2021
Signature By : [signature]

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

- ☐ DISSIPATIVE : ≥ 1 x 10^5 AND < 1 x 10^{12} OHMS/SQ
- ☐ CONDUCTIVE : < 1 X 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

DANIAL

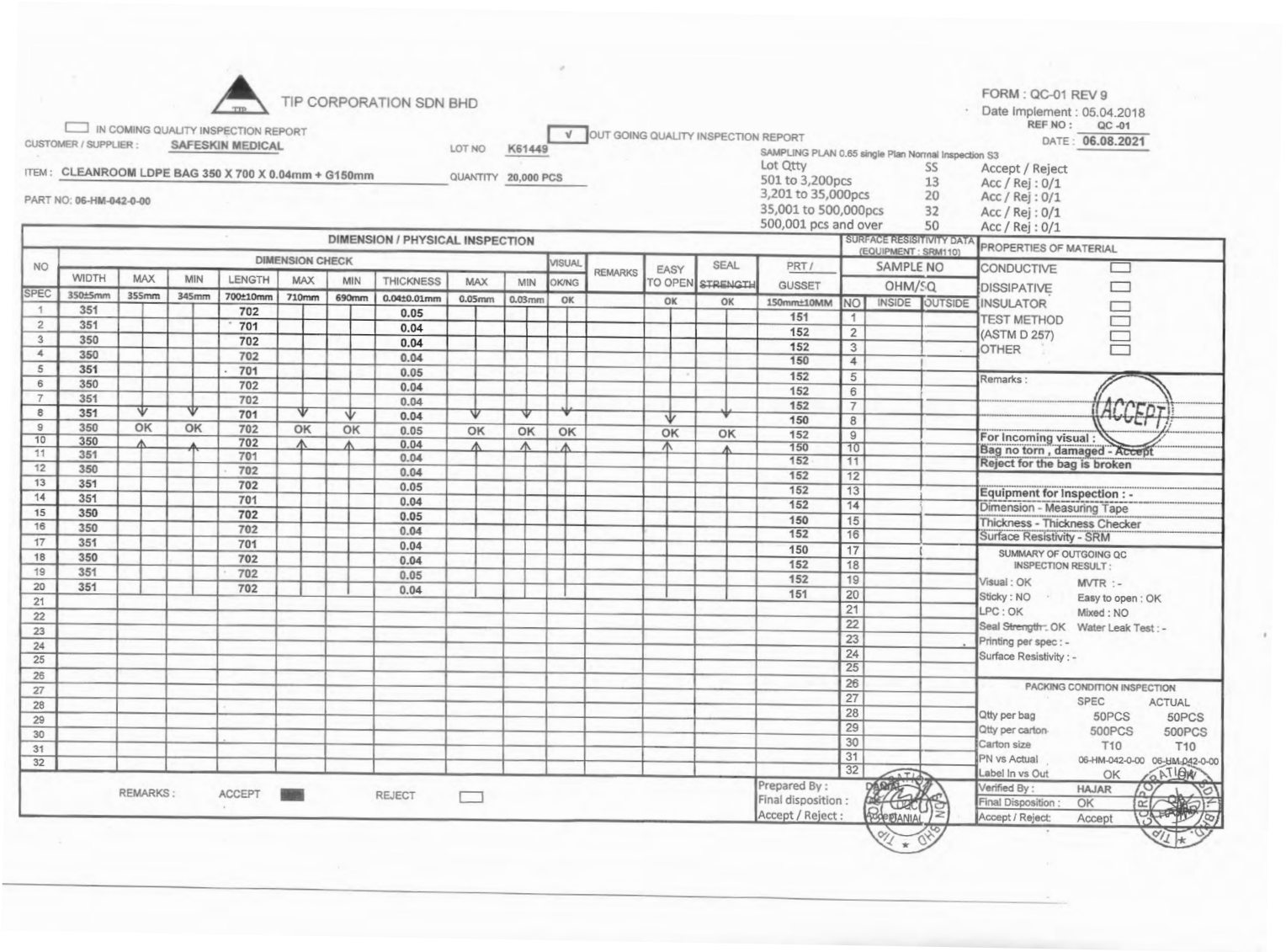
TESTED BY: QUALITY CONTROL

HAJAR

VERIFIED BY : QA 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
ITEM : CLEANROOM LDPE BAG 350 X 700 X 0.04mm + G150mm
QUANTITY 20,000 PCS
PART NO: 06-HM-042-0-00

SAMPLING PLAN 0.65 single Plan Normal Inspection S3

Lot Qtty	SS	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

NO	DIMENSION CHECK									VISUAL	REMARKS	EASY TO OPEN	SEAL STRENGTH	PRT / GUSSET
	WIDTH	MAX	MIN	LENGTH	MAX	MIN	THICKNESS	MAX	MIN	OK/NG				
SPEC	350±5mm	355mm	345mm	700±10mm	710mm	690mm	0.04±0.01mm	0.05mm	0.03mm	OK		OK	OK	150mm±10MM
1	351			702			0.05							151
2	351			701			0.04							152
3	350			702			0.04							152
4	350			702			0.04							150
5	351			701			0.05							152
6	350			702			0.04							152
7	351			702			0.04							152
8	351	↓	↓	701	↓	↓	0.04	↓	↓	↓		↓	↓	150
9	350	OK	OK	702	OK	OK	0.05	OK	OK	OK		OK	OK	152
10	350	↑	↑	702	↑	↑	0.04	↑	↑	↑		↑	↑	150
11	351			701			0.04							152
12	350			702			0.04							152
13	351			702			0.05							152
14	351			701			0.04							152
15	350			702			0.05							150
16	350			702			0.04							152
17	351			701			0.04							150
18	350			702			0.04							152
19	351			702			0.05							152
20	351			702			0.04							151
21														
22														
23														
24														
25														
26														
27														
28														
29														
30														
31														
32														

SURFACE RESISITIVITY DATA (EQUIPMENT : SRM110)

NO	SAMPLE NO OHM/SQ INSIDE	OUTSIDE
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
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27		
28		
29		
30		
31		
32		

PROPERTIES OF MATERIAL
- CONDUCTIVE ☐
- DISSIPATIVE ☐
- INSULATOR ☐
- TEST METHOD ☐
- (ASTM D 257) ☐
- OTHER ☐

Remarks : ACCEPT

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	

Verified By : HAJAR
Final Disposition : OK
Accept / Reject: Accept

REMARKS : ACCEPT ■ REJECT ☐

Prepared By : DIANA
Final disposition :
Accept / Reject : ACCEPT/DIANA

CASE LINER COC

TIP CORPORATION SDN BHD Reg. No: 198901010228 (187530-A)

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
Testing Date: 06.08.2021
Customer : SAFESKIN

Lot No: K61449
Size: 650X700X0.04MM
Method: BY SHAKER
Machine: KCCS-6

Blank Particle Counts (Cumulative)

	Blank Cts 1 Counts	Blank Cts 2 Counts	Blank Ct 3 Counts	Average Blank (A) 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 Counts	Washed Cts 2 Counts	Washed Cts 3 Counts	Average Washed (B) 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

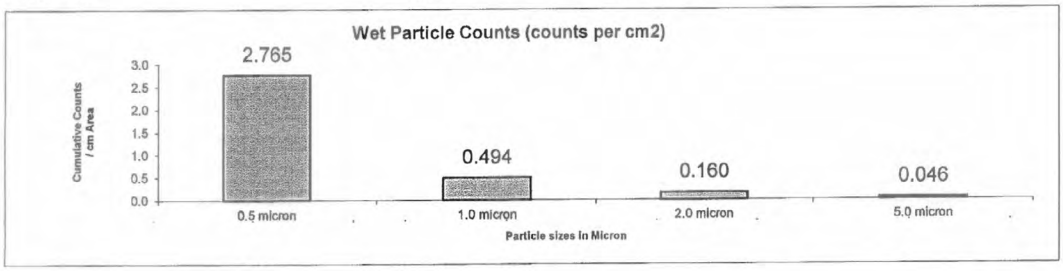
Total Washed Area 8775 cm^2

(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^2 (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



Cts/cm2

Total Particle (≥0.5) : **3.464 (PASSED)**

SPEC: ≥ 0.5u ≤100 COUNTS/CM^2

Tested By : SUHAIDA
Date : 06.08.2021

Verified By : HAJAR
Date : 06.08.2021



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

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

4. FIRST AID MEASURES

Inhalation: No first aid needed.

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

Eye contact: No first aid needed.

Ingestion: Not a relevant route of exposure.

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

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

5. FIRE-FIGHTING MEASURES

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

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

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

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

6. ACCIDENTAL RELEASE MEASURES

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

Environmental Precautions: None required.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling: No special handling is required.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)

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

Appropriate Engineering Controls: None required.

Individual Protection Measures, such as Personal Protective Equipment:

Respiratory Protection: None required.

Protective Gloves: None required.

Eye Protection: None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.

Chemical Stability: Stable at ambient temperature and pressure.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: Avoid heat and flames.

Incompatible Materials: None known.

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

11. TOXICOLOGICAL INFORMATION

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

Inhalation: Not applicable.

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

Eye contact: None expected.

Ingestion: Not applicable.

Chronic toxicity: None expected.

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

Reproductive Toxicity: None known.

Numerical Measures of Toxicity:
Not acutely toxic.

12. ECOLOGICAL INFORMATION

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

Persistence and Degradability: Not degradable.

Bioaccumulative Potential: Not bioaccumulative.

Mobility in Soil: Not mobile.

Other Adverse Effects: None currently known.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

US DOT Shipping Description: Not regulated

IATA Shipping Description (Air): Not regulated

IMDG Shipping Description (Vessel): Not regulated

15. REGULATORY INFORMATION

US Regulations

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

SARA 302 Listed Chemicals: None.

SARA 311/312 Hazard Categories: Not applicable to articles

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

16. OTHER INFORMATION

Date Prepared: 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 or call us directly at (844) 425-9273.

Sincerely,

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

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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* **PURE**ZERO* HG5 White Nitrile Gloves	CLN30512XS CLN30512SM CLN30512MD CLN30512LG CLN30512XL
HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves	CLN92512XS CLN92512SM CLN92512MD CLN92512LG CLN92512XL

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ISO 9001:2015

bsi.

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.™

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An electronic certificate can be authenticated online.
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.

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	Registered Activities
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	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
Effective Date: 2021-08-12
Latest Revision Date: 2021-07-16
Expiry Date: 2024-08-11

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An electronic certificate can be authenticated online.
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.

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 13485:2016

bsi.

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.

ISO 14001:2015

bsi.

By Royal Charter

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* PURE**ZERO**HG3 and HG5 Nitrile Gloves**

Dear Valued Customer,

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

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

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

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

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

Sincerely,

Shannon Smith

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

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

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

COPY-04632

May 9rd, 2023

RE: **HALYARD* PURE**ZERO**HG5 Nitrile Gloves**

Dear Valued Customer,

This letter is in response to your recent inquiry regarding food contact tesintg of **HALYARD* PURE**ZERO**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^2)	Requirement (mg/in2)	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 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/dm2)	Requirement (mg/dm2)	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 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.

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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, **PURE**ZERO* HG5 Cleanroom Gloves are **now tested against 2 chemotherapy drugs and 21 chemicals**.

CHEMOTHERAPY DRUG RESISTANCE GUIDE[4]

Chemotherapy Agent (Concentration in mg/ml)	**PURE**ZERO* HG5 White Nitrile Gloves 12"		**PURE**ZERO* HG5 Blue SGX* Nitrile Gloves 12"	
	Minimum Breakthrough Time (minutes)	Permeation Rate (µg/cm²/min)	Minimum Breakthrough Time (minutes)	Permeation Rate (µg/cm²/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 µg/cm²/min) as defined within ASTM D6978.

CAUTION: It's the user's responsbility 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 (µg/cm²/min).

PUREZERO*

HG5 Nitrile Cleanroom Gloves

CHEMICAL RESISTANCE GUIDE[5]

	PUREZERO* HG5 White Nitrile Gloves 12"		**PURE**ZERO* HG5 Blue SGX* Nitrile Gloves 12"	
Chemical (Concentration %)	Minimum Breakthrough Time (minutes)	Permeation Rate (µg/cm²/min)	Minimum Breakthrough Time (minutes)	Permeation Rate (µg/cm²/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 breakthough is poor - avoid use with this chemical.
11 - 479	Glove is suitable under careful control of its use.
>480	Permeation breakthough is excellent.

The following gloves are applicable to this chart:
HALYARD* **PURE**ZERO* HG5 White Nitrile Gloves
HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves

*** Though detected at trace amounts, the permeation did not hit the required rate of 1.0 µg/cm²/min to be deemed as Standardized Breakthrough per EN 16523-01:2015.
DISCLAIMER: The permeation breakthough times presented in this chart were evaluated using the Test Method EN 16523-1.

* Permeation Time (minutes) and Permeation Rate (µg/cm²/min) using Test Method EN 16523-1
Contact your Sales Representative for additional chemical and chemotherapy drug testing information.

November 13th, 2023

RE: **ESD Testing for HALYARD* PURE**ZERO*** Nitrile Gloves**

Dear Valued Customer,

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

The following **HALYARD* PURE**ZERO*** 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

Glove Description	Code
HALYARD* **PURE**ZERO* HG3 White Nitrile Gloves	CLN3031XS
HALYARD* **PURE**ZERO* HG3 White Nitrile Gloves	CLN3031SM
HALYARD* **PURE**ZERO* HG3 White Nitrile Gloves	CLN3031MD
HALYARD* **PURE**ZERO* HG3 White Nitrile Gloves	CLN3031LG
HALYARD* **PURE**ZERO* HG3 White Nitrile Gloves	CLN3031XL
HALYARD* **PURE**ZERO* HG3 Blue Nitrile Gloves	CLN9031XS
HALYARD* **PURE**ZERO* HG3 Blue Nitrile Gloves	CLN9031SM
HALYARD* **PURE**ZERO* HG3 Blue Nitrile Gloves	CLN9031MD
HALYARD* **PURE**ZERO* HG3 Blue Nitrile Gloves	CLN9031LG
HALYARD* **PURE**ZERO* HG3 Blue Nitrile Gloves	CLN9031XL
HALYARD* **PURE**ZERO* HG3 White SGX* Nitrile Gloves	CLN3231XS
HALYARD* **PURE**ZERO* HG3 White SGX* Nitrile Gloves	CLN3231SM
HALYARD* **PURE**ZERO* HG3 White SGX* Nitrile Gloves	CLN3231MD
HALYARD* **PURE**ZERO* HG3 White SGX* Nitrile Gloves	CLN3231LG
HALYARD* **PURE**ZERO* HG3 White SGX* Nitrile Gloves	CLN3231XL
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323260
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323265
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323270
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323275
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323280
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323285
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323290
HALYARD* **PURE**ZERO* HG3 White Sterile Nitrile Gloves	CLN323210

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

HALYARD* PUREZERO* HG5 Cleanroom Nitrile Gloves

Glove Description	Code
HALYARD* **PURE**ZERO* HG5 White Nitrile Gloves	CLN30512XS
HALYARD* **PURE**ZERO* HG5 White Nitrile Gloves	CLN30512SM
HALYARD* **PURE**ZERO* HG5 White Nitrile Gloves	CLN30512MD
HALYARD* **PURE**ZERO* HG5 White Nitrile Gloves	CLN30512LG
HALYARD* **PURE**ZERO* HG5 White Nitrile Gloves	CLN30512XL
HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves	CLN92512XS
HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves	CLN92512SM
HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves	CLN92512MD
HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves	CLN92512LG
HALYARD* **PURE**ZERO* HG5 Blue SGX* Nitrile Gloves	CLN92512XL

HALYARD* PUREZERO* Nitrile Exam Gloves

Glove Description	Code
HALYARD* **PURE**ZERO* MARIN* Nitrile Exam Gloves	LFS111XS
HALYARD* **PURE**ZERO* MARIN* Nitrile Exam Gloves	LFS111SM
HALYARD* **PURE**ZERO* MARIN* Nitrile Exam Gloves	LFS111MD
HALYARD* **PURE**ZERO* MARIN* Nitrile Exam Gloves	LFS111LG
HALYARD* **PURE**ZERO* MARIN* Nitrile Exam Gloves	LFS111XL
HALYARD* **PURE**ZERO* MARIN-XTRA* Nitrile Exam Gloves	LFS121XS
HALYARD* **PURE**ZERO* MARIN-XTRA* Nitrile Exam Gloves	LFS121SM
HALYARD* **PURE**ZERO* MARIN-XTRA* Nitrile Exam Gloves	LFS121MD
HALYARD* **PURE**ZERO* MARIN-XTRA* Nitrile Exam Gloves	LFS121LG
HALYARD* **PURE**ZERO* MARIN-XTRA* Nitrile Exam Gloves	LFS121XL
HALYARD* **PURE**ZERO* LIMON* Nitrile Exam Gloves	LFS311XS
HALYARD* **PURE**ZERO* LIMON* Nitrile Exam Gloves	LFS311SM
HALYARD* **PURE**ZERO* LIMON* Nitrile Exam Gloves	LFS311MD

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

HALYARD* PUREZERO* **Nitrile Gloves**

Glove Description	**Code**
HALYARD* **PURE**ZERO* MARIN* Nitrile Gloves	LFS1117XS
HALYARD* **PURE**ZERO* MARIN* Nitrile Gloves	LFS1117SM
HALYARD* **PURE**ZERO* MARIN* Nitrile Gloves	LFS1117MD
HALYARD* **PURE**ZERO* MARIN* Nitrile Gloves	LFS1117LG
HALYARD* **PURE**ZERO* MARIN* Nitrile Gloves	LFS1117XL
HALYARD* **PURE**ZERO* LIMON* Nitrile Gloves	LFS3117XS
HALYARD* **PURE**ZERO* LIMON* Nitrile Gloves	LFS3117SM
HALYARD* **PURE**ZERO* LIMON* Nitrile Gloves	LFS3117MD
HALYARD* **PURE**ZERO* LIMON* Nitrile Gloves	LFS3117LG
HALYARD* **PURE**ZERO* LIMON* Nitrile Gloves	LFS3117XL
HALYARD* **PURE**ZERO* ULTRA VIOLET* Nitrile Gloves	LFS5117XS
HALYARD* **PURE**ZERO* ULTRA VIOLET* Nitrile Gloves	LFS5117SM
HALYARD* **PURE**ZERO* ULTRA VIOLET* Nitrile Gloves	LFS5117MD
HALYARD* **PURE**ZERO* ULTRA VIOLET* Nitrile Gloves	LFS5117LG
HALYARD* **PURE**ZERO* 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* PURE**ZERO*** 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* PURE**ZERO*** 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* **PURE**ZERO* Nitrile Gloves

Please be advised that to the best of O&M Halyard knowledge, the **PURE**ZERO* HG3 Nitrile Gloves and HALYARD* **PURE**ZERO* 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* PURE**ZERO*** Nitrile Gloves**

Dear Valued Customer,

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

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

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

Theresa McCoy

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 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 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 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 or call us directly at (844) 425-9273.

Sincerely

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COPY-04662

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COPY-04662

October 2023

TITLE: HALYARD* **PURE**ZERO***** HG3 & HG5 Nitrile Gloves Packaging

UPDATE: Alternate packaging supplier for HALYARD* **PURE**ZERO***** 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* PURE**ZERO*** 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* PURE**ZERO*** 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.

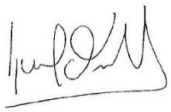
PRODUCTS IMPACTED BY THIS CHANGE:

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

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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