

Bayer U.S. LLC

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News Release

BAYER ISSUES VOLUNTARY RECALL OF SPECIFIC LOTRIMIN® AND TINACTIN® SPRAY PRODUCTS DUE TO THE PRESENCE OF BENZENE

WHIPPANY, N.J., October 1, 2021 -- Bayer is voluntarily recalling all unexpired Lotrimin® AF and Tinactin® spray products with lot numbers beginning with TN, CV or NAA, distributed between September 2018 to September 2021, to the consumer level due to the presence of benzene in some samples of the products. Benzene is not an ingredient in any of Bayer Consumer Health products. It is important to note that Bayer's decision to voluntarily recall these products is a precautionary measure and that the levels detected are not expected to cause adverse health consequences in consumers.

Risk Statement: Benzene is classified as a human carcinogen. Exposure to benzene can occur by inhalation, orally, and through the skin. Depending on duration and level of exposure, it can result in cancers including leukemia, and blood cancer of the bone marrow and blood disorders which can be life-threatening. Benzene is found in the environment from natural sources and human activity. Humans around the world are exposed to it from multiple sources and pathways, including inhalation, through the skin, and orally. To date, Bayer has no known reports of adverse events related to this recall.

The affected Lotrimin® and Tinactin® spray products are over the counter antifungal products, sold individually or in combo packs. The impacted products are:

- Lotrimin® Anti-Fungal (AF) Athlete's Foot Powder Spray
- Lotrimin® Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray
- Lotrimin® Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray
- Lotrimin® AF Athlete's Foot Liquid Spray
- Lotrimin® AF Athlete's Foot Daily Prevention Deodorant Powder Spray
- Tinactin® Jock Itch (JI) Powder Spray
- Tinactin® Athlete's Foot Deodorant Powder Spray
- Tinactin® Athlete's Foot Powder Spray

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• Tinactin® Athlete's Foot Liquid Spray

Product images and information on which lot numbers fall under this recall are available at: <u>https://livewell.bayer.com/document/2011</u>.

There are no issues of concern with Lotrimin®/Tinactin® creams, including Lotrimin® Ultra, or any other Bayer products.

The recalled products are all packaged in aerosol spray cans. The products were distributed in the U.S., Puerto Rico, Canada and Mexico through a variety of retail channels.

Bayer is also notifying its distributors and retailers by letter and is arranging for returns of all voluntarily recalled products. Consumers may request a refund by visiting <u>www.lotrimin.com</u> or <u>www.tinactin.com</u>, and may contact Bayer with questions by calling 1-866-360-3266, Monday-Friday between the hours of 8 a.m. and 8 p.m. Eastern Time. A photo of the product will be required to receive a refund. After taking your photo and completing the refund process, please discard the product appropriately. Consumers who have the products that are being recalled should stop using. Consumers should contact their physician or healthcare provider if they have any questions, concerns or have experienced any problems related to using these aerosol antifungal products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program by:

- Filing the report online: <u>www.fda.gov/medwatch/report.htm</u>
- Filing the report via regular mail or fax: Download form <u>www.fda.gov/MedWatch/getforms.htm</u> 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 voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable

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development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to <u>www.bayer.com</u>.

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Social Media Channels

- Facebook: <u>BayerUnitedStates</u>
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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at <u>www.bayer.com</u>. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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