



User Information Sheet

UltraSAFE Violet Nitrile Gloves

Product name	UltraSAFE Violet Nitrile Gloves
Product codes	1116, 1117, 1118, 1119
Available sizes	Small, Medium, Large, Extra large
Manufacturer	PRO Hygiene Products
Manufacturer address	PO Box 168, BRISTOL, BS31 9EE, UK

1) Medical Device Directive (MDD)

- This product is classified under Class I Medical Device per Rule 1 and Rule 5 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.
- This product complies with European Standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

2) PPE EU Type-Examination

- This product is classed as Category III of Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425 and has been shown to comply with this Regulation through the Harmonised European Standards BS EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016.
- Notified Body responsible for certification and Module B compliance is BSI Group The Netherlands B.V. (2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands.
- Notified Body responsible for Quality Assurance of the Production Process (Module D) is BSI Group The Netherlands B.V. (2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands.
- EU Declaration of Conformity is accessible at www.prohygieneproducts.com.

3) Marking

- Micro Organism Hazards Pictogram: EN ISO 374-5:2016
Protect against Bacteria, Fungi and Virus. No penetration of bacteriophages through the specimen and the following pictogram is applied.



VIRUS

- Chemical Hazards Pictogram: BS EN 16523-1:2015; Additional information on chemical resistance obtainable from manufacturer.

EN ISO 374-1:2016 permeation levels are based on breakthrough times as follows:

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



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This product complies with Type B requirements and the following pictogram shall be used with reference to clause 6.3 of ISO 374-1.

ISO 374-1/Type B



KPT

4) Performance and Limitation of Use

- a) This product had been tested in accordance with EN ISO 374-5:2016.
Protection against bacteria and fungi – Pass
Protection against viruses - Pass
- b) Gloves had been tested in accordance with BS EN 16523-1:2015 resistance to permeation by chemicals and achieved the following performance levels:

Chemicals	Performance Level
Toluene (F)	0
n-Heptane (J)	1
40% Sodium Hydroxide (K)	6
96% Sulphuric acid (L)	0
25% Ammonium Hydroxide (O)	1
30% Hydrogen Peroxide (P)	5
37% Formaldehyde (T)	6
5% Ethidium Bromide	6
50% Glutaraldehyde	6
70% Isopropanol	2
0.1% Phenol	6
1.5% Methanol	6

- i) This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
- ii) 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 400mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical used in a mixture.
- iii) 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.
- iv) 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.
- v) Before usage, inspect the gloves for any defect or imperfections.



- c) This product had been tested in accordance with BS EN 374-4:2013 and achieved the following degradation results:

Chemicals	Mean Degradation / %
Toluene (F)	62.2
n-Heptane (J)	18.7
40% Sodium Hydroxide (K)	-66.1
96% Sulphuric acid (L)	100.0
25% Ammonium Hydroxide (O)	31.6
30% Hydrogen Peroxide (P)	26.9
37% Formaldehyde (T)	-9.0
5% Ethidium Bromide	-33.8
50% Glutaraldehyde	-42.5
70% Isopropanol	25.9
0.1% Phenol	-3.7
1.5% Methanol	-20.3

- i) EN 374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemicals.
- d) This product provides protection against Bacteria, Fungi and Virus. The gloves had been tested in accordance with ISO 16604:2014 to meet the requirements of BS EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage.
- i) The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.
- e) The gloves were found to meet with the REACH annex XVII requirements for Polycyclic Aromatic Hydrocarbons (PAHs).
- f) Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek for medical advice immediately.

5) Gloves for Special Applications (EN 420:2003, Clause 5.1.3)

These gloves are designed to protect the hand surface from chemical splashes. Therefore, the length of the gloves is below EN requirements of total minimum glove length, and deems as 'Fit for Special Purpose'.



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6) Product Instruction for Use

- a) Usage – For Single Use only. If re-used, the risk of contamination and infection increases due to improper cleaning processes; and increased risk of holes and tear during re-use due to weakening of gloves by cleaning processes.
- b) Sizing – Select the right size glove for your hand.
- c) Donning – Hold glove by the bead with one hand. Align the glove thumb with your other hand thumb and slide your hand into the glove, one finger into each glove finger. Pull by the glove palm to get a good fit. Don the other glove by the same procedure.
- d) Inspection – Punctures or tears may occur after donning. Inspect each glove after donning, and immediately discontinue use if found damaged.
- e) Doffing – Hold glove bead and pull toward the finger until the glove come off.
- f) Disposal – Properly disposal of all used gloves. Follow your Institution's policies for disposal.

7) Handling and Storage

Store in a cool and dry place. Opened boxes should be kept away from fluorescent and sunlight. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

8) Shelf life

The shelf life of product is 3 years from date of manufacture.