Article 2215 - Nitril-Disposable Gloves, powder-free - PPE category III: high risk - size(s): S (7)-XXL (11)

# Manufacturer's Information

**pursuant to PPE Regulation (EU) 2016/425, Annex II, Section 1.4. (Published in the Official Journal of the European Union)**

Please read carefully before using! You are required to enclose this information leaflet when passing on the personal protective equipment, or to present it personally to the recipient. You may therefore reproduce this leaflet at your own discretion.

**Declaration of Conformity**

CE These gloves are classified as personal protective equipment (PPE). The CE mark confirms that the product satisfies the applicable requirements of Regulation (EU) 2016/425.

## A. Markings on the gloves:

Trademark, model no., size, CE icon, testing institute identification number, pictograms, i-mark, factory icon with month/year of manufacture

| | |
|---|---|
| teXXor | Brand label of manufacturer |
| 2215 | Article no. of the manufacturer |
| 10 | Glove sizes according to EN ISO 21420:2020 (example) |
|    | Pictograms with the corresponding numbers of the relevant European PPE standards (example, detailed pictogram see previous pages). |
|  | The glass and fork symbol testifies that the product complies with the applicable requirements of Regulation (EC) 1935:2004 (and subsequent amendments) and can be used in the preparation and handling of foodstuffs. |
|  | Do not reuse |
| CE | The CE marking confirms compliance with the requirements of European Regulation 2016/425. |
| 2777 | Four-digit number of the testing institute, which monitors the quality assurance of the manufacturer. This will be attached to the CE mark on the product. |
|  | i mark: Reference to the manufacturer's information. |
|  | Date of manufacture year/month/day: 0000/00/00 |
|  | Expiry date year/month/day: 0000/00/00 |

## B. Explanation and numbers of the standards whose requirements the gloves satisfy:

Standards retrieved from: the Official Journal of the European Union. Available from DIN Media GmbH, D-10787 Berlin. www.dinmedia.de

**EN ISO 21420:2020 - General requirements and test methods for gloves**

**Protective gloves against dangerous chemicals and micro-organisms:**

| | |
|---|---|
| **EN ISO 374-1:2016+A1:2018, Part 1:** | **Terminology and performance requirements for chemical risks** |
| **EN ISO 374-2:2019, Part 2:** | **Determination of resistance to penetration** |
| **EN ISO 374-4:2019, Part 4:** | **Determination of resistance to degradation by chemicals** |
| **EN ISO 374-5:2016, Part 5:** | **Terminology and performance requirements for risks by micro-organisms** |
| **EN 16523-1:2015+A1:2018, Part 1:** | **Determination of material resistance to permeation by chemicals – Part 1 Permeation by liquid chemicals under conditions of continuous contact** |

**Definition of terms:**

| | |
|---|---|
| Degradation: | An adverse change in one or more properties of a material used in a protective glove due to contact with a chemical. NB: Examples of degradation include flaking, swelling, disintegration, embrittlement, discolouration, a change in appearance, hardening or softening etc. |
| Penetration: | Movement of a chemical through materials, seams, pinholes or other imperfections in the protective glove material at a non-molecular level. |
| Permeation: | Movement process of a chemical through the material of the protective glove material at a molecular level. NB: Permeation includes the following: Absorption of molecules of the chemical into the contacted (outside) surface of a material; Diffusion of the absorbed molecules in the material; Desorption of the molecules from the opposite (inside) surface of the material. |

**Terminology and performance requirements for micro-organisms risks EN ISO 374-5:2016:**

| Article | Result article 2215 |
|---|---|
| Resistance to Bacteria & Fungi | passed |
| Resistance to Virus | passed |

**Resistance to penetration EN ISO 374-2:2019 - Acceptable quality limit (AQL):**

| Performance level | Acceptable quality limit (AQL) | Inspection level | Article 2215 |
|---|---|---|---|
| 3 | < 0,65 | G1 | |
| 2 | < 1,50 | G1 | AQL = 1,50 |
| 2 | < 4,00 | S4 | |

**Determination of resistance to degradation EN ISO 374-4:2019:**

| Code letter | Test chemical | CAS-RN | Class | Article 2215 |
|---|---|---|---|---|
| K | 40% Sodium hydroxide | 1310-73-2 | Inorganic alkali | swelling, -25.7% |
| P | 30% Hydrogen peroxide | 7722-84-1 | Peroxide | swelling, 44.8% |
| T | 37% Formaldehyde | 50-00-0 | Aldehyde | swollen and softened, -17.1% |

**Material resistance to permeation by chemicals EN ISO 374-1:2016+A1:2018:**

| Breakthrough time (min.) | Performance level for permeation |
|---|---|
| > 10 | 1 |
| > 30 | 2 |
| > 60 | 3 |
| > 120 | 4 |
| > 240 | 5 |
| > 480 | 6 |

**Protective gloves against chemicals are classified in three types, based on their permeation performance:**

- Type A: The permeation performance must satisfy at least Level 2 for no less than six test chemicals according to the following table.
- Type B: The permeation performance must satisfy at least Level 2 for no less than three test chemicals according to the following table.
- Type C: The permeation performance must satisfy at least Level 1 for no less than one test chemical according to the following table.

**List of test chemicals:**

| Code letter | Test chemical | CAS-RN | Class | Breakthrough time (min.) art. 2215 | Level art. 2215 |
|---|---|---|---|---|---|
| A | Methanol | 67-56-1 | Primary alcohol | | |
| B | Acetone | 67-64-1 | Ketone | | |
| C | Acetonitril | 75-05-8 | Nitrile | | |
| D | Dichloromethane | 75-09-2 | Chlorinated hydrocarbon | | |
| E | Carbon sulphide | 75-15-0 | Sulphur-containing organic compound | | |
| F | Toluene | 108-88-3 | Aromatic hydrocarbon | | |
| G | Diethylamine | 109-89-7 | Amine | | |
| H | Tetrahydrofuran | 109-99-9 | Heterocyclic and ether compounds | | |
| I | Ethyl acetate | 141-78-6 | Ester | | |
| J | n-heptane | 142-82-5 | Aliphatic hydrocarbons | | |
| K | Sodium hydroxide 40% | 1310-73-2 | Inorganic alkali | > 480 | 6 |
| L | Sulphuric acid 96% | 7664-93-9 | Inorganic acid, oxidizing | | |
| M | Nitric acid 65% | 7697-37-2 | Inorganic acid, oxidizing | | |
| N | Acetic acid 99% | 64-19-7 | Organic acid | | |
| O | Ammonia water 25% | 1336-21-6 | Organic alkali | | |
| P | Hydrogen peroxide 30% | 7722-84-1 | Peroxide | > 30 | 2 |
| S | Hydrofluoric acid 40% | 7664-39-3 | Inorganic acid | | |
| T | Formaldehyde 37% | 50-00-0 | Aldehyde | > 240 | 5 |

**Type B:**

The three tested chemicals must be identified by their code letter, positioned below the pictogram as shown below. If chemicals not included in the list are also tested, information on the performance levels must be made available in the user instructions.

EN ISO 374-1:2016+A1:2018/Typ B



KPT

**WARNINGS:**

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

**The chemicals 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.**

**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.**

**The manufacturer must provide decontamination instructions for reusable gloves. Gloves are for single-use only if they do not include decontamination instructions, and the following warning must be added: To be used only once.**

**Protection against micro-organisms (bacteria, fungi and viruses) according to EN ISO 374-5:2016**

**Marking of gloves that protect against bacteria, fungi and viruses**

EN ISO 374-5:2016



VIRUS

**The bacteriophage penetration test according to ISO 16604:2004 (method B) must be performed and passed if a protection against viruses be stated.**

**WARNINGS:**

**Resistance to penetration was assessed under laboratory conditions and refers exclusively to the tested samples.**

**Materials and articles in contact with foodstuffs**

The gloves have been tested for migration behaviour in accordance with the EN 1186, EN 13130 and CEN/TS 14234 series of standards 'Materials and articles in contact with food - Plastics', current status.
They comply with the provisions of:
- Regulation (EC) No. 1935:2004 of the European Parliament and of the Council of 27 October 2004
The gloves can therefore be used safely in the food industry for the preparation and handling of foodstuffs.

Detailed information on this can be found in the declaration of conformity for contact with foodstuffs.

**C. Purpose, applications and risk assessment:**

Applicable for many hygiene tasks and/or to protect the wearer, such as in the food processing industry, building cleaning and cleaning in general, warehousing and logistics, sorting and packaging work

These gloves satisfy the requirements of the quoted standards. Please note that the actual conditions of use cannot be simulated and that the decision on the glove's suitability for its intended purpose therefore lies exclusively with the user. The manufacturer is not responsible for improper use. Hence, an assessment of the residual risk should be performed before use in order to determine whether this glove is suitable for its intended purpose.

**Kindly note the printed pictograms and performance levels.**

### Precautionary measures before use:

When donning the glove, please ensure that both glove and hand are clean, glove size is right, and it is properly fit on the contours and crotches of fingers. In case of contamination / perspiration, take off the glove, allow it to dry before wearing again and/or discard depending on the condition of glove.

When an indication of hand hygiene precedes a contact that also requires glove usage, hand rubbing or hand washing should be performed before donning glove.

### Precautionary measures during use:

- Only use gloves with a printed chemical pictogram when handling chemicals.
- Make certain that the selected glove is resistant to the chemicals being used.
- Do not use these gloves to protect against serrated edges or blades, etc.
- If gloves for heat application are requested, make certain that they satisfy the requirements of EN 407:2020 and that they were tested as specified therein.
- Do not use the gloves close to moving machine parts.
- Check the gloves carefully before use to make certain there are no defects or imperfections.
- Gloves meeting the requirement for resistance to puncture in accordance with EN388:2016+A1:2018 may not be suitable for protection against sharply pointed objects such as hypodermic needles.
- Discard damaged, worn, dirty or soiled gloves, irrespective of the substance (including on the inside), as they may lead to skin irritation and rashes. Consult a doctor or dermatologist should such cases arise.
- For further information regarding the permissible user exposure, e.g. temperature, duration please contact the manufacturer.

### Doffing instruction:

Clean off the outside of the gloves at least daily and prior to removing them.
Loosen the gloves on both hands. Hold hands down to prevent the material, product, or contaminated water from dripping onto your skin or clothing.
Keep the gloves down and remove the first glove only to the fingers – the cuff will remain over your palm
Grab the second glove with the first glove and remove it. The first glove should slip off.
Handle gloves by the inside only – the area not contaminated. Avoid touching the outside of the glove.
Wash your hands with soap and water – do not use hand sanitizers.

### D. Cleaning, care and disinfecting:

### Care instructions:



This product is a disposable single use product and therefore should not be washed, bleached, tumble-dried, ironed, professionally dry cleaned or wet cleaned.

The gloves must be carefully examined before they are worn to ensure that there is no damage. These gloves are single-use, disposable products; used gloves must be properly disposed of after use. If the gloves are contaminated with impurities that could pose a hazard, we recommend that the gloves be carefully wiped down alternating right and left. Use the gloved hand in such a way that the gloves can be removed without unprotected hands coming into contact with the impurities.

### E. Storage and ageing:

Keep in a cool, dry place; do not expose to direct sunlight; keep away from any ignition sources; store in the original packaging if possible. The mechanical properties of the gloves will not change for a period of up to 5 years from the manufacturing date, provided they are stored as recommended. A precise service life cannot be stated, as it depends on the type of use and on whether the user ensures that the gloves are used exclusively for their intended purpose. The manufacturing date (year/month/day) is stated on the gloves.

### F. Disposal:

Used gloves may be contaminated with environmentally harmful or hazardous substances. Dispose of the gloves in accordance with applicable local laws.

### G. Material composition:

**Nitrile**

### H. Packaging:

This item will be delivered in a uniform cardboard box with a content of: 10 box
The smallest sales unit is: 100 piece

### I. Health risks:

The product contains zinc dibutyldithiocarbamate (ZDBC) – do not use if you are intolerant to this substance.

### Notified body responsible for the EU Type Examination:

SATRA Technology Europe Ltd.
Bracetown Business Park
Clonee, Dublin D15 YN2P
Ireland
Notified Body No.: 2777

in accordance with EU PPE Regulation 2016/425.

### Notified body that monitors the manufacturer’s quality assurance based on the production process (module D, in accordance with Annex VIII of PPE regulation (EU) 2016/425):

SATRA Technology Europe Ltd.
Bracetown Business Park
Clonee, Dublin D15 YN2P
Ireland
Notified Body No.: 2777

### Manufacturer’s name and address:

BIG Arbeitsschutz GmbH, Bundesstraße 17, 21244 Buchholz/Nordheide, Germany

### For the full Declaration of Conformity and additional technical information, please visit:

**www.big-arbeitsschutz.de/ info@big-arbeitsschutz.de**

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