sempermed®
YOUR GLOBAL GLOVE EXPERT

CHANGES IN THE REGULATORY FRAMEWORK FOR PROTECTIVE GLOVES

THE NEW PPE REGULATION

In April 2018, a **new PPE Regulation (EU) 2016/425 will become applicable** and **replace the existing PPE Directive 89/686/EEC.**

NEW

In future, the Declaration of Conformity for PPE-labelled gloves will be accessible on our website and packaging will include a direct link (QR Code) to access the Declaration of Conformity for each product!

THE **NEW EN ISO 374-1:2016** STANDARD FOR CHEMICAL PROTECTIVE GLOVES

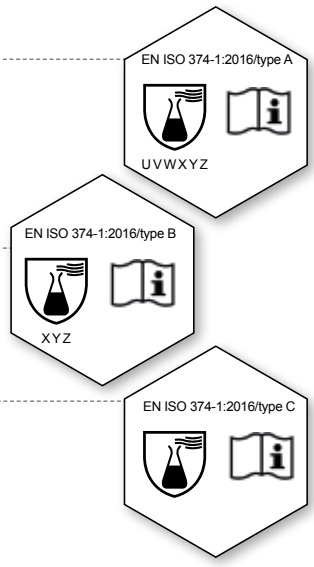
1

The new standard considers three types of chemical protective gloves:

TYPE A GLOVES
need to achieve at least a permeation level of 2 (longer than 30 min.) against six of the chemicals listed in EN ISO 374-1. As a minimum the six tested chemicals shall be identified by their code letters under the flask pictogram.

TYPE B GLOVES
need to achieve at least a permeation level of 2 (longer than 30 min.) against at least three of the chemicals listed in EN ISO 374-1. The tested chemicals shall be identified by their code letter under the flask pictogram.

TYPE C GLOVES
need to achieve at least a permeation level 1 (longer than 10 min.) against one of the chemicals listed in EN ISO 374-1.



Sempermed *Always keeping you up to date.*

2

3

4

The list of challenge chemicals in EN ISO 374-1 was enlarged by 6 additional chemicals:

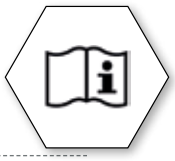
Code letter	Chemical	CAS no	Class
A	Methanol	67-56-1	Primary alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile compound
D	Dichloromethane	75-09-2	Chlorinated paraffin
E	Carbon disulphide	75-15-0	Organic compound containing sulphur
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofuran	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 mineral acid
N	Acetic acid (99 %)	64-19-7	Organic acid
O	Ammonium hydroxide (25 %)	1336-21-6	Organic base
P	Hydrogen peroxide (30 %)	7722-84-1	Peroxide
S	Hydrofluoric acid (40 %)	7664-39-3	Inorganic mineral acid
T	Formaldehyde (37 %)	50-00-0	Aldehyde

NEW

As a newly added part to the standard series of chemical protective gloves, EN 374-4 specifies the determination of resistance to degradation by chemicals.

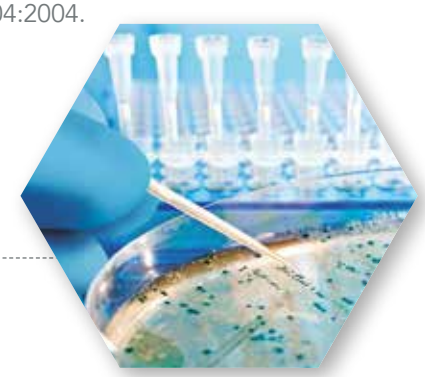
Coming into contact with a chemical can have an impact on the material properties of a protective glove, not only during contact with the chemical but also subsequently. Degradation testing therefore includes the testing of the change of material's properties after exposure to chemicals.

Although EN ISO 374-1 contains no performance requirements for degradation, the EN 374-4 result will need to be included in the user instructions and is indicated as a percentage degradation.



EN ISO 374-5:2016 is a newly introduced standard and specifies the requirements and test methods for protective gloves intended to protect the user against micro-organisms. It refers to resistance testing to **penetration of virus, fungi and bacteria** and relates to the testing standard ISO 16604:2004.

Sempermed chooses to continue to test and certify its gloves to the more stringent ASTM standard for microorganisms, which is FDA-approved and also accepted by the PPE Notified Body as part of the EU type examination procedure. As such, Sempermed will continue to label in accordance with the internationally accepted ASTM F1671/F1671M-13 testing standard.



Semperit, together with its trusted Notified Bodies, are jointly working on a transition plan in order to continuously issue new EU type examination certificates and respective Declarations of Conformity in accordance with PPE Regulation (EU) 2016/425 from April 2018 onwards. In the course of this process, all category III marked protective gloves will be tested and certified according to the **newest EN ISO 374-1:2016 standard.**

Sempermed *Always keeping you up to date.*

Semperit Technische Produkte Gesellschaft m.b.H., Division Sempermed, Modecenterstrasse 22, A-1030 Vienna
Tel. +43-1-79 777-000, Fax: +43-1-79 777-630, Email: sempermed@semperitgroup.com www.sempermed.com

Version 1 11/2017 DM1500882