Vasco® OP eco

STERILE SURGICAL AND PROTECTIVE GLOVES | DATA SHEET

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

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 according to Personal Protective Equipment Regulation (PPER) EU 2016/425
	EN 421, EN 420, EN 374, ISO 16523, ISO 16604, ASTM F1671
QUALITY CERTIFICATES	ISO 9001, ISO 13485
PERSONAL PROTECTIVE EQUIPMENT	Information and Declaration of Conformity according to PPER (EU) 2016/425:

www.bbraun.com/gloves-declarations-of-conformity

Digitally signed by Șarco Alexandru
Date: 2024.03.26 11:03:50 EET
Reason: MoldSign Signature
Location: Moldova

B. Braun Melsungen AG

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

Vasco® OP eco

STERILE SURGICAL AND PROTECTIVE GLOVES | REGULATORY INFORMATION

MEDICAL DEVICE INFORMATION

MDD 93/42/EEC (CLASS IIa), EN 455

CE 0123

°C 10 30

LATEX

STERILE R

PERSONAL PROTECTIVE EQUIPMENT INFORMATION

CE 2777

PPE Regulation (EU) 2016/425 (Cat. III);
EN 420:2003+A1:2009

Tested in accordance with:

ISO 374-1:2016/Type B

KPT

Code letter	Test chemical	EN 374-1:2016 Permeation level	EN 374-4:2013 Mean degradation
K	Sodium hydroxide 40 %	Level 6	-6,3%
P	Hydrogen peroxide 30 %	Level 6	-16,0 %
T	Formaldehyde 37 %	Level 6	9,0 %

Tested acc. to EN 16523-1:2015

Performance levels acc. EN 374-1:2016 +A1:2018	1	2	3	4	5	6
Measured breakthrough times (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

ISO 374-5:2016

VIRUS

AQL 0.65

Resistance to bacteria and fungi	pass
Resistance to virus	pass

EN 421:2010

Protection against particulate radioactive contamination.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical and penetration resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections.

Vasco® OP eco

STERILE SURGICAL AND PROTECTIVE GLOVES | TECHNICAL DATA

SIZE	REF	GLOVE DIMENSIONS (EN 455) Width of palm	Total length
5.5	6081308	72 ± 4 mm	≥ 260 mm
6	6081316	77 ± 5 mm	≥ 260 mm
6.5	6081324	83 ± 5 mm	≥ 260 mm
7	6081332	89 ± 5 mm	≥ 270 mm
7.5	6081340	95 ± 5 mm	≥ 270 mm
8	6081359	102 ± 6 mm	≥ 270 mm
8.5	6081367	108 ± 6 mm	≥ 280 mm
9	6081375	114 ± 6 mm	≥ 280 mm

			Min. specification	Typical value
PHYSICAL PROPERTIES	Wall thickness	Palm	0.165 mm	0.19 mm
		Cuff	0.145 mm	0.165 mm
	Force at break (acc. to EN 455)	During shelf life	9 N	16 N before ageing 14 N after ageing
	Elongation at break (acc. to ASTM D 3577)	Before ageing	750 %	786 %
		After ageing	560 %	847 %
	Tensile strength (acc. to ASTM D 3577)	Before ageing	24 MPa	30 MPa
		After ageing	18 MPa	28 MPa
GLOVE DESIGN	Colour	natural white		
	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	Natural rubber latex	Protein content ≤ 50 µg/g, lower claims are not considered to be reliable given the expected process variation in manufacture and inter-laboratory testing (EN 455-3)		
	Latex allergy risk	containing natural rubber latex which may cause allergic reactions including anaphylactic reactions		
ACCELERATORS	Zn-dithiocarbamate			
	Free of thiurames, thioureas and thiazoles - including mercaptobenzothiazole MBT			
STERILIZATION	Gamma irradiation			
LOGISTIC INFORMATION	Peel pouch	1 pair	270 x 150 mm (L x W)	
	Dispenser pack	40 pairs	270 x 150 x 205 mm (L x W x H)	
	Transportation carton	10 dispenser packs	785 x 283 x 417 mm (L x W x H)	
	Shelf life	3 years		
	Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone		

Vasco® OP eco

STERILE SURGICAL AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS

Tested by SATRA, UK in accordance with

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

EN 16523-1: Determination of material 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	not recommended	1 – 10 min
Acrylamide 40 %	79-06-1	level 6	> 480 min
Ammonium hydroxide 25 %	1336-21-6	not recommended	1 – 10 min
Chlorhexidine digluconate 0.5 %	18472-51-0	level 6	> 480 min
Chloroform	67-66-3	not recommended	immediate
Dichlormethane	75-09-2	not recommended	immediate
Diethylamine	109-89-7	not recommended	immediate
Diethyl ether	60-29-7	not recommended	immediate
Ethanol 10 %	64-17-5	not recommended	1 – 10 min
Ethanol 20 %	64-17-5	not recommended	1 – 10 min
Ethanol 70 %	64-17-5	not recommended	immediate
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Ethyl acetate	141-78-6	not recommended	immediate
Formaldehyde 37 %	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
Hydrogen peroxide 30 %	7722-84-1	level 6	> 480 min
Isopropyl alcohol 70 %	67-63-0	not recommended	1 – 10 min
Methanol p.a.	67-56-1	not recommended	immediate
Methyl methacrylate	80-62-6	not recommended	immediate
Ninhydrin 0.2 %	485-47-2	level 6	> 480 min
Nitric acid 10 %	7697-37-2	level 6	> 480 min
Phosphoric acid 85 %	7664-38-2	level 6	> 480 min
Potassium hydroxide 50 %	1310-58-3	level 6	> 480 min
Povidone-iodine 10 %	25655-41-8	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 6	> 480 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	95-47-6	not recommended	immediate