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## 60 DAY NOTICE OF VIOLATION

SENT IN COMPLIANCE WITH CALIFORNIA HEALTH & SAFETY CODE §25249.7(d)

**October 6, 2021**

**VIA CERTIFIED U.S. MAIL**

Patrick Lockwood-Taylor, CEO  
Bayer U.S., LLC  
100 Bayer Boulevard  
Whippany, NJ 07981

Werner Baumann, CEO  
Bayer Corporation  
100 Bayer Boulevard  
Whippany, NJ 07981

CSC Lawyers Incorporating Service  
as Registered Agent for Bayer U.S., LLC and Bayer Corporation  
2710 Gateway Oaks Drive, Suite 150N  
Sacramento, CA 95833-3505.

Rob Bonta, Attorney General  
Office of the Attorney General of California  
Attn: Prop 65 Coordinator  
1515 Clay Street, Suite 2000  
Post Office Box 70550  
Oakland, California 94612-0550  
<https://oag.ca.gov/prop65/add-60-day-notice>

*[Additional District & City Attorneys Copied]*

**Re: 60-Day Notice Pursuant to Cal. Health & Safety Code § 25249.5, et seq.  
Violation of Proposition 65 Warning by Target Corporation**

To Bayer U.S., LLC, Bayer Corporation, Mr. Bonta, and Whomever Else it May Concern:

I represent California consumer Scott McAdam in this matter and write on his behalf, pursuant to California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), which is codified at California Health and Safety Code section 25249.5, et seq., to notify you of Bayer

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U.S., LLC's and Bayer Corporation's (collectively, "Bayer" or the "Violator") violations of Proposition 65 in its sale of the following products (the "Products"), which were recently recalled (see Appendix C):

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

- 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
- Tinactin® Athlete's Foot Liquid Spray

Product images and information on the specific lot numbers that violate Proposition 65 are available at: <https://livewell.bayer.com/document/2011>.

The violations alleged by this notice consist of types of harm that may potentially result from exposures to the toxic chemical benzene, which was listed as a known hazardous substance in February of 1987. This letter serves as a notice of these violations to the alleged Violator and the appropriate public enforcement agencies. Pursuant to section 25249.7(d) of the statute, Mr. McAdam intends to file a private enforcement action in the public interest 60 days after effective service of this notice unless the public enforcement agencies have commenced and are diligently prosecuting an action to rectify these violations.

#### **General Information about Proposition 65.**

A copy of a summary of Proposition 65, prepared by the Office of Environmental Health hazard Assessment, is attached with the copy of this letter served to the alleged Violator identified below.

#### **Alleged Violator.**

The name of the company covered by this notice that violated Proposition 65 is: Bayer U.S., LLC and Bayer Corporation.

#### **Consumer Product and Listed Chemical.**

The Products that are the subject of this notice are Lotrimin® and Tinactin®, which are over the counter antifungal products, sold individually or in combo packs, including:

- Lotrimin® Anti-Fungal (AF) Athlete's Foot Powder Spray

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- 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
  - Tinactin® Athlete’s Foot Liquid Spray

Product images and information on the specific lot numbers that violate Proposition 65 are available at: <https://livewell.bayer.com/document/2011>.

The chemical in that product identified as exceeding allowable levels is benzene (CAS No. 71-43-2). On February 27, 1987, the State of California officially listed benzene as a chemical known to cause cancer.

### **Provision of Proposition 65.**

This notice covers the “warning provision” of Proposition 65, which is found at California Health & Safety Code § 25249.6.

### **Route of Exposure.**

The consumer exposures that are the subject of this notice result from the purchase, acquisition, and recommended use of the Products. Consequently, the primary route of exposure to these chemicals has been and continues to be through dermal absorption through direct skin contact with the Products. There is also a risk of exposure through ingestion.

### **Violations.**

The Violator has exposed and continues to expose consumers within the State of California to benzene at levels that, upon reasonable use of the Products, exceed the No Significant Risk Level and the Maximum Allowable Dose Level without providing clear and reasonable warning of this exposure. In particular, the Violator does not warn that the Products contain a chemical known to the State of California to cause cancer.

### **Approximate Time Period of Violations.**

Ongoing violations have occurred every day since September 2018 or earlier, as well as every day since the Products were introduced into the California marketplace, and will continue every day until clear and reasonable warnings are provided to Products purchasers or until these known toxic chemicals are either removed from or reduced to allowable levels in the Products. Proposition 65 requires that a clear and reasonable warning be provided prior to exposure to the identified chemicals. The method of warning should be a warning that appears where the

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product is sold. The Violator violated Proposition 65 because it failed to provide persons using these Products with appropriate warnings that they are being exposed to benzene.

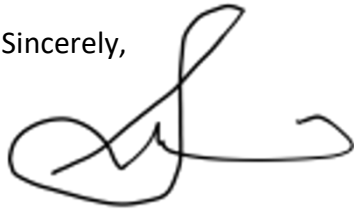
**Resolution of Noticed Claims.**

Based on the allegations set forth in this notice, Mr. McAdam intends to file a citizen enforcement lawsuit against Bayer unless it agrees to provide clear and reasonable warnings for products sold or otherwise provided to consumers in the future to eliminate unknowing exposures to benzene, and pay an appropriate civil penalty based on the factors enumerated in California Health and Safety Code Section 25249.7(b).

I am representing myself in this matter, as a licensed member of the California bar, in good standing, since 1999.

***Please direct all communications regarding this notice to my attention via email at [smcadam@mc2firm.com](mailto:smcadam@mc2firm.com).***

Sincerely,

A handwritten signature in black ink, appearing to read 'Scott C. McAdam', with a stylized flourish at the end.

Scott C. McAdam, Esq.

Attachments:

- Appendix A: OEHHA Summary (to Violators only)
- Appendix B: Special Compliance Procedure
- Certificate of Merit
- Appendix C: Bayer Product Recall Notice
- Proof of Service

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## APPENDIX A

### OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

#### THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65): A SUMMARY

The following summary has been prepared by the California Office of Environmental Health Hazard Assessment (OEHHA), the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as "Proposition 65"). A copy of this summary must be included as an attachment to any notice of violation served upon an alleged violator of the Act. The summary provides basic information about the provisions of the law, and is intended to serve only as a convenient source of general information. It is not intended to provide authoritative guidance on the meaning or application of the law. Please refer to the statute and OEHHA's implementing regulations (see citations below) for further information.

FOR INFORMATION CONCERNING THE BASIS FOR THE ALLEGATIONS IN THE NOTICE RELATED TO YOUR BUSINESS, CONTACT THE PERSON IDENTIFIED ON THE NOTICE.

The text of Proposition 65 (Health and Safety Code Sections 25249.5 through 25249.13) is available online at: <http://oehha.ca.gov/prop65/law/P65law72003.html>. Regulations that provide more specific guidance on compliance, and that specify procedures to be followed by the State in carrying out certain aspects of the law, are found in Title 27 of the California Code of Regulations, sections 25102 through 27001.<sup>1</sup> These implementing regulations are available online at: <http://oehha.ca.gov/prop65/law/P65Regs.html>.

#### WHAT DOES PROPOSITION 65 REQUIRE?

The "Proposition 65 List." Under Proposition 65, the lead agency (OEHHA) publishes a list of chemicals that are known to the State of California to cause cancer and/or reproductive toxicity. Chemicals are placed on the Proposition 65 list if they are known to cause cancer and/or birth defects or other reproductive harm, such as damage to female or male reproductive systems or to the developing fetus. This list must be updated at least once a year. The current Proposition 65 list of chemicals is available on the OEHHA website at [http://www.oehha.ca.gov/prop65/prop65\\_list/Newlist.html](http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html).

Only those chemicals that are on the list are regulated under Proposition 65. Businesses that produce, use, release or otherwise engage in activities involving listed chemicals must comply with the following:

Clear and reasonable warnings. A business is required to warn a person before "knowingly and intentionally" exposing that person to a listed chemical unless an exemption applies. The warning given must be "clear and reasonable." This means that the warning must: (1) clearly say that the chemical involved is known to cause cancer, or birth defects or other reproductive harm and (2) be given in such a way that it will effectively reach the person before he or she is exposed to that chemical. Some exposures are exempt from the warning requirement under certain circumstances discussed below.

Prohibition from discharges into drinking water. A business must not knowingly discharge or release a listed chemical into water or onto land where it passes or probably will pass into a source of drinking water. Some discharges are exempt from this requirement under certain circumstances discussed below.

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## DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. You should consult the current version of the statute and regulations (<http://www.oehha.ca.gov/prop65/law/index.html>) to determine all applicable exemptions, the most common of which are the following:

**Grace Periods.** Proposition 65 warning requirements do not apply until 12 months after the chemical has been listed. The Proposition 65 discharge prohibition does not apply to a discharge or release of a chemical that takes place less than 20 months after the listing of the chemical.

**Governmental agencies and public water utilities.** All agencies of the federal, state or local government, as well as entities operating public water systems, are exempt.

**Businesses with nine or fewer employees.** Neither the warning requirement nor the discharge prohibition applies to a business that employs a total of nine or fewer employees. This includes all full and part-time employees, not just those present in California.

**Exposures that pose no significant risk of cancer.** For chemicals that are listed under Proposition 65 as known to the State to cause cancer, a warning is not required if the business causing the exposure can demonstrate that the exposure occurs at a level that poses "no significant risk." This means that the exposure is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. The Proposition 65 regulations identify specific "No Significant Risk Levels" (NSRLs) for many listed carcinogens. Exposures below these levels are exempt from the warning requirement. See OEHHA's website at: <http://www.oehha.ca.gov/prop65/getNSRLs.html> for a list of NSRLs, and Section 25701 et seq. of the regulations for information concerning how these levels are calculated.

**Exposures that will produce no observable reproductive effect at 1,000 times the level in question.** For chemicals known to the State to cause reproductive toxicity, a warning is not required if the business causing the exposure can demonstrate that the exposure will produce no observable effect, even at 1,000 times the level in question. In other words, the level of exposure must be below the "no observable effect level" divided by 1,000. This number is known as the Maximum Allowable Dose Level (MADL). See OEHHA's website at: <http://www.oehha.ca.gov/prop65/getNSRLs.html> for a list of MADLs, and Section 25801 et seq. of the regulations for information concerning how these levels are calculated.

**Exposures to Naturally Occurring Chemicals in a Food.** Certain exposures to chemicals that naturally occur in foods (i.e., that do not result from any known human activity, including activity by someone other than the person causing the exposure) are exempt from the warning requirements of the law. If the chemical is a contaminant<sup>2</sup> it must be reduced to the lowest level feasible. Regulations explaining this exemption can be found in Section 25501.

**Discharges that do not result in a "significant amount" of the listed chemical entering into any source of drinking water.** The prohibition from discharges into drinking water does not apply if the discharger is able to demonstrate that a "significant amount" of the listed chemical has not, does

<sup>1</sup> All further regulatory references are to sections of Title 27 of the California Code of Regulations unless otherwise indicated. The statute, regulations and relevant case law are available on the OEHHA website at: <http://www.oehha.ca.gov/prop65/law/index.html>. <sup>2</sup> See Section 25501(a)(4).

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not, or will not pass into or probably pass into a source of drinking water, and that the discharge complies with all other applicable laws, regulations, permits, requirements, or orders. A "significant amount" means any detectable amount, except an amount that would meet the "no significant risk" level for chemicals that cause cancer or that is 1,000 times below the "no observable effect" level for chemicals that cause reproductive toxicity, if an individual were exposed to that amount in drinking water.

#### HOW IS PROPOSITION 65 ENFORCED?

Enforcement is carried out through civil lawsuits. These lawsuits may be brought by the Attorney General, any district attorney, or certain city attorneys. Lawsuits may also be brought by private parties acting in the public interest, but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation. The notice must provide adequate information to allow the recipient to assess the nature of the alleged violation. The notice must comply with the information and procedural requirements specified in Section 25903 of Title 27 sections 3100-3103 of Title 11. A private party may not pursue an independent enforcement action under Proposition 65 if one of the governmental officials noted above initiates an enforcement action within sixty days of the notice.

A business found to be in violation of Proposition 65 is subject to civil penalties of up to \$2,500 per day for each violation. In addition, the business may be ordered by a court to stop committing the violation.

A private party may not file an enforcement action based on certain exposures if the

alleged violator meets specific conditions. For the following types of exposures, the Act provides an opportunity for the business to correct the alleged violation:

- An exposure to alcoholic beverages that are consumed on the alleged violator's premises to the extent onsite consumption is permitted by law;
- An exposure to a Proposition 65 listed chemical in a food or beverage prepared and sold on the alleged violator's premises that is primarily intended for immediate consumption on- or off-premises. This only applies if the chemical was not intentionally added to the food, and was formed by cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination;
- An exposure to environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises;
- An exposure to listed chemicals in engine exhaust, to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking non-commercial vehicles.

If a private party alleges that a violation occurred based on one of the exposures described above, the private party must first provide the alleged violator a notice of special compliance procedure and proof of compliance form.

A private party may not file an action against the alleged violator for these exposures, or recover in a settlement any payment in lieu of penalties or any reimbursement for costs and attorney's fees, if the notice of violation was served on or after October 5, 2013, and the alleged violator has done all of the following within 14 days of being served notice:

- 
- Corrected the alleged violation;
  - Agreed to pay a civil penalty of \$500 (subject to change as noted below) to the private party within 30 days; and
  - Notified the private party serving the notice in writing that the violation has been corrected. The written notification to the private-party must include a notice of special compliance procedure and proof of compliance form completed by the alleged violator as directed in the notice. On April 1, 2019, and every five years thereafter, the dollar amount of the civil penalty will be adjusted by the Judicial Council based on the change in the annual California Consumer Price Index. The Judicial Council will publish the dollar amount of the adjusted civil penalty at each five-year interval, together with the date of the next scheduled adjustment. An alleged violator may satisfy these conditions only one time for a violation arising from the same exposure in the same facility or on the same premises. The satisfaction of these conditions does not prevent the Attorney General, a district attorney, a city attorney of a city greater than 750,000 in population, or any full-time city prosecutor with the consent of the district attorney, from filing an enforcement action against an alleged violator. The amount of any civil penalty for a violation shall be reduced to reflect any payment made by the alleged violator for the same alleged violation to a private-party. A copy of the notice of special compliance procedure and proof of compliance form is included with this notice and can be downloaded from OEHHA's website at: <http://oehha.ca.gov/prop65/law/p65law72003.html>. The notice is reproduced here:



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## **APPENDIX B**

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT  
CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
(PROPOSITION 65): SPECIAL COMPLIANCE PROCEDURE

This Appendix B contains the notice of special compliance procedure and proof of compliance form prepared by the California Office of Environmental Health Hazard Assessment (OEHHA), the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as “Proposition 65”). Under the Act, a private party may not file an enforcement action based on certain exposures if the alleged violator meets specific conditions. These exposures are:

- An exposure to alcoholic beverages that are consumed on the alleged violator's premises to the extent onsite consumption is permitted by law;
- An exposure to a Proposition 65 listed chemical in a food or beverage prepared and sold on the alleged violator's premises that is primarily intended for immediate consumption on- or off- premises. This only applies if the chemical was not intentionally added to the food, and was formed by cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination;
- An exposure to environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises;
- An exposure to listed chemicals in engine exhaust, to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking non-commercial vehicles.

A private party may not file an action against the alleged violator for these exposures, or recover in a settlement any payment in lieu of penalties any reimbursement for costs and attorney's fees, if the alleged violator has done *all* of the following within 14 days of being served notice.

- Corrected the alleged violation;
- Agreed to pay a civil penalty of \$500 (subject to change in 2019 and every five years thereafter) to the private party within 30 days; and
- Notified the private party serving the notice in writing that the violation has been corrected.

An alleged violator may satisfy these conditions only one time for a violation arising from the same exposure in the same facility or on the same premises. The satisfaction of these conditions does not prevent the Attorney General, a district attorney, a city attorney of a city of greater than 750,000 population, or any full-time city prosecutor with the consent of the district attorney, from filing an enforcement action against an alleged violator.

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When a private party sends a notice of alleged violation that alleges one or more of the exposures listed above, the notice must include a notice of special compliance procedure, and a proof of compliance form to be completed by the alleged violator as directed in the notice.

The notice and proof of compliance form is reproduced here:

Page 1

Date: October 6, 2021

Name of Noticing Party or attorney for Noticing Party: Scott C. McAdam, Esq.

Address: c/o D-O Capital Partners, 2700 E. Coast Highway, Suite 100, Corona del Mar, CA 92625

Phone number: (310) 259-3751

**SPECIAL COMPLIANCE PROCEDURE  
PROOF OF COMPLIANCE**

You are receiving this form because the Noticing Party listed above has alleged that you are violating California Health and Safety Code §25249.6 (Prop. 65).

**The Noticing Party may not bring any legal proceedings against you for the alleged violation checked below if:**

- 1. You have actually taken the corrective steps that you have certified in this form**
- 2. The Noticing Party has received this form at the address shown above, accurately completed by you, postmarked within 14 days of your receiving this notice**
- 3. The Noticing Party receives the required \$500 penalty payment from you at the address shown above postmarked within 30 days of your receiving this notice.**
- 4. This is the first time you have submitted a Proof of Compliance for a violation arising from the same exposure in the same facility on the same premises.**

**PART 1: TO BE COMPLETED BY THE NOTICING PARTY OR ATTORNEY FOR THE NOTICING PARTY**

The alleged violation is for an exposure to: (check one)

Alcoholic beverages that are consumed on the alleged violator's premises to the extent on-site consumption is permitted by law.

A chemical known to the state to cause cancer or reproductive toxicity in a food or beverage prepared and sold on the alleged violator's premises for immediate consumption on or off premises to the extent: (1) the chemical was not intentionally added; and (2) the chemical was formed by cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination.

Environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises.

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\_\_\_ Chemicals known to the State to cause cancer or reproductive toxicity in engine exhaust, to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking noncommercial vehicles.

**IMPORTANT NOTES:**

1. You have no potential liability under California Health and Safety Code §25249.6 if your business has nine (9) or fewer employees.
2. Using this form will NOT prevent the Attorney General, a district attorney, a city attorney, or a prosecutor in whose jurisdiction the violation is alleged to have occurred from filing an action over the same alleged violations, and that in any such action, the amount of civil penalty shall be reduced to reflect any payment made at this time.

[continued on next page]

Date: October 6, 2021

Name of Noticing Party or attorney for Noticing Party: Scott C. McAdam, Esq.

Address: c/o D-O Capital Partners, 2700 E. Coast Highway, Suite 100, Corona del Mar, CA 92625

Phone number: (310) 259-3751

**PART 2: TO BE COMPLETED BY THE ALLEGED VIOLATOR OR AUTHORIZED REPRESENTATIVE**

**Certification of Compliance**

Accurate completion of this form will demonstrate that you are now in compliance with California Health and Safety Code §25249.6 for the alleged violation listed above. You must complete and submit the form below to the Noticing Party at the address shown above, postmarked within 14 days of you receiving this notice.

I hereby agree to pay, within 30 days of completion of this notice, a civil penalty of \$500 to the Noticing Party only and certify that I have complied with Health and Safety Code §25249.6 by (check only one of the following):

- Posting a warning or warnings about the alleged exposure that complies with the law, and attaching a copy of that warning and a photograph accurately showing its placement on my premises;
- Posting the warning or warnings demanded in writing by the Noticing Party, and attaching a copy of that warning and a photograph accurately its placement on my premises; OR
- Eliminating the alleged exposure, and attaching a statement accurately describing how the alleged exposure has been eliminated.

**Certification**

My statements on this form, and on any attachments to it, are true, complete, and correct to the best of my knowledge and belief and are made in good faith. I have carefully read the instructions to complete this form. I understand that if I make a false statement on this form, I may be subject to additional penalties under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

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Signature of alleged violator or authorized representative Date

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Name and title of signatory

*FOR FURTHER INFORMATION ABOUT THE LAW OR REGULATIONS. . .*

Contact the Office of Environmental Health Hazard Assessment's Proposition 65 Implementation Office at (916) 445-6900 or via e-mail at [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov).  
Revised: May 2017

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Note: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.7, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

### **HISTORY**

1. New Appendix B filed 8-23-2017; operative 10-1-2017 (Register 2017, No. 34).

This database is current through 9/24/21 Register 2021, No. 39

27 CCR Appendix B, 27 CA ADC Appendix B

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## CERTIFICATE OF MERIT

Health and Safety Code Section 25249.7(d)

I, Scott C. McAdam, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged that the party identified in the notice has violated Health and Safety Code §25249.6 by failing to provide clear and reasonable warnings;
2. I am the attorney for the noticing party;
3. I have consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the alleged exposure to the listed chemical that is the subject of this action;
4. Based on the information obtained through those consultations, and on all other information in my possession, I believe there is a reasonable and meritorious case for the private action. I understand that "reasonable and meritorious case for the private action" means that the information provides a credible basis that all elements of the plaintiff's case can be established and the information did not prove that the alleged Violator will be able to establish any of the affirmative defenses set forth in the statute;
5. The copy of this Certificate of Merit served on the Attorney General attaches to it factual information sufficient to establish the basis for this certificate, including information identified in Health and Safety Code §25249.7(h)(2) (i.e., (1) the identity of the persons consulted with and relied on by the certifier, and (2) the facts, studies, or other data reviewed by those persons).

Dated: October 6, 2021



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Scott C. McAdam

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**APPENDIX C**

**Bayer Product Recall Announcement**

[attached]



## COMPANY ANNOUNCEMENT

# Bayer Issues Voluntary Recall of Specific Lotrimin® and Tinactin® Spray Products Due to the Presence of Benzene

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:** October 01, 2021  
**FDA Publish Date:** October 01, 2021  
**Product Type:** Drugs  
**Reason for Announcement:** Presence of benzene  
**Company Name:** Bayer U.S. LLC  
**Brand Name:** Lotrimin® AF and Tinactin®  
**Product Description:** Over the Counter (OTC) antifungal spray products

**Content current as of:**  
10/01/2021

**Regulated Product(s)**  
Drugs

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## Company Announcement

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
- Tinactin® Athlete's Foot Liquid Spray

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

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 [www.lotrimin.com](http://www.lotrimin.com) or [www.tinactin.com](http://www.tinactin.com), 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 FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) 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.

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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 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 [www.bayer.com](http://www.bayer.com)

## Social Media Channels

- Facebook: [BayerUnitedStates](#)
- Twitter: [BayerUS](#)
- Instagram: [BayerUS](#)
- YouTube: [BayerUS](#)

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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 [www.bayer.com](http://www.bayer.com). The company assumes no liability whatsoever to update these forwardlooking statements or to conform them to future events or developments.

## Company Contact Information

### Consumers:

Bayer  
 1-866-360-3266

### Media:

Chris Loder Bayer U.S.  
 (862) 404-7437  
[chris.loder@bayer.com](mailto:chris.loder@bayer.com)

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**PROOF OF SERVICE**

I, the undersigned, declare under penalty of perjury:

I am a citizen of the United States, over the age of 18 years, and not a party to the within action; my business address is, c/o D-O Capital Partners, 2700 E. Coast Highway, Suite 100, Corona del Mar, CA 92625.

On October 7, 2021, I served the following documents:

60-DAY NOTICE OF VIOLATION SENT IN COMPLIANCE WITH HEALTH & SAFETY CODE  
§25249.7(d); PROPOSITION 65: SUMMARY; CERTIFICATE OF MERIT; AND CERTIFICATE  
OF MERIT ATTACHMENTS

on the Violator listed below via First Class Certified Mail through the United States Postal Service by placing true and correct copy in a sealed envelope, addressed to the Violator and providing such envelope to a United States Postal Service Representative:

Patrick Lockwood-Taylor, CEO  
Bayer U.S., LLC  
c/o CSC Lawyers Incorporating Service  
2710 Gateway Oaks Drive, Suite 150N  
Sacramento, CA 95833-3505

Werner Baumann, CEO  
Bayer Corporation  
c/o CSC Lawyers Incorporating Service  
2710 Gateway Oaks Drive, Suite 150N  
Sacramento, CA 95833-3505

as well as providing copies of the notice to the public enforcers by placing a true and correct copy in a sealed envelope, addressed to each party listed below and served as follows:


By Uploading onto <a href="https://oag.ca.gov/prop65/add-60-day-notice">https://oag.ca.gov/prop65/add-60-day-notice</a>	The Attorney General of the State of California
By placing each envelope in a United States Postal Service Box, first class postage pre-paid	The District Attorneys for 33 California Counties and; The City Attorneys for Los Angeles, San Jose.
By sending electronic mail	The following District Attorneys: Alameda, San Joaquin, San Luis Obispo, Sonoma,

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	Santa Clara, Napa, Lassen, Riverside, Tulare, Ventura, Yolo, Monterey, Sacramento, San Francisco, Santa Barbara, San Diego, Santa Cruz, Contra Costa, Inyo, Mariposa, Merced, Nevada, Placer, Plumas and Calaveras County  The City Attorneys for San Diego and San Francisco
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A list of address for each of the recipient's is attached.

Executed on October 7, 2021 Las Vegas, Nevada



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Scott C. McAdam, Esq.

**By US First Class Mail:**

COLUSA COUNTY  
547 Market Street, Ste. 102  
Colusa, CA 95932

DEL NORTE COUNTY  
450 H Street, Room 171  
Crescent City, CA 95531

ALPINE COUNTY  
PO Box 248  
Markleeville, CA 96120

EL DORADO COUNTY  
778 Pacific Street  
Placerville, CA 95667

AMADOR COUNTY  
708 Court Street #202  
Jackson, CA 95642

FRESNO COUNTY  
2220 Tulare Street, Ste. 1000  
Fresno, CA 93721

GLENN COUNTY  
PO Box 430  
Willows, CA 95988

BUTTE COUNTY  
25 County Center Drive --  
Administration Building  
Oroville, CA 95965

HUMBOLDT COUNTY  
825 5th Street  
Eureka, CA 95501

**By Electronic Mail:**

ALAMEDA COUNTY  
Attn: Nancy O'Malley  
[CEPDProp65@acgov.org](mailto:CEPDProp65@acgov.org)

CALAVERAS COUNTY  
Attn: Barbara Yook  
[Prop65Env@co.calaveras.ca.us](mailto:Prop65Env@co.calaveras.ca.us)

CONTRA COSTA COUNTY  
Attn: Stacey Grassini  
[sgrassini@contracostada.org](mailto:sgrassini@contracostada.org)

INYO COUNTY  
Attn: Thomas L. Hardy  
[invoda@invocounty.us](mailto:invoda@invocounty.us)

SAN DIEGO COUNTY  
Attn: Summer Stephan  
[SanDiegoDAProp65@sdcda.org](mailto:SanDiegoDAProp65@sdcda.org)

SAN DIEGO CITY ATTORNEY  
Attn: Mark Ankorn  
[CityAttyProp65@sandiego.gov](mailto:CityAttyProp65@sandiego.gov)

SAN JOAQUIN COUNTY  
Attn: Tori Verber  
[DAConsumer.Environmental@sjecda.org](mailto:DAConsumer.Environmental@sjecda.org)

MADERA COUNTY  
209 West Yosemite Avenue  
Madera, CA 93637

MARIN COUNTY  
3501 Civic Center Drive,  
Room 130  
San Rafael, CA 94903

MENDOCINO COUNTY  
PO BOX 1000  
Ukiah, CA 95482

MODOC COUNTY  
204 S. Court Street, Room 202  
Alturas, CA 96101

MONO COUNTY  
PO BOX 617  
Bridgeport, CA 93546

County of Los Angeles  
210 West Temple Street,  
Suite 18000  
Los Angeles, CA 90012-3210

ORANGE COUNTY  
401 Civic Center Drive West  
Santa Ana, CA 92701

SAN BENITO COUNTY  
419 4th Street  
Hollister, CA 95023-3801

LASSEN COUNTY  
Attn: Michelle Latimer  
[mlatimer@co.lassen.ca.us](mailto:mlatimer@co.lassen.ca.us)

MARIPOSA COUNTY  
Attn: Walter W. Wall  
[mceda@mariposacounty.org](mailto:mceda@mariposacounty.org)

MONTEREY COUNTY  
Attn: Jeannine M. Pacioni  
[Prop65DA@co.monterey.ca.us](mailto:Prop65DA@co.monterey.ca.us)

NAPA COUNTY  
Attn: Gary Lieberstein  
[CEPD@countvofnapa.org](mailto:CEPD@countvofnapa.org)

SAN FRANCISCO COUNTY  
Attn: Gregory Alker  
[Gregory.alker@sfgov.org](mailto:Gregory.alker@sfgov.org)

SAN FRANCISCO CITY  
Attn: Valerie Lopez  
[Valerie.Lopez@sfcivatty.org](mailto:Valerie.Lopez@sfcivatty.org)

SAN LUIS OBISPO COUNTY  
Attn: Eric J. Dobroth  
[edobroth@co.slo.ca.us](mailto:edobroth@co.slo.ca.us)

SAN MATEO COUNTY  
400 County Center, Third Floor  
Redwood City, CA 94063

SHASTA COUNTY  
1355 West Street  
Redding, CA 96001

SIERRA COUNTY  
100 Courthouse Square  
Downieville, CA 95936

SISKIYOU COUNTY  
PO BOX 986  
Yreka, CA 96097

SOLANO COUNTY  
675 Texas Street, Ste. 4500  
Fairfield, CA 94533

SAN BERNARDINO COUNTY  
316 N. Mountain View Ave  
San Bernardino, CA 92415-0004

KERN COUNTY  
1215 Truxtun Avenue  
Bakersfield, CA 93301

LAKE COUNTY  
255 N. Forbes Street  
Lakeport, CA 95453

IMPERIAL COUNTY  
940 West Main Street, Ste. 102  
El Centro, CA 92243

NEVADA COUNTY  
Attn: Clifford H. Newell  
[DA.Prop65@co.nevada.ca.us](mailto:DA.Prop65@co.nevada.ca.us)

PLUMAS COUNTY  
Attn: David Hollister  
[davidhollister@countyofplumas.com](mailto:davidhollister@countyofplumas.com)

RIVERSIDE COUNTY  
Attn: Paul E. Zellerbach  
[Prop65@rivcoda.org](mailto:Prop65@rivcoda.org)

SACRAMENTO COUNTY  
Attn: Anne Marie Schubert  
[Prop65@saecda.org](mailto:Prop65@saecda.org)

SANTA BARBARA COUNTY  
Attn: Christopher Dalbey  
[DAProp65@co.santa-barbara.ca.us](mailto:DAProp65@co.santa-barbara.ca.us)

SANTA CLARA COUNTY  
Attn: Bud Porter  
[EPU@da.sccgov.org](mailto:EPU@da.sccgov.org)

SANTA CRUZ COUNTY  
Attn: Jeffrey S. Rosell  
[Prop65DA@santacruzcounty.us](mailto:Prop65DA@santacruzcounty.us)

STANISLAUS COUNTY  
832 12th Street, Ste. 300  
Modesto, CA 95353

SUTTER COUNTY  
446 2nd Street, Suite 102  
Yuba City, CA 95991

TEHAMA COUNTY  
PO BOX 519  
Red Bluff, CA 96080

TRINITY COUNTY  
PO BOX 310  
Weaverville, CA 96093

TUOLUMNE COUNTY  
423 No. Washington Street  
Sonora, CA 95370

YUBA COUNTY  
215 Fifth Street, Ste. 152  
Marysville, CA 95901

Office of the City Attorney  
CITY OF LOS ANGELES  
200 N. Main Street  
Los Angeles, CA 90012

Office of the City Attorney  
City of San Jose  
200 East Santa Clara Street  
16th Floor  
San Jose, CA 95113

KINGS COUNTY  
1400 West Lacey Blvd.  
Hanford, CA 93230

SONOMA COUNTY  
Attn: Stephan R. Passalacqua  
[jbarnes@sonoma-county.org](mailto:jbarnes@sonoma-county.org)

TULARE COUNTY  
Attn: Phillip J. Cline  
[Prop65@co.tulare.ca.us](mailto:Prop65@co.tulare.ca.us)

VENTURA COUNTY  
Attn: Gregory D. Totten  
[daspecialops@ventura.org](mailto:daspecialops@ventura.org)

YOLO COUNTY  
Attn: Jeff W. Reisig  
[cfepd@volocounty.org](mailto:cfepd@volocounty.org)

PLACER COUNTY  
Attn: Morgan Briggs Gire  
[prop65@placer.ca.gov](mailto:prop65@placer.ca.gov)

MERCED COUNTY  
Attn: Kimberly Lewis  
[Prop65@countyofmerced.com](mailto:Prop65@countyofmerced.com)