Honeywell Safety Products USA, Inc. Issues Voluntary Worldwide Recall of Honeywell eyesaline® Saline Eyewash Solution Cartridges # 32-002050-0000 used with the Fendall 2000 Eyewash Station Due to a Lack of Appropriate Policies and Procedures by Honeywell's Supplier

Company Contact
Honeywell Customer Service
Phone Number: 1-800-430-5490

FOR IMMEDIATE RELEASE – March 27, 2024 – Charlotte, NC, Honeywell Safety Products USA, Inc. is voluntarily recalling Honeywell eyesaline® Saline Eyewash Solution Cartridges for the Fendall 2000 Eyewash Station. This recall is being conducted at the consumer level. The Honeywell eyesaline® Saline Eyewash Solution Cartridges for the Fendall 2000 Eyewash Station have been found to be non-compliant with current good manufacturing practice (cGMP) requirements.

Risk Statement: Use of or exposure to the eyewash without seeking medical attention afterwards could result in a range of ocular infections such bacterial keratitis or endophthalmitis. Immunocompromised individuals, those sustaining ocular injuries that damage the corneal epithelium, and those sustaining penetrating ocular injuries are at higher risk of potential infection. Honeywell Safety Products USA, Inc. has not received any reports of adverse events related to this recall.

The Honeywell eyesaline® Saline Eyewash Solution Cartridges for the Fendall 2000 Eyewash Station is used for flushing or irrigating the eye to reduce chances of severe injury caused by acid, alkali, or particulate contamination. Product is contained in a 25-liter Ethylene-vinyl acetate (EVA) bag that is designed for use with the Fendall 2000 Eyewash Station. Only the Fendall 2000 refill cartridges are subject to this review, not the Fendall 2000 Eyewash Station. The saline eyewash solution contains purified water, benzalkonium chloride, edetate disodium, sodium chloride, sodium phosphate diabasic, and sodium phosphate monobasic. It is not marketed as sterile.

Product and Distribution Information Table

Product Name	Manufacturer's Product Number/ Catalog Number	Manufacturing Dates (MMM/YYYY)	Expiration Date (MMM/YYYY)	Region	Quantity
Purified Cartridge for Fendall 2000	32-002050-0000	Oct- 2021 through Jun-2023	Oct-2023 through June-2025	USA	6,954

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Purified Cartridge for Fendall 2000	32-002050-0000	Oct- 2021 through Jun-2023	Oct-2023 through June-2025	Canada	3,651

Honeywell Safety Products USA, Inc. is notifying its distributors and customers by email, telephone and certified mail and is requesting anyone with product in its inventory to destroy or dispose of all units subject to the recall. Consumers / distributors / retailers that have Honeywell eyesaline® Saline Eyewash Solution Cartridges should stop selling, shipping and using the product immediately and destroy or dispose of it.

Consumers with questions regarding this recall can contact Honeywell Safety Products USA, Inc. by telephone USA 1-800-430-5490, Canada 1-888-212-7233 or CustomerServiceInquiryBox@Honeywell.com between the hours of 8:00AM to 4:00PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this eyewash solution.

Adverse reactions experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.