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## **Hy-Care® Multipurpose Solution – Field Safety Corrective Action**

### FREQUENTLY ASKED QUESTIONS AND ANSWERS

#### **Why is CooperVision recalling Hy-Care® multipurpose solution?**

Our quality testing has determined that the product may not offer appropriate levels of disinfection in some circumstances against high levels of a particular yeast organism. Although no complaints have been received and there have been no confirmed incidents attributed to inadequate disinfection, we are acting out of an abundance of caution.

#### **Does Hy-Care® pose any danger to someone if used?**

We have received no complaints and there have been no confirmed incidents attributed to inadequate disinfection. However, the product may not be effective to the standards we expect if a lens is contaminated with high levels of a particular yeast organism. We are taking this action in line with our quality standards and out of an abundance of caution.

#### **Have there been any adverse events, injuries, or complaints reported?**

We have received no complaints and there have been no confirmed incidents attributed to inadequate disinfection.

#### **Which brands are affected?**

The withdrawal affects all configurations of Hy-Care® multipurpose solution (60ml & 360ml). No other CooperVision products are included in this action.

#### **What countries are included in the recall?**

The affected bottles were shipped to:

Andorra, Argentina, Aruba\*, Austria, Belarus, Belgium, Bolivia, Botswana\*, Bulgaria, Chile, Costa Rica, Cyprus, Czech Republic, Denmark, Ecuador, Finland, France, Georgia, Germany, Greece, Greenland, Guernsey (UK), Hong Kong, Hungary, Iceland, India\*, Ireland, Israel, Italy, Jersey (UK), Jordan, Kenya, Latvia, Lesotho\*, Lithuania, Luxembourg, Malta, Mauritius, Mozambique\*, Namibia\*, Netherlands, Netherlands Antilles, Norway, Paraguay, Poland, Portugal, Qatar, Russia, San Marino, Saudi Arabia, Serbia, Seychelles\*, Slovakia, Slovenia, South Africa, Spain, Suriname\*, Swaziland\*, Sweden, Switzerland  
Tanzania\*, Turkey, Ukraine, United Arab Emirates, United Kingdom, Uruguay, Zambia\*  
Zimbabwe\*.

\*Awaiting confirmation of whether in scope.

#### **Is the recall a mandated or voluntary action?**

The highest standards of product quality is a priority for CooperVision, and this action is being undertaken voluntarily.

#### **Has the company notified the appropriate competent authorities?**

Communications with the relevant authorities is underway and will occur within the required deadlines. .

#### **Could other CooperVision solutions also be affected?**

No, this recall is specific to Hy-Care® multipurpose solution.



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**Do any other CooperVision solutions use this formulation?**

No, this formulation is specific to Hy-Care®.

**Can you be more specific regarding how disinfection performance lagged?**

Laboratory testing indicated that the product may not be effective to the standards we expect if a lens is contaminated with high levels of a particular yeast organism.

**Was there a certain bacteria or fungus against which the solution was ineffective?**

Yes, *Candida albicans*, on certain lens types - group IV (hydrogel) and group V(A) (a subset of silicone hydrogel) lenses.

**What should consumers who have Hy-Care® do with it?**

Consumers who have Hy-Care® solution should cease use but keep the bottle. We are preparing a website that will have further information with instructions on what consumers should do, including reimbursement.

**Why isn't that available now?**

We have acted swiftly to notify relevant competent authorities and customers of our actions. We did not want to delay this while we created the website for consumers.

**Will the Hy-Care® brand return to the marketplace at some point?**

We will keep you updated on this.