



Date

Urgent-Product Notification
Hydrogen Peroxide Concentration of GLOSAIR™ 400 Cartridge Not Meeting Product Specification
P/N GLO2040000 or CRGSE100

Dear Valued Customers,

Advanced Sterilization Products (ASP) recently determined, as part of its routine quality program, that some GLOSAIR™ 400 Cartridge lots did not meet the Hydrogen Peroxide concentration specification (5.50% -6.00%) per the finished good specification.

Description of the Issue

ASP has recently identified some GLOSAIR™ 400 Cartridge batches did not meet the Hydrogen Peroxide concentration specification (5.50% -6.00%) per the finished good specification. This issue affects both product codes GLO2040000 (package of 6 cartridges) and product code CRGSE100 (individual cartridge).

Why you are being contacted:

You are receiving this letter because our records indicate you have received one or more of the affected GLOSAIR™ 400 Cartridge products subject to this notification. To report any complaints or suspected problems with GLOSAIR™ 400 Cartridge related to this letter, please contact [\[enter local contact details\]](#). For questions regarding the business reply form, please contact [\[enter local contact details\]](#).

What Actions Are Recommended?

- Evaluate your current inventory of GLOSAIR™ 400 Cartridges. If you have inventory of the following affected GLOSAIR™ 400 Cartridge lots, inspect and segregate these lots from your current inventory and follow the instructions below for unopened and opened product. Refer to Appendix 1 of the letter for images of lot information on the individual cartridge label and on the package label of the cartridges.
1168801, 1169301, 1169701, 1169901, 1170501, 1271201, 1271801, 1272401, 1273101
 1. For any unopened cartridges from these lots, please follow the provided Product Return Instructions section below.
 2. For any opened cartridges from these lots, please follow the disposal information in sections 7 and 8 of the GLOSAIR™ 400 User's Guide (GLOGB40001) for purging and discard.
- Ensure anyone in your facility impacted by this notification reads this letter and follows your risk management procedures in the event affected product was used.
- Maintain a copy of this communication where GLOSAIR™ 400 Cartridge is stored.
- Please complete and return the attached Business Reply Form [\[enter local contact details\]](#).

Product Return Instructions:

To assist ASP with return and replacing any affected product, please complete the following two (2) steps:

1. Examine your inventory and return all unopened affected GLOSAIR™ 400 Cartridge product to [\[enter local contact details\]](#).
2. Physically count your entire inventory of affected product and record the total number of unopened cartridge on the enclosed Business Reply Form. It is very important that you complete the requested information on the enclosed Business Reply Form and return it to [\[enter local contact details\]](#). Incomplete Business Reply Forms cannot be processed.

If you have distributed the affected product to other locations within your healthcare system, please notify them of this notification and ask them to contact [\[enter local contact details\]](#) to arrange for return of the product. If you have any questions or need additional packing labels, please call [\[enter local contact details\]](#).

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CL-90098-080



We know you place high value in our products. We appreciate your cooperation in this matter and value you as our customer. ASP is committed to maintaining your confidence in the safety and quality of our products.

Sincerely,

John Glaccum
Sr. Director Quality Systems
Advanced Sterilization Products

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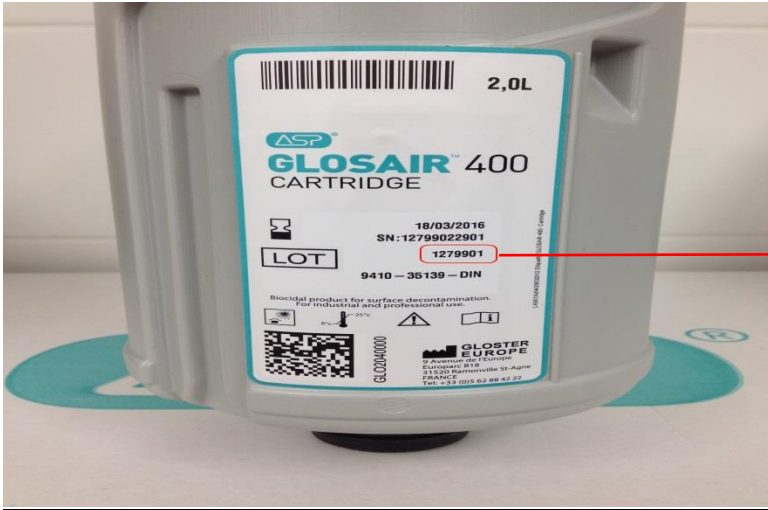
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Appendix 1



Lot Information on the Individual Cartridge Label



Lot Information on the Package Label of the Cartridges

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