

MEDECO B.V.

Test Results

Brand : Klinion® Personal Protection ULTRA SAFE

Product : Nitrile, powder-free, non-sterile, medical examination gloves

Product Reference

Product Reference	Description	Size	Color
165040-165044	Klinion Protection Nitrile ULTRA SAFE Examination Gloves (4.6)	XS-XL	Blue

[EN 374-2:2015](#); Determination of resistance to penetration

[EN 420:2003 + A1:2009](#); General requirements and test methods

[EN ISO 374-5:2016](#); Terminology and performance requirements for micro-organisms risks

Test	Result
Water Leak	Pass
pH value between 3.5 and 9.5	Pass
Protection against bacteria and fungi	Pass
Protection against viruses (Resistance to penetration by blood-borne pathogens).	Pass

Food safety (according to Regulation (EU) No. 10/2011 with amendments and hence Article 3 of European Regulation No. 1935/2004)

Extraction Conditions	Temperature (°C)	Time (Hour)	Result
3% (v/v) Acetic solution	40	1	Pass
10% (v/v) Ethanol solution	40	1	Pass
20% (v/v) Ethanol solution	40	1	Pass
50% (v/v) Ethanol solution	40	1	Pass
Vegetable oil	40	1	Pass

[EN ISO 374-1: 2016](#); Terminology and performance requirements for chemical risks

Permeation levels are based on breakthrough times as follows:

Performance level	1	2	3	4	5	6
Minimum breakthrough time (minutes)	>10	>30	>60	>120	>240	>480

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[EN 16523-1: 2015](#); Permeation performance Level

[EN 374-4:2013](#); Determination of resistance to degradation by chemicals

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenged chemical.

Chemical	CAS no	EN 16523-1: 2015 Permeation performance	Tested minimum breakthrough time in minutes	EN 374-4 Degradation %
Acetic acid 10 %	64-19-7	Level 4	131	66,7
Ammonium Hydroxide 25% (O)	1336-21-6	Level 1	11	-52.0
Chlorhexidine Gluconate 4% *	18472-51-0	Level 6	> 480	19.0
Ethidium Bromide 5%	1239-45-8	Level 6	> 480	3,4
Formaldehyde 37% (T) ***	50-00-0	Level 4	181	-51.5
Glutaraldehyde 50%	111-30-8	Level 6	> 480	27.4
Hydrogen Peroxide 30% (P)	7722-84-1	Level 2	31	22.8
Methanol 1,5% in Water	67-57-1	Level 6	> 480	21.9
Phenol 0.1%	108-95-2	Level 6	> 480	33.8
Povidone-iodine 3%	25655-41-8	Level 6	> 480	33.7
Sodium Hydroxide 40% (K)	1310-73-2	Level 6	> 480	-42.9
Sodium Hypochlorite 10-13%	7681-52-9	Level 6	> 480	14.7
Sodium Percarbonate 10%	5630-89-4	Level 6	> 480	15.4
Sulphuric Acid 50%	7664-93-9	Level 6	> 480	-20.5
Benzalkonium Chloride 20% **	63449-41-2	Level 6	> 480	4.9
Hydrochloric acid 25%	7647-01-0	Level 6	> 480	-2.1
Isopropanol 40% ***	67-63-01	Level 1	13	-35.8
Methanol 5%	67-57-1	Level 6	> 480	23.8
Phosphoric Acid 30%	7664-38-2	Level 6	> 480	18.3
Potassium Hydroxide 30%	1310-58-3	Level 6	> 480	33.4
Sulphuric acid 25% ***	7664-93-9	Level 6	> 480	N/A
Acetic Acid 99% (N)	64-19-7	Did not meet minimum required breakthrough time for level 1	2	93.9
Cyclohexanol ***	108-93-0	Did not meet minimum required breakthrough time for level 1	10	N/A
Ethanol 35%	64-17-5	Did not meet minimum required breakthrough time for level 1	3	38.8
Ethanol 70% ***	64-17-5	Did not meet minimum required breakthrough time for level 1	4	N/A
Hexane ***	110-54-3	Did not meet minimum required breakthrough time for level 1	4	N/A
Isopropanol 70%	67-63-0	Did not meet minimum required breakthrough time for level 1	2	62.2
Nitric Acid 65% (M)	7696-37-2	Did not meet minimum required breakthrough time for level 1	3	97.6
Sulphuric acid 96% ***	7664-93-9	Did not meet minimum required breakthrough time for level 1	7	N/A

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* Permeation rate 7 µg/cm²/min

** Permeation rate 33 µg/cm²/min

*** Specifically tested on Ultra Safe gloves. Formaldehyde results are different compared to artwork and IFU. Test results on IFU and / or artwork are based on thinnest conventional nitrile glove.

ASTM D6978-05

Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Chemotherapy Drug	Concentration (mg/ml)	Minimum Breakthrough Detection Time (min)
Carmustine (BCNU)	3.3	10.1
Cisplatin	1.0	>240
Cyclophosphamide (Cytoxan)	20	>240
Cytarabine	100	>240
Dacarbazine (DTIC)	10.0	>240
Doxorubicin Hydrochloride	2.0	>240
Etoposide (Toposar)	20.0	>240
Fluorouracil (Adrucil)	50.0	>240
Ifosfamide	50.0	>240
Methotrexate	25	>240
Mitomycin C	0.5	>240
Mitoxantrone	2.0	>240
Paclitaxel (Taxol)	6.0	>240
ThioTEPA	10.0	30.2
Vincristine Sulfate	1.0	>240

Chemical Residue Analysis: Identification of accelerators and antioxidants in cured and uncured rubber compounds by thin layer chromatography.

Chemical	Results
Butylated Hydroxyanisole (BHA) (%)	Not Detected
Butylated Hydroxytoluene (BHT) (%)	Not Detected
Diphenyl Thiourea (DPT) (%)	Not Detected
Mercaptobenzothiazole (MBT) (%)	Not Detected
Tetramethylthiuram Disulphide (TMTD) (%)	Not Detected
Zinc Dibutyldithiocarbamate (ZDBC) (%)	Not Detected
Zinc Diethyldithiocarbamate (ZDEC) (%)	Not Detected
Zinc Dimethyldithiocarbamate (ZDMC) (%)	Not Detected
Zinc Mercaptobenzothiazole (ZMBT) (%)	Not Detected
Zinc Methylmercaptobenzimidazole (ZMMBI) (%)	Not Detected
Zinc Pentamethylenedithiocarbamate (ZPMC) (%)	Not Detected

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Disclaimer: The Klinion Protection examination gloves are intended to be worn on the hand for medical purposes and to help prevent contamination between patient and examiner. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture.

The viral penetration resistance has been assessed under laboratory conditions and relates only to tested species.

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.

This product provides protection against bacteria, fungi and virus. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

The product contains zinc dibutyl dithiocarbamates and should not be used in case of hypersensitivity to these substances.

Before usage, inspect the gloves for any defect or imperfections.
For single use only. Re-use can cause contamination or infection.

- ❖ Components used in glove manufacturing may cause allergic reactions to some users. If allergic reactions occur, seek for medical advice immediately.

Approval	Name	Date	Signature
Product Manager	Levine van Buren	6 May 2019	
RA-Manager	Francis Dekker	6 May 2019	