

Certification

New EN ISO 374 Standard

Brought To You by Ansell | Jul 31, 2017

What You Need To Know

Why do we have the new standard and new tests?

What is the timeline/transition period to the new standard?

For degradation data, does it mean that each glove will have a specific IFU?



Ansell support for the transition to the new EN ISO 374 Standard

Over the past year Ansell has been preparing its chemical and single use glove portfolio to comply with changes to the new EN ISO 374 standard. Ansell will provide a suite of resources to help you understand the changes to the standard and what they mean for you. Despite the new glove tests and performance ratings, please be assured that Ansell gloves remain the same quality; it's the same protection you can rely and depend on.

In this document we've prepared a number of questions that may be on your mind as it pertains to understanding the new EN ISO 374 performance ratings, test methods, and new ratings symbols. Should you require additional information you can always ask your Ansell Sales representative.

Look for future updates. Ansell will provide additional regulatory updates as more gloves are tested.

Visit the *Ansell EN Resource Center* for more information.

Frequently Asked Questions

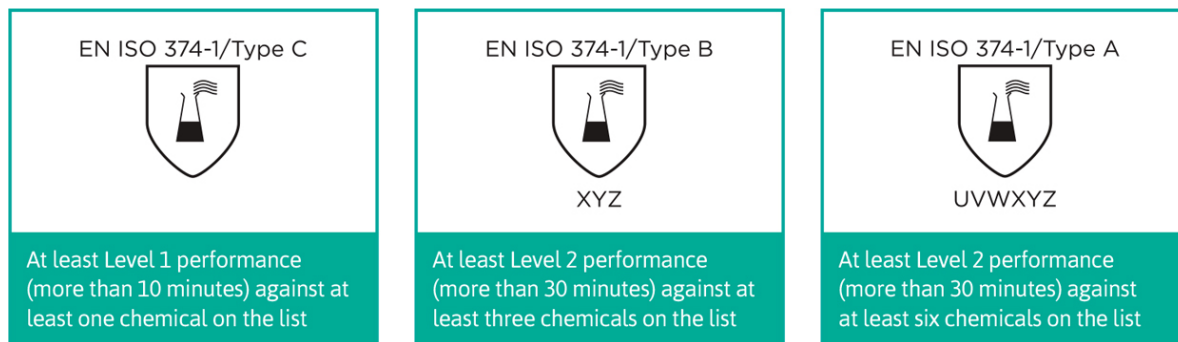
Q: Why is there a new standard and new tests?

The standard was changed to address the following needs:

- To ensure consistency between test results on chemical resistance: permeation, liquid-proof, degradation, micro-organisms
- To better assist users and safety managers in their glove choice by more accurately reflecting the chemicals being used throughout the industry.

Q: How will the new tests be represented in glove pictograms?

- There is a new three tiered system to report chemical performance against a specific number of chemicals.
- It is reported with a new pictogram icon and a marking above each that describes its performance. For example, the Type A glove is the most versatile chemical glove as it was tested for more than 30 minutes against at least six chemicals on the test list. Refer to the diagrams here.
- The type of chemical glove you need is dependent on the type and number of chemicals you frequently use.



Q: Are the type C, B and A markings mandatory on the pictogram?

Yes, above each pictogram, the marking Type C, Type B or Type A will be marked.

Q: When was the new standard published?

The new EN ISO 374-1:2016 and EN ISO 374-5:2016 were approved November 23, 2016. From this date, the new EN ISO 374 standards became official and new certifications can be issued based on these new standards.

Q: What strategy will Ansell follow in regard to the new standard?

Ansell has tested a significant number of gloves and single use styles at Centexbel as per the new EN ISO 374-1:2016 and EN ISO 374-5:2016. Ansell will ensure portfolio compliance with the new EN ISO 374 standard offering a range of products that have also gone through additional testing at our state-of-the-art R&D labs. Ansell will be a leading resource for introducing customers to the new standard, and remain a trusted source for reliable information and education about the EN ISO 374:2016 standard.

Q: What are the implications for distributors based on EN ISO 374 changes?

The standard primarily affects the manufacturers of chemical protective and single use gloves. Distributors must ensure that their print and digital content is updated to align with updated glove markings.

Q: Have the EN ISO 374-1 and EN ISO 374-5 been officially published yet and what does that mean for recertifying the products to these standards?

- The new EN ISO 374-1:2016 and EN ISO 374-5:2016, which were officially accepted in November 2016, have been published by the European Commission on 12 April 2017 and are therefore officially "harmonized" since that date.
- In this official publication, it also states that the old EN 374:2003 will cease to provide presumption of conformity to the EU legislation as of end May 2017.
- This means that for any EN 374 compliant glove style it will be mandatory to be certified to these newest EN ISO 374:2016 standards as of June 1st, 2017 for any new products. In regards to existing certified products, recertification needs to happen at the latest before the expiry of the existing CE-certificates as of June 1, 2017.

Q: What is the timeline/transition period to the new standard?

The new standard has been official since November 23, 2016. Any product launched after November 23, 2016 can be certified under the new EN ISO 374:2016 standard. Ansell will begin to ship newly marked gloves at the end of the calendar year 2017 and will continue to do so over the following year. Inventory and customer needs will influence our production timing.

Q: How will Ansell keep you informed?

- Ansell prides itself on providing accurate and reliable information and intends to be among the first to communicate the changes to the standard.
- Ansell will continue to engage with end users and distributors through our comprehensive educational and awareness campaign, "Well Informed, Well Protected, Well Ahead."
- The campaign will feature:
 - a) Print and digital advertising
 - b) A series of email blasts with a variety of educational tools including quick reference guides
 - c) FAQ and comparison style guides with new performance ratings, revised PDS and technical data sheets
 - d) An EN ISO 374 informational video

Q: When will the Ansell campaign and communications effort begin?

Ansell will start its communication campaign in mid-2017 and will continue throughout the calendar year.

Q: How many gloves will be tested – chemical and single use? When will we see the new EN ISO 374 markings on the gloves?

Certification to the new EN ISO 374:2016 standard will occur in phases. In the first phase Ansell will test 20 of our chemical gloves and 62 of our best-selling single-use gloves. Ansell intends to commence shipping gloves with the new markings by end of calendar year 2017. Our sales team will help guide you through this transition phase.

Q: What is Ansell's position on product testing?

- Ansell intends to lead the market and set the pace for adoption of the new standard.
- Ansell maintains the largest testing and R&D facilities in the world, and will be the first manufacturer offering customers products tested as per the new test method, ensuring their compliance with the new standard.
- Ansell has also committed considerable resources to the effort to raise awareness of the shift towards the new standard — what has changed and why it's important.
- Compliance with the new standard will be paramount. Ansell wants to help you to ensure you are compliant with the latest regulatory norms so your teams are well protected.

Q: When doing the certification for EN ISO 374 is it mandatory to also test as per EN 388:2016?

Yes, every time you want to certify a chemical glove, the mechanical tests also have to be performed and marked.

Q: AQL is removed from the EN 374-2 standard. Will Ansell still claim the AQL?

Yes, Ansell will continue to claim AQL; Ansell holds itself accountable to higher voluntary quality standards.

Q: Do we have to test the cuff for micro-organisms and virus protection for gloves 400 mm or longer?

Yes, just like for chemical permeation.

Q: For permeation data, when we test the palm and the cuff, which permeation data do we claim?

Ansell is claiming the lowest data between the two measurements.

Q: For degradation data, does it mean that each glove will have a specific IFU?

No, a link to a webpage will be mentioned on the IFU (Information for Use). On this webpage, customers can select the right style and access the degradation data. You can also reference our Chemical Resistance Guide for degradation data.

Q: Are the extra 6 chemicals now included in the permeation test more aggressive than the existing 12?

No, they are not more aggressive. They were added because they are more representative of chemicals in the modern industrial landscape.

Q: What if the glove does not have a letter on it? Does it mean it is not safe to use with the chemical?

It depends. A letter only goes onto the glove if it reaches a permeation time of over 30 minutes (Type B or Type A). If a permeation time of under 30 minutes suffices for an application, the glove may still work for that use. Ansell recommend that you contact your Ansell sales representative to ensure you have the proper protection.

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