

Vasco® OP Free Sterile Surgical and Protective Gloves

DATA SHEET



STERILE R



EN 374:2003



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AQL 0.65

B. Braun Melsungen AG confirms that Vasco® OP Free gloves comply with the following standards and directives:

EC CERTIFICATES AND APPLIED STANDARDS

Medical device class IIa CE 0123 (TÜV Süd, DE)
according to MDD 93/42/EEC
EN 455 1-4, ISO 10282, ISO 10993, ISO 11137,
ASTM D3577, ASTM D5712

Personal protective equipment category III CE 0321 (SATRA, UK)
according to 89/686/EEC
EN 420, EN 374 1-3, EN 16523, EN 388,
ASTM F1671, ASTM D6978

QUALITY CERTIFICATES

ISO 9001, ISO 13485

Certificates and complete list of applied standards are available on request.

B. Braun Melsungen AG

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs OPM Germany

Vasco[®] OP Free Sterile Surgical and Protective Gloves

TECHNICAL DATA



REF	SIZE	GLOVE DIMENSIONS (ACC. EN 455)		WALL THICKNESS Single wall
		Width of palm	Total length	
9208291	5.5	73 ± 3 mm	≥ 270 mm	
9208305	6	79 ± 3 mm	≥ 270 mm	
9208313	6.5	85 ± 3 mm	≥ 270 mm	finger ≥ 0.185 mm
9208321	7	91 ± 3 mm	≥ 280 mm	palm ≥ 0.19 mm
9208330	7.5	97 ± 3 mm	≥ 280 mm	
9208348	8	105 ± 3 mm	≥ 280 mm	cuff ≥ 0.175 mm
9208356	8.5	111 ± 3 mm	≥ 285 mm	
9208364	9	112 ± 3 mm	≥ 285 mm	

GLOVE DESIGN

Colour	cream-coloured
Shape	fully anatomical shape with curved fingers
Cuff	rolled rim
Surface finish	micro rough, silicone treated
Inner glove surface	polymer coated, powder-free

GLOVE MATERIAL

Polyisoprene
Free of natural rubber latex

ACCELERATORS

Zn-dithiocarbamate
Free of thiurames, thioureas and thiazoles - including mercaptobenzothiazole MBT

PHYSICAL PROPERTIES

Force at break (median)	≥ 9 N during shelf life		
Elongation at break (median)	before ageing	≥ 880 %	after ageing ≥ 800 %
Tensile strength (median)	before ageing	≥ 26 MPa	after ageing ≥ 25 MPa
Water-tightness	AQL 0.65		

STERILIZATION

Gamma irradiation

LOGISTIC INFORMATION

Peel pouch	sterile film peel packs with 1 pair of gloves left/right with folded cuffs in paper cover		
Packaging dimensions	peel pouch	270 x 150 mm	
	dispenser box	270 x 150 x 205 mm (L x W x H)	
Packaging levels	40 pairs/box	10 boxes/carton (400 pairs)	
Shelf life	3 years		
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone		

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BARRIER PROPERTIES – CHEMICALS



Tested by SATRA, UK and ProQuares, NL in accordance with

EN 374-3: Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals.

CHEMICAL	CAS REGISTRY NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
Acetic acid 10 %	64-19-7	level 6	> 480 min
Acetone	67-64-1	not recommended	immediate
Acetonitrile	75-05-8	splash guard	1 – 10 min
Acrylamide 40 %	79-06-1	level 6	> 480 min
Ammonium hydroxide 25 %	1336-21-6	level 1	> 10 min
Chlorhexidine digluconate 0.5 %	18472-51-0	level 6	> 480 min
Chlorhexidine 4 %	55-56-1	level 6	> 480 min
Chloroform	67-66-3	not recommended	immediate
Cyclohexanol	108-93-0	level 2	> 30 min
Dichlormethane	75-09-2	not recommended	immediate
Diesel fuel (100 %)		splash guard	1 – 10 min
Diethylamine	109-89-7	not recommended	immediate
Diethyl ether	60-29-7	not recommended	immediate
Dimethyl sulfoxide DMSO	67-68-5	level 3	> 60 min
Ethanol 20 %	64-17-5	splash guard	1 – 10 min
Ethanol 80 %	64-17-5	splash guard	1 – 10 min
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Ethyl acetate	141-78-6	splash guard	1 – 10 min
Formaldehyde 37 % (in Methanol 10 %)	50-00-0	level 6	> 480 min
Glutaraldehyde 5 %	111-30-8	level 6	> 480 min
Heptane-n	142-82-5	not recommended	immediate
Hexane-n	110-54-3	not recommended	immediate
Hydrochloric acid 10 %	7647-01-0	level 6	> 480 min
Hydrochloric acid 36 %	7647-01-0	level 3	> 60 min
Iodine 1 % (in Alcohol 70 %)	7553-56-2	level 6	> 480 min
Isopropyl alcohol	67-63-0	splash guard	1 – 10 min
Linseed oil		level 6	> 480 min
Methanol	67-56-1	splash guard	1 – 10 min
Methyl methacrylate	80-62-6	splash guard	1 – 10 min
Nitric acid 10 %	7697-37-2	level 6	> 480 min
Nitric acid 50 %	7697-37-2	level 5	> 240 min
Povidone-iodine 10 %	25655-41-8	level 6	> 480 min
Sodium hydroxide 30 %	1310-73-2	level 6	> 480 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sodium hypochlorite 10 %	7681-52-9	level 6	> 480 min
Sulfuric acid 30 %	7664-93-9	level 1	> 10 min
Sulfuric acid 96 %	7664-93-9	level 1	> 10 min
Toluene	108-88-3	not recommended	immediate
Trichloroethane	71-55-6	not recommended	immediate
Xylene	1330-20-7	splash guard	1 – 10 min

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BARRIER PROPERTIES – CYTOSTATIC DRUGS



Tested by ARDL, USA and ProQuares, NL in accordance with

EN 374-3: Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals. Minimum detection rate $1 \mu\text{g}/\text{cm}^2/\text{min}$ ①

ASTM F 739: Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases under Conditions of Continuous Contact. Minimum detection rate $0,1 \mu\text{g}/\text{cm}^2/\text{min}$ ②

ASTM D 6978: Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum detection rate $0,01 \mu\text{g}/\text{cm}^2/\text{min}$ ③

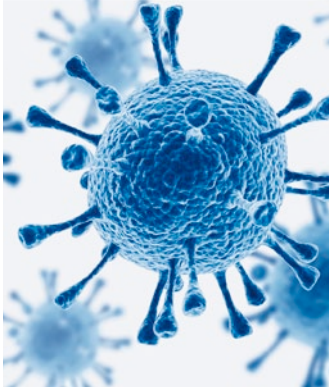
CLASSIFICATION

- Not suitable
- Suitable if changed before permeation breakthrough
- Suitable for prolonged use

CHEMOTHERAPY DRUG	mg/ml	CAS registry no.	MIN BREAKTHROUGH DETECTION TIME
Bleomycin sulphate	15	9041-93-4	■ > 240 min ③
Carboplatin	10	41575-94-4	■ > 240 min ③
Carmustine (BiCNU)	3.3	154-93-8	■ > 240 min ②
Cisplatin	1.0	15663-27-1	■ > 240 min ②
Cyclophosphamide (Cytoxan)	20.0	6055-19-2	■ > 480 min ②
Cytarabine HCl	100	147-94-4	■ > 240 min ③
Dacarbazine (DTIC)	10.0	4342-03-4	■ > 480 min ②
Daunorubicin HCl	5	20830-81-3	■ > 240 min ③
Doxorubicin HCl	2.0	25316-40-9	■ > 480 min ②
Docetaxel	10	114977-28-5	■ > 240 min ③
Epirubicin	2.0	56420-45-2	■ > 240 min ③
Etoposide	20.0	33419-42-0	■ > 240 min ③
5-Fluorouracil	10.0	51-21-8	■ > 480 min ②
Gemcitabine	38	95058-81-4	■ > 240 min ③
Idarubicin	1	58957-92-9	■ > 240 min ③
Irinotecan	20	100286-90-6	■ > 240 min ③
Ifosfamide	50	3778-73-2	■ 120 min ③
Melphalan (Alkeran)	5.0	148-82-3	■ > 480 min ①
Methotrexate (Amethopterin Hydrate)	25.0	59-05-2	■ > 480 min ②
Mitomycin C	0.5	50-07-7	■ > 480 min ①
Mitoxantrone	2.0	65271-80-9	■ > 240 min ②
Oxaliplatin	5	63121-00-6	■ > 240 min ③
Paclitaxel (Taxol)	6.0	33069-62-4	■ > 240 min ②
Thio-Tepa	10.0	52-24-4	■ > 480 min ②
Topotecan	1	123948-87-8	■ > 240 min ③
Vinblastin	1	865-21-4	■ > 240 min ③
Vinorelbine	0.1	71486-22-1	■ > 240 min ③
Vincristine	1.0	57-22-7	■ > 240 min ③

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BARRIER PROPERTIES – VIRAL PENETRATION



Tested by NELSON, USA in accordance with

ASTM F 1671: Standard Test Method for Resistance of Materials used in Protective Clothing to Penetration by Blood Borne Pathogens using Phi-X 174 Bacteriophage Penetration as a Test System.

Specimens that exhibit no detectable (< 1 PFU/mL) Phi-X174 in the assay titer pass the test.

TEST RESULT	ASSESSMENT		VALUE
Pass	No plaques	No virus penetration	< 1 PFU/mL (PFU: Plaque-forming unit)

NOTE

All tests are conducted under laboratory conditions. The product properties are directly dependant upon the conditions of use. The gloves should be checked in advance for any holes or tears. Damaged or swelling gloves must be replaced immediately. In general, it is recommended to change gloves after 1-2 hours of working. In special cases, double gloving (colored underglove as indicator glove and white overglove) may be appropriate.

Tests and certificates can only be regarded as general information and do not reflect all actual working conditions. Glove selection shall be based on a risk assessment procedure. Hand hygiene by rubbing or washing is basic for hand decontamination before and after glove use.