

Guiding Hands

What changes to European PPE Glove Standards mean for you



Forthcoming revisions to several European Glove Standards could soon have an impact on your organisation. This paper outlines the key updates based upon the latest available information, which is subject to change pending formal review, across EU member states.

The PPE Regulation (EU) 2016/425 was published in the Official Journal of the European Union on the 31st of March 2016. The Regulation comes into force from 21st April 2018, by which all manufacturers will need to comply with the new requirements. Kimberly-Clark will ensure compliance to the new Regulation within the specified timeframe. The impact of this will be explored in a subsequent paper, firstly the changes to EN standards on Protective Gloves are explained.

Glove Standards update

EN 420:2003 +A1:2009 "Protective Gloves – General requirements and tests methods", the suite of standards EN 374 "Protective Gloves against dangerous chemical and micro-organisms" and EN 388:2003 "Protective Gloves against mechanical risks" are under revision. This document

will focus on EN 374 changes that will impact protective gloves. For further detail regarding gloves certified against EN 388 more information can be found on the BSI white paper Technical Guide: Glove Standards Update⁽¹⁾.



“The most visible change for our customers will be the new icons on the glove packaging.”



Changes to EN 374

The EN 374 suite of standards specify the protection capabilities of gloves to various chemicals and micro-organisms. In the table below the specific changes to EN 374 regulations are explained.

Table 1: Summary of the changes to EN 374

OLD	NEW
Part 1 - Terminology and performance requirements (EN 374-1:2003)	Part 1 - Terminology and performance requirements for chemical risks
Part 2 – Determination of Resistance to Penetration (EN 374-2:2014)	No change
Part 3- Determination of resistance to permeation by chemicals (EN 374-3: 2003)	EN 16523-1:2015 Permeation by liquid chemicals under condition of continuous contact
Part 4- Determination of Resistance to Degradation by Chemicals (EN 374-4: 2013)	Becomes mandatory
N/A	Part 5- Terminology and performance requirements for micro-organisms risk (prEN ISO 374-5)

These changes are each explained in more detail below.

Diagram 1:
Pictogram Changes

EN 374-1/Type A



UVWXYZ

EN 374-1/Type B



XYZ

EN 374-1/Type C



The changes to prEN ISO 374-1

The latest draft of EN ISO 374-1 covers terminology and requirements associated with chemical and micro-organism risks. In future only terminology and requirements associated with chemical risks will be addressed in prEN ISO 374-1. Micro-organism risks will instead be addressed in the newly created standard prEN ISO 374-5 (see page 4).

Under prEN ISO 374-1 gloves will be categorised into three Types (A, B or C) based on their chemical permeation performance against an extended list of chemicals, which has increased from twelve to eighteen (See table 3). These classifications are shown below:

Table 2: The new prEN ISO 374-1 classifications

New classification	Min. Performance Level Required	Min. Number of Chemicals from the 18 listed
Type A	Level 2 (≥30 min breakthrough)	6
Type B	Level 2 (≥30 min breakthrough)	3
Type C	Level 1 (≥10 min breakthrough)	1

The most visible change for our customers will be new icons on glove packaging that reflect the new standards, these are shown on the left hand side of this page. In addition the beaker pictogram shown on packaging, as currently used for EN374-1:2003 for chemical splash risk, will no longer be used.



Table 3: prEN ISO 374-1 glove permeation test list

Code Letter	Chemical	Cas Number	CLASS
A	Methanol	67-56-1	Primary alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile Compound
D	Dichloromethane	75-09-2	Chlorinated paraffin
E	Carbon disulphide	75-15-0	Sulphur containing organic compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	THF	109-99-9	Heterocyclic and ether compound
I	Ethyl Acetate	141-78-6	Ester
J	N-Heptane	142-82-5	Saturated hydrocarbon
K	Sodium Hydroxide 40%	1310-73-2	Inorganic base
L	Sulphuric Acid 96%	7664-93-9	Inorganic mineral acid
M	Nitric Acid 65%	7697-37-2	Inorganic acid, oxidizing
N	Acetic acid 99%	64-19-7	Organic acid
O	Ammonia 25%	1336-21-6	Organic base
P	Hydrogen peroxide 30%	7722-84-1	Peroxide
Q	Hydrogen fluoride 40%	7664-39-3	Inorganic mineral acid, contact poison
R	Formaldehyde 37%	50-00-0	Aldehyde

Where no concentration is listed, chemical is tested at saturated concentration

Performance levels for chemical permeation will be standardised with the erlenmeyer flask pictogram and information booklet pictograms. Type A, B or C will be differentiated with the letters associated with the tested chemicals under the pictograms: Type A – 6 letters, Type B – 3 letters, Type C – 0 letters. (See Diagram 1).

EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms, and determination of resistance to penetration

This standard replaced EN 374-2:2003 with no major technical changes. The standard continues to specify the air and water leak test method for the penetration resistance of gloves that protect against dangerous chemicals and/or micro-organisms.

Notable changes include:

- Reference to EN 374-3:2003 has changed to EN 16523-1:2015



EN 374-3:2003 withdrawn

EN 374-3 has been superseded by the new EN standard as part of efforts to standardise testing protocols across product categories globally, making it easier to understand the testing procedures that a greater range of PPE is subject to.

The chemical permeation test method is now defined in EN 16523-1:2015 "Permeation by chemical liquid under

continuous contact" and supersedes EN 374-3:2003. The new method for chemical permeation is very similar to EN 374-3:2003 and any new products will need to be tested against it once prEN ISO 374-1 is published and harmonised with the new PPE regulation (EU) 2016/425, which replaces the PPE Directive 89/686/EEC.

EN 374-4:2013 Protective gloves against dangerous chemicals and micro-organisms, and the determination of resistance to degradation by chemicals

No changes are planned to the degradation standard, however the degradation test will become mandatory as stated in prEN ISO 374-1: "Degradation to be measured according to EN374-4 for each chemical tested for permeation and reported in the user leaflet."

This standard covers the test principles and methods with a mandatory puncture resistance test for natural or synthetic gloves, a non-mandatory weight change test for lined gloves, the experimental equipment and the reporting of results in terms of percentage degradation.

prEN ISO 374-5: Terminology and performance requirements for micro-organisms risks

This standard defines the requirement for protective gloves against microbiological agents. For bacteria and fungi a penetration test is required following the method described in EN 374-2:2014: air-leak and water-leak tests. For protection against viruses, compliance to ISO 16604:2004 (method B) standard is necessary.

This will lead to new marking on the packaging for gloves protecting against bacteria and fungi, and for gloves protecting against bacteria, fungi and viruses:

EN 374-5: 20XX



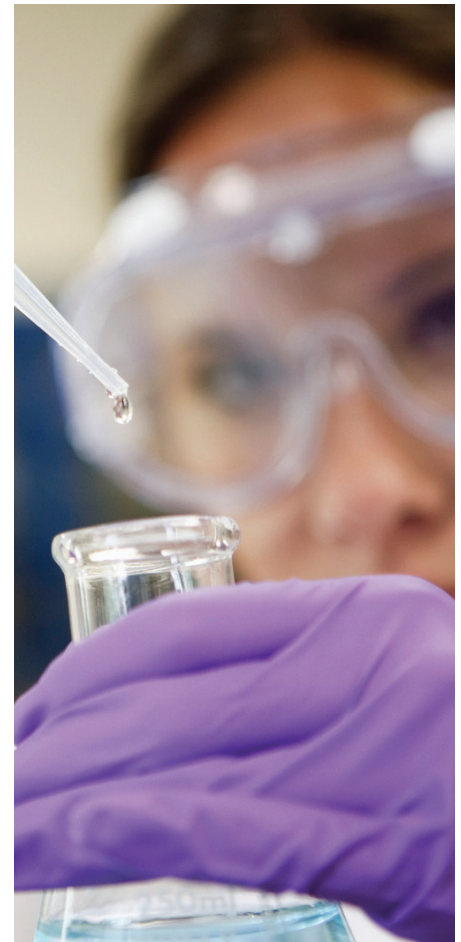
EN 374-5: 20XX



VIRUS

We aim to stay at the forefront of innovation and change in the PPE industry and help our customers to maintain compliance to evolving regulations. This document is based on the latest detail available, which may be subject

to change when the final version of the standards referenced are published. To stay up to date with standards changes, or to find out more about what new regulations mean for you, please contact us at kimtech.support@kcc.com



References

- Kimberly-Clark PROFESSIONAL* internal intelligence
- ⁽¹⁾BSI "Technical Guide Gloves Standards Changes", www.bsigroup.com/ppe

Authors

- Franck Bureth
EMEA Category Manager
KIMTECH*,
Pharma PPE
Kimberly-Clark
PROFESSIONAL*
- Manish Raval
EMEA Category Manager
KIMTECH*,
Lab & Research PPE
Kimberly-Clark
PROFESSIONAL*

www.kimtech.eu