Section 3- User Manual / PPE to fit an individual user

User Manual

Item

Disposable Nitrile Gloves Powdered & Powder Free – Blue/Black/White

Sizes – S-XL
Produced in conformance with the regulation (EU) No 2016/425 of the European Parliament and of the council and national standards EN ISO 374-1:2016+A1:2018, EN 374-2: 2014, EN 16523-1:2015, EN 420:2003+A1: 2009, EN 374-4:2013, EN ISO 374-5:2016. The relevant information and standards of the product are listed in the user manual in correspondence with Declaration of Conformity that can be found at https://www.regaldisposables.co.uk/comformity

Features

- Ambidextrous
- Straight Fingers
- Beaded Cuff
- Textured Fingertips

Instruction for individual user

1. This product is a single-use item, do not reuse.
2. The product packages in Paper Dispenser Boxes, a paper carton then encloses these Dispenser packages to be transferred. It should be stored to avoid excessive temperatures of above 40 degrees Celsius (104 degrees Fahrenheit) and should avoid exposure to direct sunlight, fluorescent lighting, and X-Ray radiation.
3. Users of this product should consider its adaptation to the environment, for example: the user is able to remove the powder from powdered gloves by wet wipes, sponges, or any other effective way.
4. This product provides a biological and chemical barrier of protection. For information, please refer to label.
5. If this product is used and contaminated, it should be disregarded/disposed of using an appropriate method.
6. If user experiences a reaction such as itchy skin, rash, or any other allergic reaction to this product, then the user should discontinue use immediately and seek medical advice.
7. If the wearer is using sharp objects, devices and/or materials they will cause ruptures or holes in the material, please be cautious.
8. It is recommended that the user check the gloves are suitable for the intended use as conditions in the workplace may differ from laboratory testing factors such as: temperature, abrasion, and degradation.

Warnings

1) This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

2) This product can cause skin irritation or reactions for some wearers. It should be used with caution. If any symptoms arise, discontinue use immediately and seek medical advice.

3) 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 related only to the chemical tested. It can be different if the chemical is used in a mixture.

4) The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

5) 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.

6) When used, protective gloves may provide less resistance to dangerous chemicals due to the changes in physical properties. Movements, snagging, rubbing, degradation caused by chemical contact may reduce actual use time significantly. For corrosive chemicals degradation can be the most important factor to consider when selecting the right chemical resistant gloves.

7) Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Relevant tests through:

EN 374-4:2013	Resistance to degradation	Mean Degradation
Sodium Hydroxide 40% / K		-13.8%
Hydrogen Peroxide 30% / P		7.6%
Formaldehyde 37% / T		-39.5%

EN ISO 374-1 Permeation performance level:

Measured breakthrough time (min)	Permeation performance level
>10	1
>30	2
>60	3
>120	4
>240	5
>480	6

Permeation levels are based on breakthrough times as follows:

EN ISO 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms	Performance Level	Breakthrough times
Sodium Hydroxide 40% / K		6	>480 min
Hydrogen Peroxide 30% / P		3	> 60 min but ≤ 120 min
Formaldehyde 37% / T		6	>480 min

EN 420:2003+A1: 2009		Pass
EN ISO 374-2: 2014		Pass
EN ISO 374-5:2016	PROTECTION AGAINST BACTERIA AND FUNGHI	Pass
	PROTECTION AGAINST VIRUSES	

CE-Type testing and assessment procedure Module C2 through:

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Notified Body Number: 2777

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Warnings

Item	Symbol	Symbol Explanation	Item	Symbol	Symbol Explanation
1		United Kingdom Conformity Assessed	10		Made using Recycled Packaging
2		CE Mark (With Notified Body number)	11		Food safe
3		Date of Manufacture	12		Consult Electronic Instructions for Use.
4		Manufacturer	13		Product is NON-STERILE
5		Batch Code (Manufacturer's Code)	14		Product is Latex Free
6		Use-by-date. Indicates the date after which the medical device is not to be used.	15		Temperature limits to which the Medical Device can be safely exposed.
7		Do not re-use. Product is for single use only.	16		Product is in conformance with EN ISO 374-5:2016

8		Keep Dry	**17**	EN ISO 374-1:2016 / Type B  KPT	Product is in conformance with EN ISO 374-1:2016 and meets requirements of Type B
9		Keep out of Direct Sunlight	**18**	AQL 1,5	Product has an Acceptable Quality Limit (AQL) of 1.5