



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 25, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: W.S. Badger Co. Inc, Recall [Drug]

AFFECTED

PRODUCT: SPF 30 Baby Sunscreen Lotion 4oz (UPC: 634084490091&634084490114)
Lot #'s 3024A, 3057B, 3063A, 3063B, 3132A, 3133A
SPF 30 Kids Sunscreen Lotion (UPC: 634084490145 & 634084490169)
Lot # 3164A

SUMMARY: Unclassified Recall; September 23, 2013 - W.S. Badger Co. Inc. today announced it is voluntarily recalling all lots of its 4-ounce SPF 30 Baby Sunscreen Lotion and one lot of its 4-ounce SPF 30 Kids Sunscreen Lotion (lot # 3164A) due to microbial contamination. The products were tested and found to be contaminated with *Pseudomonas aeruginosa*, *Candida parapsilosis* and *Acremonium fungi*.

SUGGESTED

ACTION: Recommend notification of affected parties via phone, fax, or e-mail. Both sunscreens were sold in the USA & Canada online, at major retailers, and at independent food co-ops and pharmacies. Consumers who have purchased the SPF 30 Baby Sunscreen Lotion should not use the product and may return it to the original point of purchase for a full refund, or contact Badger directly at 1-800-603-6100 or email recalls@badgerbalm.com between the hours of 8:30-4:30 ET, Monday - Friday. Furthermore, if any recalled products are found, notify this office at 317-233-3213.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company



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To promote and provide
essential public health services.

W.S. Badger Company Voluntarily Recalls Select Lots of Daily SPF 30 Kids & Baby Sunscreen Lotions Due to Microbial Contamination

Contact

Consumer:
1-800-603-6100

Media:
Deirdre Fitzgerald
603-283-5220
deef@badgerbalm.com

FOR IMMEDIATE RELEASE - September 23, 2013 - W.S. Badger Co. Inc. today announced it is voluntarily recalling all lots of its 4-ounce SPF 30 Baby Sunscreen Lotion and one lot of its 4-ounce SPF 30 Kids Sunscreen Lotion (lot # 3164A) due to microbial contamination. The products were tested and found to be contaminated with *Pseudomonas aeruginosa*, *Candida parapsilosis* and *Acremonium fungi*.

No adverse reactions have been reported in connection with these products.

Both sunscreens are sold in the USA & Canada online and at major retailers as well as independent food co-ops and pharmacies. This product can be identified by matching the UPC with the Lot code, which can be found on the top front of the tube crimp.

The affected lots include the following:

- SPF 30 Baby Sunscreen Lotion 4oz (UPC: 634084490091&634084490114) Lot #'s 3024A, 3057B, 3063A, 3063B, 3132A, 3133A
- SPF 30 Kids Sunscreen Lotion (UPC: 634084490145 & 634084490169) Lot # 3164A

Consumers who have purchased the SPF 30 Baby Sunscreen Lotion should not use these products and may return product to the original point of purchase for a full refund, or contact Badger directly at 1-800-603-6100 or email recalls@badgerbalm.com between the hours of 8:30-4:30 ET, Monday - Friday.

Adverse events that may be related to 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:

- Online: www.fda.gov/medwatch/report.htm¹
- Regular Mail: use postage-paid, pre-addresses Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm². Mail to address on the pre-addresses form.
- Fax: 1-800-FDA-0178

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

As a father and grandfather, the safety and well-being of children is my highest priority," said Badger Founder & CEO Bill Whyte. "All of these lots passed the required microbiological and comprehensive challenge testing prior to sale. It was during routine re-testing that we discovered that the preservative system in several lots had been compromised. In our 18-year history, this

voluntary recall is a first. We continue to conduct rigorous testing and are taking steps to ensure this doesn't happen in the future.”

Badger sunscreen lotions are carefully formulated using only food-grade emulsifiers and natural preservatives that are gentle on the skin. All Badger sunscreen products have obtained top safety and efficacy ratings from the [Environmental Working Group](#)³ and protect only with non-nano zinc oxide – the safest single active ingredient available.

W.S. Badger Co. Inc. manufacturers the No. 1 selling sunscreen in the U.S. Natural Markets, 1 and has produced quality, all-natural and certified organic body care products since 1995. Family owned and family run, Badger aims to protect, soothe and heal with ingredients safe for all. Badger has been awarded the B Corp Certification, after demonstrating its hard work to create a healthy business with ethical and charitable principles. Visit badgerbalm.com⁴ for more information.

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