



SkinGuard

DATA SHEET

STERILE POWDER FREE POLYCHLOROPRENE GLOVES



PRODUCT INFORMATION

PRODUCT DESCRIPTION

SkinGuard1 is a polychloroprene hand specific sterile glove specifically designed and manufactured for cleanroom compatibility giving enhanced protection from cytotoxic drugs without compromising dexterity.

PRODUCT FEATURES

- ISO Class 4 and EU GMP Grade A Compatible
- Superb chemical resistance as measured against ASTM D 6978 -05
- Combined advanced technologies that deliver a hand specific glove that is soft and pliable ensuring maximum wearer comfort without compromising grip levels
- Graduated thickness which guarantees fingertip sensitivity whilst not compromising inherent protection levels

- Enhanced surface treatments ensure stress free donning and double gloving
- Packed in specially designed cleanroom compatible packaging facilitates stress free aseptic donning
- Powder and latex free
- CE marked as a medical device and as an item of personal protective equipment
- Suitable for use in conjunction with isolator sleeve cuffs

TECHNICAL INFORMATION

MANUFACTURING

- Cleanroom washed and packed to achieve low chemical ion and low particulate contamination
- Contain no extractable latex proteins and very low levels of process chemical residues (< 0.05% w/w).

PACKAGING

Packed in cleanroom compatible packaging. Each pair is presented in a left /right wallet and then in 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 9001:2008.

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.

HAZARD STATEMENT

Non hazardous.

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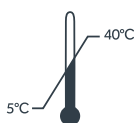


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TECHNICAL INFORMATION



IENT-RP-CC-005.3
ASTM 6978-05



CE0088
IN COMPLIANCE WITH
DIRECTIVE 89/686/EEC

EN 388	
Abrasion:	0
Cut:	0
Tear:	0
Puncture:	0

EN374-2:2003		
Performance Level	Acceptable Quality Level Unit	Inspection Levels
Level 3	<0.65	G1
Level 2	<1.5	G1
Level 1	<4.0	S4

EN374-1:2003	
Chemicals	EN374-1:2003 Performance Level
Methanol (A)	1
40% Sodium Hydroxide (K)	6
Sulphuric Acid 96% (L)	2

GENERAL PERFORMANCE CHARACTERISTICS

TEST	STANDARD	PERFORMANCE LEVEL
Size	EN 420:2003	All sizes are labelled
Dexterity	EN 420:2003	Level 5
pH	EN 420:2003	Pass
Water leak	EN 374-2:2003	Pass
	Performance Level	Acceptable quality level (AQL) unit
	Level 2	<1.5
		Inspection levels
		G1
Permeation resistance against Methanol (A)	EN 374-3:2003	Level 1
Permeation resistance against 40% Sodium Hydroxide (K)	EN 374-3:2003	Level 6
Permeation resistance against 96% Sulphuric Acid (L)	EN 374-3:2003	Level 2
Permeation resistance against Acetone	EN 374-3:2003	None
Permeation resistance against Ethyl Acetate	EN 374-3:2003	None
Permeation resistance against Heptane	EN 374-3:2003	None
Abrasion	EN 388:2003	0
Cut	EN 388:2003	0
Tear	EN 388:2003	0
Puncture	EN 388:2003	0

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PROTECTION AGAINST CYTOTOXIC DRUGS

The permeation rates of various cytostatic drugs through SkinGuard 1 gloves have been measured using the standard test method ASTM D 6978-05.

CYTOTOXIC DRUG TESTED & CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (SPECIMEN 1 / 2 / 3) [MINUTES]	STEADY STATE PERMEATION RATE (SPECIMEN 1 / 2 / 3) (µG / CM ² /MINUTE)	OTHER OBSERVATIONS
Cisplatin 1.0mg/ml (1,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Cyclophosphamide (Cytosan) 20.0mg/ml (20,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Dacarbazine (DTIC) 10.0mg/ml (10,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Doxorubicin Hydrochloride 2.0mg/ml (2,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Etoposide (Toposar) 20.0mg/ml (20,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Fluorouracil 50.0mg/ml (50,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Ifosfamide 50.0mg/ml (50,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Mechlorethamine HCl 1.0mg/ml (1,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Melphalan 5.0mg/ml (5,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Methotrexate 25.0mg/ml (25,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0mg/ml (6,000ppm)	No break through up to 240 mins	Below threshold of detection	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0mg/ml (6,000ppm)	No break through up to 240 mins	Below threshold of detection	Moderate swelling and no degradation
Carmustine (BCNU) 3.3mg/ml (3,300ppm)	0.2 (0.5, 0.2, 0.3)	0.5 (0.6, 0.5, 0.4)	Moderate swelling and no degradation
Thiotepa 10.0mg/ml (10,000ppm)	15.4 (31.0, 15.6, 15.4)	0.6 (0.6, 0.5, 0.6)	Slight swelling and no degradation

ORDERING & PACKING INFORMATION

Sterile Code	Description	Size	Pack Qty	Case Qty	Case Dimensions	Weight
GSPG31060-90	Sterile Powder Free Polychloroprene Gloves	6.0 to 9.0	10 Pairs	5 x 10 Pairs	295 x 165 x 300mm	1.34 - 1.85kg

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