

DEFENSE LOGISTICS AGENCY TROOP SUPPORT 700 ROBBINS AVENUE PHILADELPHIA, PENNSYLVANIA 19111-5092

DLATS-FTW ALFOODACT 2025-003 January 7, 2025

MEMORANDUM FOR RECORD

SUBJECT: Alcon Laboratories Issues Voluntary Nationwide Recall of One (1) Lot of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101), Due to Fungal Contamination

1. **REFERENCE:** DHA-MSR 6025.01/AR 40-660/ DLAR 6025.01/NAVSUPINST 10110.8D/AFI 48-161_IP/MCO 10110.38D, DOD Hazardous Food & Nonprescription Drug Recall System, 6 September 2018.

2. **COMPANY ANNOUNCEMENT:** Alcon Laboratories is voluntarily recalling one (1) lot of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101) to the consumer level. Alcon evaluated a consumer complaint of foreign material observed inside a sealed single use vial and determined the material to be fungal in nature.

Risk Statement: Fungal contamination of an ophthalmic product is known to potentially cause eye infections. If an infection occurs, it may be vision-threatening, and in very rare cases potentially life-threatening in immunocompromised patients. To date, Alcon Laboratories has not received any reports of adverse events related to this recall.

Systane Lubricant Eye Drops Ultra PF is used for the temporary relief of burning and irritation in persons experiencing dry eye symptoms and is packaged in a cardboard carton containing 25 sterile, single-use LDPE plastic vials of preservative free solution for ophthalmic use (NDC 0065-1432-06, UPC 300651432060). The affected Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count is limited to lot number 10101, expiration date 2025/09.

3. PRODUCTS AFFECTED: The product can be identified by the green and pink carton design, presence of "Systane" and "ULTRA PF" brand names on the front of the carton, and the "25 vials" package size. Please see product images included in this release. Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101) was distributed nationwide to retail and internet outlets.

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Product Description	Size	Lot Number	Expiration Date
Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go	25-count	10101	2025/09

4. PRODUCT LABELS/PICTURES:



5. CONTACT INFORMATION: Consumers that have the recalled Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101) which is being recalled should stop using them immediately and return to the place of purchase for a replacement or refund. Consumers with questions regarding this recall can contact Alcon Laboratories at 1-800-241-5999 between 7:30am and 6:00pm (Central), Monday to Friday.

6. POSITIVE AND NEGATIVE FINDINGS:

a. Army Veterinary Services and Air Force Public Health Personnel: Report negative and positive findings in the Veterinary Service Information Management System (VSIMS) Subsistence Recalls application. If you are not in one of these two groups, please use the instructions below (paragraphs b-d).

b. Navy:

1) SHIPS AT SEA: Must report positive and negative findings to supporting Veterinary Service unit. Are authorized to destroy or dispose of recalled products utilizing the procedures and reporting requirements outlined in NAVSUP P-486 Paragraph 5302 and 6000(4), to include completion of a DD Form 200 and Standard Form 364. Procedures for completing the DD Form 200 are found in NAVSUP P-486 Paragraph 6001. Procedures for completing Standard Form 364 are found in NAVSUP P-486 Paragraph 5300(2)(c).

2) SHIPS IN PORT/HOMEPORTED/ASHORE GALLEYS: Supporting Veterinary Service unit will conduct inspection and report positive and negative findings in VSIMS Subsistence Recalls application. Contact the appropriate DLA Account Manager via Regional NAVSUP Fleet Logistics Center (NAVSUP FLC) to arrange pickup of recall items. Contact your supporting (NAVSUP FLC) for any issues regarding PV Pickup. Proceed with the same guidance in the paragraph above.

c. Defense Logistics Agency (DLA) Contractors: Report positive and negative findings to your Contracting Officer, Contracting Specialist, TVLS, and <u>dscpconssafofc@dla.mil</u> within 72-hours. Positive Response Information required: (Vendor must provide all the following information):

- 1) ALFOODACT 202X-XXX
- 2) DLA Contract Number:
- 3) Unit of Measure:
- 4) Quantity Currently in Stock:
- 5) List of customers that received product AND (a-h) for each customer:
 - a) Customer name and location:
 - b) DLA Purchase Order Number:
 - c) Vendor Invoice Number:
 - d) Item Stock number (LSN, NSN):
 - e) Quantity Shipped:
 - f) Date Shipped:
 - g) Value of Affected Product:
 - h) Amount of credit due:

d. AAFES, MWR, NEX, MCCS, DeCA, DLA, dining facilities, and all other agencies,

report your findings and follow recall disposition in accordance with the procedures outlined by your agency.

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7. If you know of others who need to receive Subsistence Recall messages, click <u>Subscribe</u> (Add the following to an email if the link does not work; Subject: Subscribe to Subsistence Recall Notifications, Email address: <u>usarmy.jbsa.medcom.mbx.medcom-vsims@health.mil</u>). If you no longer need to receive Subsistence Recall messages, click <u>Unsubscribe</u> (Add the following to an email if the link does not work; Subject: Unsubscribe from Subsistence Recall Notifications, Email address: <u>usarmy.jbsa.medcom.vsims@health.mil</u>).

8. Previous recalls are available on the DLA-TS Food Safety Office website: <u>https://www.dla.mil/TroopSupport/Subsistence/FoodSafety/fso/ALFOODACT/</u>.

9. Point of contact for ALFOODACT messages is the undersigned at commercial telephone 215-737-8600, or <u>dscpconssafofc@dla.mil</u>.

KAYLA D. HAMMONDS Chief Warrant Officer Three, U.S. Army Consumer Safety Officer