

Product code	9520
Product name	Powder Free Blue Nitrile Gloves
Available size	XS (6), S (7), M (8), L (9), XL (10)
Mfg for	Excia Resources Sdn Bhd F-3-6, Pacific Place, Jalan PJU 1A/4A, Ara Damansara, 47301 Petaling Jaya, Selangor D.E., Malaysia.

1) Personal Protective Equipment (PPE) Regulation (CE certification)

a) These products are classed as Personal Protective Equipment (PPE) by the European PPE Regulation EU 2016/425 and have been shown to comply with this regulation through the Harmonized European Standard(s) EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016.

b) NOTIFIED BODY EU TYPE EXAMINATION: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15, D15 YN 2P, Ireland, (Notified Body: 2777)

c) NOTIFIED BODY FOR ONGOING CONFORMITY: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15, D15 YN 2P, Ireland, (Notified Body: 2777)

d) EU Declaration of Conformity is accessible at www.excia.asia

2) Indication For Use (IFU)

This glove should only be used in a splash of protection or short contact. If chemicals should come and contact with your skin, immediately wash off with plenty of water and soap. Ensure the chemicals do not enter via cuff. Gloves should not be used in applications that require mechanical or thermal protection.

Caution statement with possible allergens: Components used in manufacturing nitrile gloves may cause an allergic reaction in some users. If allergic reaction occurs, discontinue use and consult a doctor.

3) Usage

For single use only. If re-used:

- i. Extremely high risk of cross-contamination
- ii. Deterioration of barrier protection
- iii. Deterioration of glove properties
- iv. Lost of lot traceability

4) Marking

a) **Microorganism Hazards Pictogram:** EN ISO 374-5:2016 Protect against Bacteria, Fungi and Virus. No penetration of bacteriophage through the specimen and the following pictogram is applied.

EN ISO 374-5:2016

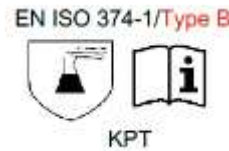


b) **Chemical Hazards Pictogram:** BS EN ISO 374-1:2016+A1:2018; Additional information on chemical resistance obtainable from manufacturer.

EN ISO 374-1:2016+A1:2018 permeation levels are based on breakthrough times as follows:

Permeation Performance Level	1	2	3	4	5	6
Measured breakthrough time (min)	10	30	60	120	240	480

EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. The results is reported as negative degradation where the glove gave extra puncture force after chemical exposure.



5) Performance and Limitation of Use

a) This product was tested in accordance with the test method specified under EN ISO 374-5:2016.

Protection against bacteria and fungi - Pass
Protection against viruses - Pass

b) This product has been tested in accordance with EN ISO 374-1:2016+A1:2018 and EN ISO 21420:2020 and achieved the following performance levels.:-

Chemicals	Performance Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	2
37% Formaldehyde (T)	4

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 is 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 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.
- v) For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.



The duration of the test is not based on actual use time since the permeation test is an accelerated test in which the surface of the specimen is in constant contact with the test chemical. Although the duration of the exposure may be for a longer period during field application with a dilute formulation, the entire surface is not in constant with the test chemical.

- c) This product was tested in accordance with EN ISO 374-4:2019 and achieved the following degradation results: -

Chemicals	Mean Degradation / %
40% Sodium Hydroxide (K)	-18.8
30% Hydrogen Peroxide (P)	13.3
37% Formaldehyde (T)	10.6

Before usage, inspect gloves for any defect or imperfections Please make sure gloves are free from defects or abnormality such as tear, hole and pinhole. If found any gloves with defects do not use the gloves. Get new gloves. Ensure chemicals cannot enter via cuff. Remove the glove immediately if contaminated by a concentrate spill.

EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemicals.

- d) The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.
- e) Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek medical advice immediately.

6) Contraindications

Persons who are known to be sensitized with chemical additives should avoid contact with this glove.

7) Warnings

Do not use if the glove is visibly torn, frayed or damaged. Due to lower tear resistance of the glove, they should not be in used where there is a risk of entanglement with moving machinery.

8) Storage conditions

Store in a cool and dry place. Recommend to store at room temperature prevailing in respective countries. Opened boxes should be kept away from fluorescent and sunlight. Gloves are packed in dispensers which are suitable for transport. Keep the gloves in the box when not in use.

9) Instruction for Use

a) Before usage, inspect the gloves for any defect or imperfections.

b) 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 tears during re-use due to weakening of gloves by cleaning processes.

c) Sizing – Select the right size glove for your hand.

d) Donning – Inspect the glove and ensure there is no pinholes and tears. Insert all five fingers into the cuff and pull the cuff over your wrist until its properly place. Check that the glove's fit is secure around the fingers and the palm. Also check the cuff, which should have a snug fit around your wrist. If the fit feels too tight or too loose, consider changing size to avoid any tears or discomfort.

e) Inspection – Punctures or tears may occur after donning. Inspect each glove after donning and immediately discontinue use if found damaged.

f) Doffing – Using a gloved hand, Grasp the outside edge of the glove near the wrist, be careful to not touch your skin. Peel the glove away from the hand, turning it inside out. Hold it in the opposite gloved hand. Slide an ungloved finger under the wrist of the remaining glove, being careful not to touch the outside of the glove. Peel the remaining glove off from the inside, creating a "bag" containing both gloves.

g) Disposal – Properly dispose of all used gloves. Follow the local regulations and your institution's policies for proper disposal.

10) Shelf life

The shelf life of product is 5 years from date of manufacture.

11) Reporting

In the event of any serious incident occurring in relation to the use of this device, please report to the manufacturer or its authorized representative, and the competent authority of the Member State in which the user is established.