



## PRODUCT SPECIFICATION

### POLYCHLOROPRENE HAND SPECIFIC GLOVE PACKED IN L/R WALLET - STERILE

SkinGuard **1**

#### PRODUCT INFORMATION

##### PRODUCT DESCRIPTION

SkinGuard 1 is a powder free polychloroprene hand specific sterile glove specifically designed and manufactured for cleanroom compatibility giving enhanced protection from cytotoxic drugs without compromising dexterity.

##### PRODUCT FEATURES

100% Polychloroprene  
CE/UKCA Marked  
Cytotoxic protection  
Hand specific  
Powder free  
Textured Palm  
Latex free  
Beaded cuff

##### MANUFACTURING

Manufactured in a facility holding the ISO 9001:2015, ISO 17025:2017, ISO 13485:2016, ISO14001:2015 registrations, PPE Regulation (EU) 2016/425 and GMP certification

##### PACKAGING

Packed in cleanroom compatible packaging.  
Each pair is presented in a left /right wallet inside a peel open pouch.

- 10 pairs per outer carton pack
- 5 packs per carton

##### STERILISATION DETAILS

Sterilised by gamma irradiation (minimum 25kGy cycle)

##### QUALITY ASSURANCE

Supplied under ISO 9001

##### SHELF LIFE

4 years from date of manufacture

##### STORAGE CONDITIONS

Store in a dry, well ventilated area and protect from direct sunlight and heat sources

## PHYSICAL PROPERTIES

<b>Physical Properties</b>	Tensile Strength Elongation	> 17 Mpa min 750%
<b>Dimensions</b>	Length Palm Width	300 +10mm 76-78mm to 119-121mm
<b>Ionic Burden</b> (microgram/ sq cm) (as determined by IES-RP-C005.4)	Fluoride<0.020 Chloride<0.650 Phosphate<0.525 Sodium<0.020 Lithium<0.0004 Copper<0.0004	Sulphate<0.550 Nitrate<0.770 Bromide<0.042 Magnesium<0.002 Potassium<0.050
<b>Liquid Particle Counts</b> (as determined by IES-RP-CC005.4)	< 700 particle counts cumulative at 0.5micron	
<b>Organics</b> (IES-RP-CC005.4)	Silicone Oil Free, detected by FTIR Spectroscopy	
<b>Non-Volatile Residue</b> (IES-RP-CC005.4)	< 6.0 microgram/sq. cm	

## TEST RESULTS

BS EN ISO 374-1:2016+A1:2018 Terminology and performance requirements for chemical risks.

Symbol	Chemical name	Permeation Level achieved	Mean Degradation %
K	40% Sodium Hydroxide	6	-36.5
L	96% Sulphuric Acid	2	13.6
P	30% Hydrogen Peroxide	6	-18.1
O	25% Ammonium Hydroxide	1	-143.2

**Type B - Minimum of 3 chemicals must reach at least level 2 permeation.**

## CYTOTOXIC DRUG TESTING

The tests were performed according to EN 16523-1:2015 + A1\_2018 with the deviations mentioned in Annex 2.

Chemical	Average Thickness (mm)	Average Weight (g/m <sup>2</sup> )	Average Breakthrough Time	Detection Limit
5-Fluorouracil (50 mg/ml), T = 23.7°C	0.15	192	>480	0.04
Carmustine (3.3 mg/ml), T = 23.0°C	0.17	218	>480	0.04
Cyclophosphamide (20 mg/ml), T = 23.3°C	0.18	222	>480	0.04
Doxorubicin HCl (2 mg/ml), T = 23.0°C	0.17	212	>480	0.04
Etoposide (20 mg/ml), T = 23.1°C	0.17	214	>480	0.04
Paclitaxel (6 mg/ml), T = 23.1°C	0.17	214	>480	0.04
ThioTEPA (10 mg/ml), T = 23.2°C	0.17	211	>480	0.04

## BS EN ISO 374-5:2016 Terminology and performance requirements for micro-organisms risks

Virus – PASS

Bacteria – PASS

Fungi - PASS

## OTHER TESTS

pH value	EN21420:2020	6.6	Pass
Extractable latex protein	EN21420:2020	<10ug/g	Pass
Size (7-9)	EN21420:2020	-	Pass
Dexterity (7-9)	EN21420:2020	Level 5	-
Air leak (7-9)	EN374-2:2019	-	Pass
Water leak (7-9)	EN374-2:2019	-	Pass
Virus Test	EN ISO 374-5:2016	-	Pass
Size (size 6)	EN21420:2020	-	Pass
Dexterity (size 6)	EN21420:2020	Level 5	-
Air leak (size 6)	EN374-2:2019	-	Pass
Water leak (size 6)	EN374-2:2019	-	Pass

## RECYCLING INFORMATION

Component Name:	Component Material:	Disposal:	Guidance:
Gloves	Polychloroprene	Recyclable	Recycle unless glove is contaminated with hazardous materials/chemicals, then dispose of as hazardous waste
L & R Wallet	HDPE	Recyclable	N/A
Pouch	LDPE	Recyclable	Check with local authority, remove any labels and tape
Irradiation Labels	Coated Gloss Paper with an Emulsion Acrylic Adhesive	Non-recyclable Individually	Check with local authority , remove from product and cardboard box
Polybag	HDPE	Recyclable	Remove all labels
Polybag Label	Coated Gloss Paper with an Emulsion Acrylic Adhesive	Non-recyclable	Remove from polybag
Polyliner	LDPE	Recyclable	Check with local authority, remove any labels
Polyliner Label	Coated Gloss Paper with an Emulsion Acrylic Adhesive	Non-recyclable	Remove from polyliner
Box	Cardboard	Recyclable	Remove irradiation label and packaging tape
Box Label	Coated Gloss Paper with an Emulsion Acrylic Adhesive	Non-recyclable Individually	Keep on cardboard box
Tape (Packaging and Pouch Tape)	OPP Tape (Bi-oriented PP Film with an Acrylic Emulsion Adhesive)	Non-recyclable	Remove from cardboard box and pouch

## ORDERING/PACKING INFORMATION

Non-Sterile Code	Sterile Code	Description	Size	Pack Qty	Case Qty
	GSPG31	Polychloroprene Hand Specific Glove Packed in L/R Wallet - Sterile	6.0 - 9.0	10 pairs	5 Packs of 10 Pairs