

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

DARRELL STEWART, CHRISTOPHER
CADORETTE, JUAN HUERTAS,
JONATHAN MARTIN, EVA MISTRETТА,
DON PENALES, JR., MIKE POOVEY,
SEAN STEINWEDEL, JOSE
VILLARREAL, and JEREMY WYANT, on
behalf of themselves and all others similarly
situated,

Plaintiffs,

v.

AEROPRES CORPORATION, BAYER
HEALTHCARE LLC, BEIERSDORF
MANUFACTURING, LLC, BEIERSDORF,
INC., and BEIERSDORF NORTH
AMERICA, INC.

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Darrell Stewart, Christopher Cadorette, Juan Huertas Jonathan Martin, Eva Mistretta, Don Penales, Jr., Mike Poovey, Sean Steinwedel, Darrell Stewart, Jose Villarreal and Jeremy Wyant (“Plaintiffs”) bring this action on behalf of themselves and all others similarly situated against Defendants Aeropres Corporation (“Aeropres”), Beiersdorf Manufacturing, LLC (“Beiersdorf LLC”), Beiersdorf, Inc. (“Beiersdorf Inc.”), Beiersdorf North America, Inc. (“Beiersdorf NA”) (collectively, Beiersdorf LLC, Beiersdorf Inc. and Beiersdorf NA are “Beiersdorf” or the “Beiersdorf Defendants”), and Bayer Healthcare LLC (“Bayer,” and together with the Beiersdorf Defendants and Aeropres, “Defendants”). Plaintiffs make the following allegations pursuant to the investigation of their counsel, the action styled *Bayer Healthcare LLC v. Aeropres Corp.*, No. 1:23-cv-04391 (N.D. Ill.), personal knowledge of the allegations specifically pertaining to themselves, and upon information and belief.

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendants' manufacturing, distribution, and sale of Lotrimin and Tinactin spray products (the "Products") without disclosing that the Products contain dangerously high levels of benzene, a carcinogenic impurity that has been linked to leukemia and other cancers.

2. In October 2021, Defendant Bayer announced a recall of unexpired Lotrimin® AF ("Lotrimin") and Tinactin® ("Tinactin") antifungal spray products as a result of benzene contamination. According to Bayer, the source of the benzene contamination was the propellant Bayer used in the recalled Products supplied by Defendant Aeropres, known as Propellant A-31.

3. In August 2021, Aeropres disclosed to the Beiersdorf Defendants, the manufacturer of the Products, that Propellant A-31 was contaminated with benzene. Beiersdorf immediately notified Bayer of the contamination. The contaminated Propellant A-31 was produced in an Aeropres facility in Morris, Illinois, and incorporated by Bayer into Bayer's Lotrimin and Tinactin spray Products at Beiersdorf's manufacturing facility located in Cleveland, Tennessee.

4. According to Bayer, Aeropres admitted the benzene contamination, stating that "Aeropres regrets this development as it is not in keeping with Aeropres' standards of product manufacture."

5. Both Lotrimin and Tinactin are anti-fungal drug products regulated by the United States Food & Drug Administration ("FDA") pursuant to the federal Food, Drug and Cosmetics Act ("FDCA"). The presence of benzene in the Products renders them adulterated and misbranded. As a result, the Products are illegal to sell under federal law and therefore worthless. *See* 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942

F.3d 1076, 1085 (11th Cir. 2019); *see also In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021); *Barnes v. Bayer United States Inc.*, 2023 WL 2456385, at *4-5 (N.D. Ill. Mar. 11, 2023); *Barnes v. Bayer United States, Inc.*, 2022 WL 2915629, at *1, *3 (N.D. Ill. July 24, 2022); *Clinger v. Edgewell Personal Care Brands, LLC*, 2023 WL 2477499, at *10 (D. Conn. March 13, 2023); *Bojko v. Pierre Fabre USA Inc.*, 2023 WL 4204663, at *2-4 (N.D. Ill. June 27, 2023); *Henning v. Luxury Brand Partners, LLC*, 2023 WL 3555998, at *3-4 (N.D. Cal. May 11, 2023).

6. While the FDA has made clear that there is no acceptable amount of benzene in consumer products, it has adopted a strict limit of 2 parts per million (ppm) for (i) drugs, (ii) where benzene is “unavoidable in order to produce a drug product with a significant therapeutic advance.”¹ As outlined below, independent lab testing shows that the Products consistently contain significant benzene levels that far exceed the 2 ppm FDA upper limit and are many times, and in one sample over 105 times, the 2 ppm limit. And, as outlined below, Bayer’s own internal testing demonstrated that its products contained levels of benzene above 2 ppm.

7. Defendants knew or should have known of the dangerous and carcinogenic effects of benzene and knew or should have known that it was producing Products that contained or risked containing benzene at levels above, and often dramatically above, 2 ppm. Nevertheless, Aeropres, Beiersdorf, and Bayer produced, distributed, and sold Propellant A-31 and millions of cans of Tinactin and Lotrimin AF sprays that contained benzene to the consuming public.

8. Plaintiffs are purchasers and users of the Products, which, as described below, were recalled by Bayer due to the presence of benzene. Plaintiffs purchased the Products to treat conditions they were intended to treat and used them in accordance with the directions provided

¹ <https://www.fda.gov/media/133650/download>, at 7.

on their packaging. Plaintiffs did so because they believed the Products had been manufactured using acceptable standards and practices and that they were safe for human use.

9. However, in reality Plaintiffs bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiffs would not have purchased and used the Products had they known they were unsafe. Plaintiffs were therefore harmed at the point of purchase of the Products when they did not receive the benefit of the bargain. Further, Plaintiffs and other Class Members were forced to discard the remainder of their Products due to the contamination, or purchase replacement products to treat their conditions. Accordingly, Plaintiffs and Class Members were also injured because they were forced to waste portions of the Products or spend additional money to purchase replacement medications that they would not have spent but for the Products being contaminated.

10. Plaintiffs bring this action on behalf of themselves, the Classes, and Subclasses for equitable relief and to recover damages or equitable relief for: (i) breach of express warranty; (ii) breach of implied warranty; (iii) violation of the consumer protection statutes; (iv) fraud; (v) negligent misrepresentation; and (vi) unjust enrichment.

PARTIES

11. Plaintiff Darrell Stewart is a citizen and resident of Sussex County, Delaware.

12. Plaintiff Juan Huertas is a citizen and resident of Nassau County, New York.

13. Plaintiff Christopher Cadorette is a citizen and resident of Essex County, Massachusetts.

14. Plaintiff Jonathan Martin is a citizen and resident of Contra Costa County, California

15. Plaintiff Eva Mistretta is a citizen and resident of Queens County, New York.

16. Plaintiff Don Penales, Jr. is a citizen and resident of Sonoma County, California.

17. Plaintiff Mike Poovey is a citizen and resident of Horry County, South Carolina.

18. Plaintiff Sean Steinwedel is a citizen and resident of Sussex County, Delaware.

19. Plaintiff Jose Villarreal is a citizen and resident of Boone County, Missouri.

20. Plaintiff Jeremy Wyant is a citizen and resident of Clinton County, Indiana.

21. Defendant Aeropres Corporation is a corporation organized and existing under the laws of the State of Louisiana, with its principal place of business at 1324 North Hearne, Suite 200, Shreveport, Louisiana 71137. Aeropres manufactured Propellant A-31, which was used in the Products sold to Plaintiffs and the consuming public, at manufacturing plants located in Morris, Illinois and Manhattan, Illinois.

22. Defendant Bayer HealthCare LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Bayer Boulevard, Whippany, New Jersey 07981. Bayer HealthCare LLC has nine members: MiraLAX LLC, Bayer Samson I LLC, Bayer Samson II LLC, Bayer Consumer Care Holdings LLC, Bayer West Coast Corporation, Bayer Essure Inc., NippoNex Inc., Bayer Medical Care Inc., and Bayer HealthCare US Funding LLC.

- a. MiraLAX LLC, Bayer Samson I LLC, and Bayer Samson II LLC are Delaware limited liability companies whose sole member is Bayer HealthCare US Funding LLC.
- b. Bayer HealthCare US Funding LLC is a Delaware limited liability company, whose sole member is Bayer US Holding LP.
- c. Bayer Consumer Care Holdings LLC is a Delaware limited liability company whose members are Bayer HealthCare US Funding LLC and

Bayer East Cost LLC, a Delaware limited liability company wholly-owned by Bayer US Holding LP.

- d. Bayer US Holding LP is a Delaware limited partnership whose partners are Bayer World Investments B.V. and Bayer Solution B.V., each of which is a private company with limited liability incorporated under Netherlands law that has its principal place of business in the Netherlands.
- e. Bayer West Coast Corporation is a Delaware corporation with its principal place of business in New Jersey.
- f. Bayer Essure Inc. is a Delaware corporation with its principal place of business in New Jersey.
- g. NippoNex Inc. is a Delaware corporation with its principal place of business in New Jersey.
- h. Bayer Medical Care Inc. is a Delaware corporation with its principal place of business in Pennsylvania.

23. Accordingly, Bayer Healthcare LLC is deemed to be a citizen of Delaware, New Jersey, Pennsylvania, and the Netherlands for purposes of federal diversity jurisdiction.

24. Defendant Beiersdorf Manufacturing, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business located at 4207 Michigan Avenue Road NE, Cleveland, Tennessee 37323.

25. Defendant Beiersdorf Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 301 Tresser Blvd., Suite 1500, Stamford, Connecticut 06901. On information and belief, Beiersdorf Inc. is a managing

member of Defendant Beiersdorf Manufacturing, LLC, and at all material times controlled in whole or in part Beiersdorf Manufacturing, LLC's conduct.

26. Defendant Beiersdorf NA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 301 Tresser Blvd., Suite 1500, Stamford, Connecticut 06901. On information and belief, Beiersdorf NA is a managing member of Defendant Beiersdorf Manufacturing, LLC, and at all material times controlled in whole or in part Beiersdorf Manufacturing, LLC's conduct.

JURISDICTION AND VENUE

27. This Court has specific personal jurisdiction over Aeropres because Aeropres purposefully availed itself of the privilege of conducting business in Illinois and has specific personal jurisdiction over Bayer and the Beiersdorf Defendants, which utilize Aeropres' goods and services in the production and sale of the Products. In addition, Plaintiffs' injuries arise from Aeropres' activities in operating its plant in Morris, Illinois and Manhattan, Illinois, and the exercise of jurisdiction over Aeropres, Bayer, and the Beiersdorf Defendants comports with traditional notions of fair play and substantial justice.

28. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005 ("CAFA"), because at least one member of the Class, as defined below, is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds \$5,000,000 exclusive of interest and costs.

29. Defendant Bayer is an "unincorporated association" under CAFA, and Defendant Bayer is therefore "a citizen of the State where it has its principal place of business [New Jersey] and the State under whose laws it is organized [Delaware]." *See* 28 U.S.C. § 1332(d)(10).

Defendant Beiersdorf LLC is an “unincorporated association” under CAFA, and Defendant Bayer is therefore “a citizen of the State where it has its principal place of business [Tennessee] and the State under whose laws it is organized [Delaware].” *See* 28 U.S.C. § 1332(d)(10).

30. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2), because a substantial part of the events giving rise to the claims occurred in this district.

FACTUAL BACKGROUND

I. AEROPRES SUPPLIES THE PROPELLANT FOR THE PRODUCTS

31. Defendant Aeropres Corporation “is a manufacturer and distributor of high-purity gases to a wide variety of markets” and “is the largest manufacturer and marketer of ecologically safe propellants, which are used in a variety of spray cans from hair spray and mousses to shaving cream and spray paint.”²

32. Pursuant to a July 2017 Quality Assurance Agreement (the “QAA”) entered into by Aeropres and Bayer, Aeropres agreed to, and did, supply to Bayer the propellant (Propellant A-31) used in Defendant Bayer’s Products.

33. Propellant A-31 supplied by Aeropres is a liquefied gas that is combined with other ingredients to create Bayer’s Lotrimin and Tinactin Products.

34. According to Bayer, Aeropres’ Good Manufacturing Practices Policy (GMP) Statement, which was appended to the QAA, provided that Aeropres “adheres to Quality System industry best practices,” and that the components of Aeropres’ propellants, including isobutane, are listed on the “Generally Recognized as Safe” List. In addition, the QAA required Aeropres to “conduct manufacturing and quality control operations of Product according to formulas, instructions and the valid manufacturing procedure set up by [Aeropres] and approved by Bayer,

² <http://www.aeropres.com/about/>

as well as applicable United States Food and Drug Administration ('FDA') requirements and GMP.”

35. Beginning in July 2017 and continuing at least through Bayer's recall, Aeropres supplied Propellant A-31 to Bayer (and to the successor manufacturer of the Products, the Beiersdorf Defendants) for use as the propellant in the Products.

36. Aeropres at all times knew that Propellant A-31 was included by Bayer (and Beiersdorf) in Bayer's Products, and specifically in products which would be applied to consumers' bodies.

37. Despite this knowledge, for years Aeropres failed to ensure that Propellant A-31 did not contain the well-known carcinogen benzene.

II. BEIERSDORF TAKES OVER MANUFACTURE OF LOTRIMIN AND TINACTIN FOR BAYER

38. On May 13, 2019, Bayer AG (the parent company of Bayer Healthcare LLC) and Beiersdorf AG (the parent company of Beiersdorf Manufacturing LLC) entered into an agreement (the “Bayer-Beiersdorf Sale Agreement”) for Bayer AG to sell to Beiersdorf AG, among other assets, a manufacturing facility located in Cleveland, Tennessee. Bayer used the Cleveland, Tennessee facility to manufacture various products, including Lotrimin and Tinactin.

39. In connection with the transaction, Defendant Beiersdorf Manufacturing, LLC (was incorporated in and under the laws of the State of Delaware on June 20, 2019, and on July 1, 2019, Beiersdorf Manufacturing, LLC registered to do business as a foreign LLC with the State of Tennessee. Upon information and belief, these actions were undertaken in order for Beiersdorf Manufacturing, LLC, with Beiersdorf, Inc. as managing member, to operate the former Bayer plant located in Cleveland, Tennessee, which was used to produce, *inter alia*, Bayer's Lotrimin and Tinactin Products.

40. On August 22, 2019, Bayer provided to Aeropres a Notice of Assignment of the QAA, notifying Aeropres of the Bayer-Beiersdorf Sale Agreement, and that as part of that transaction, the QAA (including all amendments, statements of work, exhibits, and schedules) was assigned to Beiersdorf.

41. On August 26, 2019, Aeropres acknowledged and agreed to the assignment of the QAA to Beiersdorf.

42. On August 30, 2019, the transaction between Bayer and Beiersdorf closed. As part of the transaction, Beiersdorf agreed to manufacture, package, and supply to Bayer finished Lotrimin and Tinactin spray products.

43. As described below, Bayer commissioned testing of Lotrimin and Tinactin samples which revealed that Lotrimin and Tinactin samples manufactured beginning in September 2018, the date of manufacture of the oldest unexpired lots, were contaminated with benzene.

III. TINACTIN AND LOTRIMIN AEROSOL PRODUCTS

44. Lotrimin is the brand name for Miconazole Nitrate, which is an antifungal medication. Lotrimin is an over-the-counter (“OTC”) medical product that is used to treat vaginal yeast infections, oral thrush, diaper rash, pityriasis versicolor, and types of ringworm including athlete’s foot and jock itch. Lotrimin comes in both aerosol (spray) and cream form.

45. Tinactin is the brand name for Tolnaftate, another antifungal medication that is OTC and treats a range of conditions. Tolnaftate has been found to be less useful at treating athlete’s foot than Miconazole Nitrate but has been found effective at treating ringworm that is passed from pets to humans. Tinactin comes in both aerosol (spray) and cream form.

46. Defendants manufacture, market, and sell a variety of Lotrimin and Tinactin aerosol products, including:

- a. Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray
- b. Lotrimin Anti-Fungal Jock Itch (AFJI) Powder Spray
- c. Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray
- d. Lotrimin AF Athlete's Foot Liquid Spray
- e. Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray
- f. Tinactin Jock Itch (JI) Powder Spray
- g. Tinactin Athlete's Foot Deodorant Powder Spray
- h. Tinactin Athlete's Foot Powder Spray
- i. Tinactin Athlete's Foot Liquid Spray

47. The "Drug Facts" section of each of the Products lists the active and inactive ingredients in the Products. Nowhere in that section, or on the labels in general, is "benzene" listed as an active or inactive ingredient. The labels further direct consumers to apply the Products multiple times a day over the course of several weeks, as described below.

A. Lotrimin AF Athlete's Foot Powder Spray

48. Lotrimin AF Athlete's Foot Powder Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking, burning, scaling and discomfort."³

49. The following is an image of the Lotrimin AF Athlete's Foot Powder Spray label as presented by Defendants during the Class Period:

³ https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Powder_Spray_DrugFacts.pdf

Drug Facts	
Active ingredient (To Deliver) Miconazole nitrate 2%.....	Purpose Antifungal
Uses <ul style="list-style-type: none"> ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ▪ for effective relief of itching, cracking, burning, scaling and discomfort 	
Warnings For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product <ul style="list-style-type: none"> ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ▪ irritation occurs ▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch) 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks ▪ if condition persists longer, ask a doctor ▪ this product is not effective on the scalp or nails 	
Other information store between 20° to 25°C (68° to 77°F)	
Inactive ingredients fragrance, isobutane, SD alcohol 40-B (8% v/v), stearylalkonium hectorite, talc	
Questions? 1-866-360-3266	

Lotrimin Anti-Fungal Athlete's Foot Powder Spray Label

B. Lotrimin AF Jock Itch Powder Spray

50. Lotrimin AF Jock Itch Powder Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most jock itch (tinea cruris)"; and (2) "for effective relief of itching, burning, scaling and discomfort, and chafing associated with jock itch."⁴ The label directs users to use the product "twice daily ... for 2 weeks."⁵

51. The following is an image of the Lotrimin AF Jock Itch Powder Spray label as presented by Defendants during the Class Period:

⁴ https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_JI_Powder_Spraydrug_facts.pdf

⁵ *Id.*

Drug Facts	
Active ingredient (To Deliver) Miconazole nitrate 2%.....	Purpose Antifungal
Uses <ul style="list-style-type: none"> ▪ proven clinically effective in the treatment of most jock itch (tinea cruris) ▪ for effective relief of itching, burning, scaling and discomfort, and chafing associated with jock itch 	
Warnings For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product <ul style="list-style-type: none"> ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ▪ irritation occurs ▪ there is no improvement within 2 weeks 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ use daily for 2 weeks ▪ if condition persists longer, ask a doctor ▪ this product is not effective on the scalp or nails 	
Other information store between 20° to 25°C (68° to 77°F)	
Inactive ingredients isobutane, SD alcohol 40-B (8% v/v), stearylalmonium hectorite, talc	
Questions? 1-866-360-3266	

Lotrimin Anti-Fungal Jock Itch Powder Spray Label

C. Lotrimin AF Athlete’s Foot Deodorant Powder Spray

52. Lotrimin AF Athlete’s Foot Deodorant Spray’s label lists the following uses:

(1) “proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)”; and (2) “for effective relief of itching, cracking, burning, scaling and discomfort.”⁶ The label directs users to use the product “daily for 4 weeks” for “athlete's foot and ringworm” and to use the product “daily for 2 weeks” for “jock itch.”⁷

⁶ https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Deodorant_Powder_Spray_Drug_Facts.pdf

⁷ *Id.*

53. The following is an image of the Lotrimin AF Athlete's Foot Deodorant Spray label as presented by Defendants during the Class Period:

Drug Facts	
Active ingredient (To Deliver) Miconazole nitrate 2%.....	Purpose Antifungal
Uses	
<ul style="list-style-type: none"> ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ▪ for effective relief of itching, cracking, burning, scaling and discomfort 	
Warnings	
For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product	
<ul style="list-style-type: none"> ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ▪ irritation occurs ▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch) 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks ▪ if condition persists longer, ask a doctor ▪ this product is not effective on the scalp or nails 	
Other information	
store between 20° to 25°C (68° to 77°F)	
Inactive ingredients fragrance, isobutane, SD alcohol 40-B (8% v/v), stearylalkonium hectorite, talc	
Questions? 1-866-360-3266	

Lotrimin Anti-Fungal Athlete's Foot Deodorant Spray Label

D. Lotrimin AF Athlete's Foot Liquid Spray

54. Lotrimin AF Athlete's Foot Liquid Spray's label lists the following uses:

(1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking,

burning, scaling and discomfort.”⁸ The label directs users to use the product “daily for 4 weeks” for “athlete's foot and ringworm” and to use the product “daily for 2 weeks” for “jock itch.”⁹

55. The following is an image of the Lotrimin AF Athlete’s Foot Liquid Spray label as presented by Defendants during the Class Period:

Drug Facts	
Active ingredient (To Deliver) Miconazole nitrate 2%.....	Purpose Antifungal
Uses <ul style="list-style-type: none"> ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ▪ for effective relief of itching, cracking, burning, scaling and discomfort 	
Warnings For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product <ul style="list-style-type: none"> ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. ▪ do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ▪ irritation occurs ▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch) 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks ▪ if condition persists longer, ask a doctor ▪ this product is not effective on the scalp or nails 	
Other information store between 20° to 25°C (68° to 77°F)	
Inactive ingredients dimethyl ether, polyoxyl 15 hydroxystearate, SD alcohol 40-B (16.5% v/v)	
Questions? 1-866-360-3266	

Lotrimin Anti-Fungal Athlete’s Foot Liquid Spray Label

⁸ https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Liquid_Spraydrug_facts.pdf

⁹ *Id.*

E. Lotrimin AF Athlete’s Foot Daily Prevention Deodorant Powder Spray

56. Lotrimin AF Athlete’s Foot Daily Prevention Deodorant Powder Spray’s label listed the following uses: (1) “clinically proven to prevent most athlete’s foot with daily use.”¹⁰

The label directed users to use the product “once or twice daily.”¹¹

57. The following is an image of Lotrimin AF Athlete’s Foot Daily Prevention Deodorant Powder Spray’s label as presented by Defendants during the Class Period:

Drug Facts	
Active ingredient (To Deliver) Tolnaftate 1%	Purpose Antifungal
Use ■ clinically proven to prevent most athlete’s foot with daily use	
Warnings For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor	
When using this product	
■ avoid contact with the eyes	
■ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.	
■ do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.	
Stop use and ask a doctor if irritation occurs.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
■ to prevent athlete’s foot, wash the feet and dry thoroughly.	
■ shake can well and spray a thin layer of the product on the feet once or twice daily (morning and/or night).	
■ supervise children in the use of this product.	
■ pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.	
Other information	
■ store between 20° to 25°C (68° to 77°F)	
Inactive ingredients butylated hydroxytoluene, fragrance, isobutane, PPG-12-buteth-16, SD alcohol 40-B (10.5% v/v), talc	
Questions? 1-866-360-3266	

Lotrimin Anti-Fungal Athlete’s Foot Daily Prevention Deodorant Powder Spray Label

¹⁰ <https://www.lotrimin.com/our-products/daily-prevention-athlete-deodorant-powder-spray>

¹¹ *Id.*

F. Tinactin Jock Itch Powder Spray

58. Tinactin Jock Itch Powder Spray’s “Drug Facts” indicate it should be used in the following ways: (1) “cures most jock itch”; and (2) “for effective relief of itching, chafing and burning.”¹² The directions included with Tinactin Athlete’s Foot Liquid Spray cans directed users to use the product “twice daily ... for 2 weeks.”¹³

59. The following is an image of the Tinactin Jock Itch Powder Spray label as presented by Defendants during the Class Period:

Drug Facts	
Active ingredient (To Deliver) Tolnaftate 1%.....	Purpose Antifungal
Uses	
<ul style="list-style-type: none"> ▪ cures most jock itch ▪ for effective relief of itching, chafing and burning 	
Warnings	
For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product	
<ul style="list-style-type: none"> ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ▪ irritation occurs ▪ there is no improvement within 2 weeks 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ use daily for 2 weeks; if condition persists longer, ask a doctor ▪ this product is not effective on the scalp or nails 	
Other information store between 20° to 25°C (68° to 77°F)	
Inactive ingredients butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (11% v/v), talc	
Questions? 1-866-360-3266	

Tinactin Jock Itch Powder Spray Label

¹² https://www.livewell.bayer.com/deco/omr/Tinactin_JI_Powder_Spray_drugfacts.pdf

¹³ *Id.*

G. Tinactin Athletes Foot Deodorant Spray Label

60. Tinactin Athletes Foot Deodorant Spray’s “Drug Facts” indicate it should be used in the following ways: (1) “in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)”; (2) to “help[] prevent most athlete's foot with daily use”; and (3) “for effective relief of itching, burning, and cracking.”¹⁴ The directions included with Tinactin Athlete’s Foot Liquid Spray cans directed users to use the product “twice daily ... for 4 weeks.”¹⁵

61. The following is an image of the Tinactin Athletes Foot Deodorant Spray label as presented by Defendants during the Class Period:

Drug Facts	
Active ingredient (To Deliver) Tolnaftate 1%.....	Purpose Antifungal
Uses	
<ul style="list-style-type: none"> • proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) • helps prevent most athlete's foot with daily use • for effective relief of itching, burning, and cracking 	
Warnings	
For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product	
<ul style="list-style-type: none"> • avoid contact with the eyes • use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. • contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120°F. 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • irritation occurs • there is no improvement within 4 weeks 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • wash the affected area and dry thoroughly • shake can well and spray a thin layer over affected area twice daily (morning and night) • supervise children in the use of this product • for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily • use daily for 4 weeks; if condition persists longer, ask a doctor • to prevent athlete's foot, apply once or twice daily (morning and/or night) • this product is not effective on the scalp or nails 	
Other information	
<ul style="list-style-type: none"> • store between 20° to 25°C (68° to 77° F) 	
Inactive Ingredients	
butylated hydroxytoluene, fragrance, isobutane, PPG-12-buteth-16, SD alcohol 40-B (10.5% v/v), talc	
Questions? 1-866-360-3266	

Tinactin Athlete’s Foot Deodorant Powder Spray Label

¹⁴ https://www.livewell.bayer.com/deco/omr/Tinactin_Deodorant_Powder_Spray_drugfacts.pdf

¹⁵ *Id.*

H. Tinactin Athlete’s Foot Powder Spray

62. Tinactin Athlete’s Foot Power Spray’s “Drug Facts” indicate it should be used in the following ways: (1) “in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)”; (2) to “help[] prevent most athlete's foot with daily use”; and (3) “for effective relief of itching, burning, and cracking.”¹⁶ The directions included with Tinactin Athlete’s Foot Liquid Spray cans directed users to use the product “twice daily ... for 4 weeks.”¹⁷

63. The following is an image of the Tinactin Athlete’s Foot Power Spray label as presented by Defendants during the Class Period:

Drug Facts	
Active ingredient (To Deliver) Tolnaftate 1%.....	Purpose Antifungal
Uses <ul style="list-style-type: none"> ▪ proven clinically effective in the treatment of most athlete’s foot (tinea pedis) and ringworm (tinea corporis) ▪ helps prevent most athlete's foot with daily use ▪ for effective relief of itching, burning and cracking 	
Warnings For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product <ul style="list-style-type: none"> ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ▪ irritation occurs ▪ there is no improvement within 4 weeks 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete’s foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ use daily for 4 weeks; if condition persists longer, ask a doctor ▪ to prevent athlete's foot, apply once or twice daily (morning and/or night) ▪ this product is not effective on the scalp or nails 	
Other information store between 20° to 25°C (68° to 77°F)	
Inactive ingredients butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (11% v/v), talc	
Questions? 1-866-360-3266	

Tinactin Athlete’s Foot Powder Spray

¹⁶ https://www.livewell.bayer.com/deco/omr/Tinactin_AF_Powder_Spray_drugfacts.pdf

¹⁷ *Id.*

I. Tinactin Athlete’s Foot Liquid Spray

64. Tinactin Athlete’s Foot Liquid Spray’s “Drug Facts” indicate it should be used in the following ways: (1) “in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)”; (2) to “help[] prevent most athlete's foot with daily use”; and (3) “for effective relief of itching, burning, and cracking.”¹⁸ The directions included with Tinactin Athlete’s Foot Liquid Spray cans directed users to use the product “twice daily ... for 4 weeks.”¹⁹

65. The following is an image of the Tinactin Athlete’s Foot Liquid Spray label as presented by Defendants during the Class Period:

Drug Facts	
Active ingredient (To Deliver)Tolnaftate 1%.....	Purpose Antifungal
Uses <ul style="list-style-type: none"> ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ▪ helps prevent most athlete's foot with daily use ▪ for effective relief of itching, burning, and cracking 	
Warnings For external use only	
Flammable: Do not use near heat, flame, or while smoking	
Do not use on children under 2 years of age unless directed by a doctor.	
When using this product <ul style="list-style-type: none"> ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ▪ irritation occurs ▪ there is no improvement within 4 weeks 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> ▪ wash affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ use daily for 4 weeks; if condition persists longer, ask a doctor ▪ to prevent athlete's foot, apply once or twice daily (morning and/or night) ▪ this product is not effective on the scalp or nails 	
Other information store between 20° to 25°C (68° to 77°F)	
Inactive ingredients butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (29% v/v)	
Questions? 1-866-360-3266	

Tinactin Athlete’s Foot Liquid Spray Label

¹⁸ https://www.livewell.bayer.com/deco/omr/Tinactin_Liquid_Spray_drugfacts.pdf

¹⁹ *Id.*

IV. BENZENE

66. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals. The Department of Health and Human Services has determined that benzene causes cancer in humans. Likewise, the FDA lists benzene as a “Class 1 solvent” that “should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity.” Benzene is associated with blood cancers such as leukemia.²⁰ A study from 1939 on benzene stated that “exposure over a long period of time to any concentration of benzene greater than zero is not safe,”²¹ which is a comment reiterated in a 2010 review of benzene research specifically stating: “There is probably no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion.”²²

67. The Agency for Toxic Substances and Disease Registry (“ATSDR”) warns that “[e]ating foods or drinking liquids containing high levels of benzene can cause vomiting, irritation of the stomach, dizziness, sleepiness, convulsions, rapid heart rate, coma, and death” and that “[i]f you spill benzene on your skin, it may cause redness and sores [and] Benzene in your eyes may cause general irritation and damage to your cornea.”²³

68. According to the American Cancer Society:

²⁰ National Cancer Institute, Cancer-Causing Substances, Benzene, <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene>.

²¹ Hunter, F.T. (1939). Chronic Exposure to Benzene (Benzol). II. The Clinical Effects. *Journal of Industrial Hygiene and Toxicology*. 1939 Vol.21 pp.331-54, <https://www.cabdirect.org/cabdirect/abstract/19402700388>.

²² Smith, Martyn T. (2010). Advances in Understanding Benzene Health Effects and Susceptibility. *Annual Review of Public Health*. 2010 Vol. 31:133-148, <https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646>.

²³ BENZENE, https://www.atsdr.cdc.gov/sites/toxzine/benzene_toxzine.html.

IARC classifies benzene as “carcinogenic to humans,” based on sufficient evidence that benzene causes acute myeloid leukemia (AML). IARC also notes that benzene exposure has been linked with acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma.²⁴

69. Moreover, “[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation.”²⁵

70. According to the National Institute for Occupational Safety and Health, humans can become exposed to benzene through “inhalation, skin absorption, ingestion, skin and/or eye contact.”²⁶ Skin absorption is particularly concerning as there have been multiple FDA studies showing that structurally similar chemicals in sunscreen products are found in the blood at high levels after application to exposed skin.

71. The National Institute for Occupational Safety and Health also recommends protective equipment be worn by workers expecting to be exposed to benzene at concentrations of even 0.1 ppm.

SUBSTANTIVE ALLEGATIONS

I. BAYER’S TINACTIN AND LOTRIMIN AF SPRAYS CONTAIN UNACCEPTABLE LEVELS OF BENZENE

72. On August 11, 2021, Aeropres notified Beiersdorf that Propellant A-31 supplied from its Morris, IL production facility may be contaminated with benzene. Recognizing it was at

²⁴ American Cancer Society. Benzene and Cancer Risk (January 5, 2016), <https://www.cancer.org/cancer/cancer-causes/benzene.html>.

²⁵ Centers for Disease Control and Prevention, Facts About Benzene, <https://emergency.cdc.gov/agent/benzene/basics/facts.asp>.

²⁶ National Institute for Occupational Safety and Health (NIOSH), Benzene, <https://www.cdc.gov/niosh/npg/npgd0049.html>.

fault, Aeropres stated that it “regrets this development as it is not in keeping with Aeropres’ standards of product manufacture.”²⁷

73. Aeropres warned that “the nature of the hydrocarbon origin of the raw materials precludes our ability to assure that there are no residual solvents in the finished product.”

Aeropres also informed Beiersdorf that “benzene can only be introduced into Aeropres’ products by way of contamination of its natural gas liquid feedstock.”²⁸

74. On August 13, 2021, Beiersdorf notified Bayer of the benzene contamination.²⁹

75. In September 2021, Beiersdorf received results of testing that confirmed benzene levels in samples of certain finished, unexpired Lotrimin and Tinactin products were above the FDA’s acceptable limit of 2 parts per million.³⁰

76. Bayer kept selling benzene-contaminated products however, and it was not until October 2021 that Bayer announced a recall of “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.” Bayer also instructed users to “stop using” the Products.³¹ Even then, however, Bayer (falsely) maintained that “the levels detected are not expected to cause adverse health consequences in consumers.”³²

²⁷ *Bayer Healthcare LLC v. Aeropres Corp.*, No. 1:23-cv-04391, Dkt. No. 1 (N.D. Ill. 2023) (“Bayer Complaint”), at ¶ 5.

²⁸ *Id.* at ¶ 36.

²⁹ *Id.* at ¶ 39.

³⁰ *Id.* at ¶ 40.

³¹ FDA, Bayer Issues Voluntary Recall of Specific Lotrimin® and Tinactin® Spray Products Due to the Presence of Benzene, Oct. 1, 2021, <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene>.

³² *Id.*

77. As a result of Defendants' failure to keep benzene out of the Products, millions of consumers have been repeatedly and consistently exposed to dangerous levels of a known carcinogen by using the Products as intended and directed by Bayer. Each of the Products direct users to apply the spray multiple times per day for prolonged periods of time, often weeks.

78. In the recall notice, Bayer admitted that “[b]enzene is *not* an ingredient in any of Bayer Consumer Health products.”³³ Thus, the presence of benzene in Bayer's Products appears to be the result of contamination or a deficiency the manufacturing process designed, implemented, and used by Defendants to manufacture the Products.

79. Accordingly, because the presence of benzene is the result of contamination, benzene is not unavoidable in the manufacture of the Products, and any significant detection of benzene in such products is unacceptable.

80. In October 2021, pharmaceutical testing laboratory Valisure, LLC (“Valisure”) tested a sampling of Lotrimin and Tinactin Products that were part of the lots recalled by Bayer. The Valisure results (as set forth herein) confirm that the Products are contaminated with unsafe levels of the carcinogen benzene.

81. Valisure tested 13 Bayer Products from separate lots, 6 of which were Lotrimin Products and 7 were Tinactin Products. Valisure's testing found detectable levels of benzene in 12 of the 13 Products tested (92%), with benzene levels that significantly exceeded the guidelines established by the FDA of 2 parts ppm for “drug product[s] with a significant therapeutic advance” in 11 of the 13 Products Valisure tested (85%).³⁴

³³ *Id.* (emphasis added).

³⁴ One product tested at a level of 1.60 ppm, between the Limit of Quantification Valisure set at 0.10 ppm to indicate measurable/detectable levels of benzene, and the FDA's 2ppm limit.

82. Notably, these results contradict Bayer’s statement that “the levels detected [in the Products] are not expected to cause adverse health consequences in consumers.”³⁵

83. The tested Products yielded startling results, including levels of benzene that were 7, 8, 10, 24, 26, 51, 78 and, in one product sample, over 105 times the 2 ppm strict limit set by the FDA for drug products (including eight samples that tested over 10 times the FDA’s limit, and ten samples that tested above twice the 2 ppm FDA limit).

84. The Valisure results concerning the Bayer Products with detectable levels of benzene are set forth in the table below:

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN005K8	041100590367	Lotrimin Athlete's Foot Daily Prevention Deodorant Powder Spray - 4.6 oz	06/2022	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 5, 2021	<u>16.62</u>
TN006MX	311017410059	Tinactin Antifungal Liquid Spray - 5.3 oz	10/2022	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12- Buteth-16, SD Alcohol 40-B (29% v/v)	October 5, 2021	<u>3.64</u>
TN0047R	311017410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	05/2023	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12- Buteth-16, SD Alcohol 40-B (11% v/v), talc	October 5, 2021	<u>1.60</u>

³⁵ <https://www.tinactin.com/spray-recall>.

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN006TD	311017410257	Lotrimin AF Antifungal Powder Aerosol Spray, Super Size - 4.6 oz	03/2023	2% Miconazole Nitrate	Isobutane, SD Alcohol 40- B (8% v/v), Stearalkonium Hectorite, Talc	October 4, 2021	<u>49.61</u>
TN004BX	041100587206	Lotrimin Athlete's Foot Daily Prevention Deodorant Powder Spray - 5.6 oz	06/2022	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 4, 2021	<u>20.53</u>
TN008CY	311017410318	Lotrimin AF Antifungal Jock Itch Aerosol Powder Spray, Super Size - 4.6 oz	04/2023	2% Miconazole Nitrate	Isobutane, SD Alcohol 40- B (8% v/v), Stearalkonium Hectorite, Talc	October 4, 2021	<u>156.40</u>
TN008CZ	311017410318	Lotrimin AF Antifungal Jock Itch Aerosol Powder Spray, Super Size - 4.6 oz	04/2023	2% Miconazole Nitrate	Isobutane, SD Alcohol 40- B (8% v/v), Stearalkonium Hectorite, Talc	October 4, 2021	<u>211.46</u>
TN007TJ	311017410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	03/2023	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12- Buteth-16, SD Alcohol 40- B (11% v/v), talc	October 4, 2021	<u>155.53</u>

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN008CT	311017410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	03/2023	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12- Buteth-16, SD Alcohol 40-B (11% v/v), talc	October 4, 2021	<u>103.35</u>
TN006AT	311017410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	12/2022	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12- Buteth-16, SD Alcohol 40-B (11% v/v), talc	October 4, 2021	<u>14.98</u>
TN0067A	311017410004	Tinactin Deodorant Powder Spray - 4.6 oz	02/2023	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 4, 2021	<u>21.56</u>
TN008CU	311017410004	Tinactin Deodorant Powder Spray - 4.6 oz	04/2023	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 4, 2021	<u>53.44</u>

85. Valisure's testing results contrast markedly with Bayer's public statements – and call into question whether Bayer withheld or misrepresented information on testing it conducted or that Bayer's testing was flawed.

86. The notable consistency with which unacceptable levels of benzene were detected by Valisure in the Products they tested indicates that the Products Plaintiffs and members of the Classes purchased contained impermissible levels of benzene.

II. BENZENE CONTAMINATION RENDERS THE PRODUCTS WORTHLESS

87. Because the Products contained or risked containing benzene, they were not just worthless to Plaintiffs. They were dangerous to use and could not actually be sold under FDA guidelines.

88. As OTC drug products regulated by the FDA, the Products must be both safe and effective and are subject to federal current Good Manufacturing Practices (“cGMP”) regulations and the FDCA’s state-law analogues. These cGMP regulations require OTC medications like the Products to meet safety, quality, purity, identity, and strength standards. See 21 U.S.C. § 351(a)(1)(B). Federal and state regulatory regimes require that labeling for OTC products identify each active and inactive ingredient.³⁶

89. 21 C.F.R. § 201.66 establishes labeling requirements for OTC products and defines an inactive ingredient as “any component other than an active ingredient.” An “active ingredient” is “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. *The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form* intended to furnish the specified activity or effect.” (Emphasis added).

³⁶ <https://www.fda.gov/media/72250/download>.

90. 21 C.F.R. § 210.1(a) states that the cGMPs establish “minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.” In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

91. The FDA’s cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

92. Any drug product not manufactured in accordance with cGMPs is deemed “adulterated” or “misbranded” and may not be distributed or sold in the United States. See 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

93. FDA regulations require a drug product manufacturer to have “written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.” 21 C.F.R. § 211.100.

94. A drug product manufacturer’s “[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans,

and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.” 21 C.F.R. § 211.160.

95. “Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays” and a “statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.” 21 C.F.R. § 211.194.

96. Defendants disregarded the cGMPs outlined above. If Defendants had not routinely disregarded the FDA’s cGMPs, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of the benzene contaminant almost immediately.

97. Further, had Defendants adequately tested the Products for benzene and other carcinogens, reproductive toxins, and impurities, they would have discovered that the Products contained benzene at levels far above the legal limit, making those products ineligible for distribution, marketing, and sale.

98. Accordingly, Defendants knowingly, or at least negligently, introduced contaminated, adulterated, and/or misbranded antifungal medications containing dangerous amounts of benzene into the U.S. market.

99. Defendants also knew or should have known about the carcinogenic potential of benzene because it is classified as a Group 1 compound by the World Health Organization and the International Agency for Research on Cancer, thereby defining it as “carcinogenic to humans.”

100. Pursuant to 21 U.S.C. § 331(a) of the Food, Drug, and Cosmetics Act, the “introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded” is categorically prohibited.

101. Defendants’ failure to control for benzene contamination and sale of its adulterated products constitutes actionable fraud.

102. Plaintiffs and the Class were injured by the full purchase price of the Products because the Products are worthless, as they are adulterated and contain harmful levels of benzene, and Defendants have failed to warn consumers of this fact. Such illegally sold products are worthless and have no value, as multiple courts in this District and others have found:

- a. *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019)
- b. *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021) (“This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for.”).
- c. *Barnes v. Bayer United States Inc.*, 2023 WL 2456385, at *4-5 (N.D. Ill. Mar. 11, 2023) (“Barnes has sufficiently alleged actual damages by alleging that she paid a higher price because the products were something less than she expected. ... This is particularly so in view of the fact that benzene is contended to be a carcinogen and a substance that lingers in the human body, affecting several organs and causing cells not to work correctly.”) (cleaned up).
- d. *Barnes v. Bayer United States, Inc.*, 2022 WL 2915629, at *1 (N.D. Ill. July 24, 2022) (“Barnes alleges that she was deprived of the benefit of her bargain, in that she would not have purchased the products, or would not have purchased them for the listed price, had she known they contained a human carcinogen ... [T]his is a sufficient allegation of an injury in fact.”).

- e. *Clinger v. Edgewell Personal Care Brands, LLC*, 2023 WL 2477499, at *10 (D. Conn. March 13, 2023) (“The plaintiffs have plausibly alleged that the defendants sold a product which, because of its actual or risk of benzene contamination, was worth less than its purchase price. When the plaintiffs overpaid for the product, the defendants therefore unjustly received an unearned benefit, leaving the plaintiffs out the difference. ... The defendants next argue that the plaintiffs got the benefit of their bargain: they purchased sunscreen to protect them from the risks of sun exposure, and that is what the product did. This argument misses the point. The plaintiffs’ claim is that the presence of benzene in sunscreen undermines its protective function by exposing them to carcinogenic benzene. In other words, the sunscreen was defective in some way and therefore worth less than the price the plaintiffs paid for it.”).
- f. *Bojko v. Pierre Fabre USA Inc.*, 2023 WL 4204663, at *7 (N.D. Ill. June 27, 2023) (“Plaintiffs allege that the presence of benzene rendered the Products ‘worthless’ and that they would not have bought the Products or would have paid less for the Products had they known the Products contained or risked containing benzene. In so alleging, Plaintiffs adequately plead actual damages.”).
- g. *Henning v. Luxury Brand Partners, LLC*, 2023 WL 3555998, at *3 (N.D. Cal. May 11, 2023) (“Here, Plaintiff alleged that she would not have purchased the Products or would have paid less for the Products had she known that the Products contained or risked containing benzene. Plaintiff also alleged that there is no safe level of benzene, that Valisure tested all the Products for benzene, and that benzene was detected in all the tested batches of Products. Thus, Plaintiff plausibly alleged the risk of benzene and that she would not have purchased the Products had she known about the risk. This is sufficient to plead standing based on economic injury.”) (cleaned up).

103. Plaintiffs and the Class bargained for an antifungal product free of contaminants and dangerous substances and were deprived the basis of their bargain when Defendants sold them products containing the dangerous substance benzene, which rendered the Products unmerchantable and unfit for use.

104. As the Products expose consumers to benzene well above the legal limit, the Products are not fit for use by humans. Plaintiffs are further entitled to damages for the injury

sustained in being exposed to high levels of acutely-toxic benzene, damages related to Bayer's conduct, and injunctive relief.

105. Further, Plaintiffs and other Class Members were forced to discard the remainder of their Products due to the contamination or to buy replacement products to treat their athlete's foot or other conditions. Accordingly, Plaintiffs and Class Members were also injured because they were forced to waste portions of the Products or to spend additional money to purchase replacement medications that they would not have spent but for the Products being contaminated.

106. Plaintiffs and members of the Classes were also injured because their exposure to a substance that is dangerous carcinogen means they will be forced to undergo medical monitoring at considerable expense.

107. Accordingly, Plaintiffs and the Classes seek to recover damages because, *inter alia*, the Products are adulterated, defective, worthless, and unfit for human use due to the presence of benzene, a carcinogenic and toxic chemical impurity and because Plaintiffs and members of the Classes will have to undertake significant monitoring they otherwise would not have to detect the possible development of cancers and other ailments.

III. THE REFUND OFFERED BY BAYER WAS INADEQUATE TO COMPENSATE CONSUMERS

A. Bayer Required Photographs Of Purchased Recalled Products To Issue Refunds To Limit The Expense Of The Recall

108. Bayer limited the expense of the recall by requiring that individuals (1) visit one of the two websites; (2) fill out the forms presented to them; and (3) provide a photograph of each product for which consumers seek a refund for. This procedure improperly burdens consumers that have done nothing wrong and does not allow them to collect refunds for products purchased unless they are able to provide information regarding the purchase and provide a

photograph of each product they purchased, even though some of the products are over three years old.

109. Consumers who could not take photographs of the Recalled Sprays for any reason, including the fact that the product was used and discarded three years ago, were excluded. Consumers were harmed, and deprived of the benefit of the bargain, at the point of purchase. By requiring photos of used sprays, Bayer substantially limited compensation to consumers who purchased contaminated Recalled Sprays. It is noteworthy that, for example, other companies that recalled aerosol spray products due to the presence of benzene did not require photographs of the products.³⁷

B. Plaintiffs And Class Members Require Medical Monitoring

i. Plaintiffs and Class Members Have a Significantly Increased Risk of Contracting Benzene-Caused Cancer Due to Regular Usage of the Products

110. As alleged below, Plaintiffs regularly used the Products as directed on the Products' labels to treat medical conditions the Products are intended to treat such as athlete's foot, jock itch, and other conditions.

111. Based on prevailing scientific evidence, and the classifications adopted by numerous agencies, regulatory bodies, and scientific organizations discussed *supra*, exposure to benzene via skin absorption can cause cancer, including leukemia and other blood-related cancers.

112. Plaintiffs used the Products manufactured and distributed by Bayer as directed by the Products' labels. As the labels included above show, this often meant that Plaintiffs applied

³⁷ [https://www.ccc-consumercarecenter.com/UCUConfiguration?id=a071i00000zs7tqAAA#etd:::00c?Z9W00Y00MVvu?,TV9Z00ww\\$](https://www.ccc-consumercarecenter.com/UCUConfiguration?id=a071i00000zs7tqAAA#etd:::00c?Z9W00Y00MVvu?,TV9Z00ww$); *see also* Coppertone Sunscreen Recall Claim Form: <https://secure.sunscreenrecall2021.com/>.

the Products multiple times a day for a period of time that could last as long as four weeks. These products, unbeknownst to Plaintiffs, contained benzene, a known carcinogen.

113. Thus, as a direct and proximate result of using Bayer's Products for years, Plaintiffs are at a significantly increased risk of contracting Benzene-caused Cancers. Plaintiffs' lengthy duration of exposure to benzene from Bayer's Products warrants additional medical testing not routinely provided to the public at large.

ii. Plaintiffs and Class Members Require Diagnostic Medical Testing That Differs From Routine Medical Care

114. Physicians evaluate a person's exposure to toxic and carcinogenic substances, including benzene, when determining what diagnostic testing and treatment is necessary.

115. A reasonably prudent person would conclude that Plaintiffs' repeated exposure to significant, unsafe levels of benzene over lengthy periods of time necessitates specialized testing (with resultant treatments) that is not generally given to the public at large as a part of routine medical care.

116. The available monitoring regime, discussed in greater detail below, is reasonably necessary and specific for individuals exposed to products known to significantly increase the risk of the Benzene-Caused Cancers because of exposure to benzene. It is different from that normally recommended in the absence of exposure to this risk of harm (in kind and/or frequency) and is not generally available in a general practitioner setting.

117. The available medical monitoring regime will mitigate the development of and health effects associated with the Benzene-Caused Cancers, improving prognosis, outcome, and quality of life, and reducing medical costs.

118. Consistent with best practices, Plaintiffs seek to implement a medical monitoring program which begins with screening to determine whether more invasive or costly tests are

warranted. This screening may be conducted via questionnaire, in-person before a medical practitioner, or via a tele-health appointment.

119. Medical practitioners will review the questionnaire or the results of a screening appointment to determine whether additional testing, such as a blood test, for purposes of diagnosis is required. Leukemia and other Benzene-Caused Cancers are typically found via blood tests and can be detected before symptoms begin.³⁸

120. Additional testing may include blood tests and/or bone marrow tests.³⁹ Blood tests allow doctors to determine whether an individual has abnormal levels of red or white blood cells or platelets, which may suggest leukemia, or can show the presence of leukemia cells.⁴⁰ Bone marrow tests are used to determine whether leukemia cells which can avoid detection in blood tests are present.⁴¹

121. Screening and testing in the medical monitoring program will likely occur for an extended period of time. This permits the medical practitioners to monitor changes in symptoms or follow anomalies that may appear in tests over time, and accommodates latency periods associated with the Benzene-Caused Cancers.

C. The Recall Thus Fails to Adequately Compensate Plaintiffs On A Number Of Levels

122. Taken together, the recall is thus inadequate for at least the following reasons:
- a. Bayer did not adequately publicize the refund remedy, such that many consumers were not aware that they could request a refund from Bayer.

³⁸ <https://www.mayoclinic.org/diseases-conditions/leukemia/diagnosis-treatment/drc-20374378>.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

- b. Bayer has admitted a mere 35,000 consumers submitted a refund request through the recall, out of the hundreds of thousands if not millions who purchased the Products over a three-year span.
- c. Bayer required consumers to submit a photo of the product, even though the Products are disposable OTC medications that many consumers may no longer have. Thus, the refund remedy excluded innumerable consumers who purchased and used the Products but have no record of the same. This is particularly important given that the contamination extended at least as far back as September 2018, and consumers unlikely had empty bottles of the Products that are three years old.
- d. The recall did not promise any changes to Bayer's manufacturing and distribution process so as to prevent future contamination.
- e. The recall did not fully compensate consumers in states like New York, and other states in which Plaintiffs (and members of the Classes) reside, where consumers are entitled to statutory damages above the purchase price of the Products under the state's consumer protection laws.
- f. It is unknown what criteria Bayer used to determine whether to issue a refund to consumers who purchased the Products.
- g. Bayer's notice accompanying the recall downplayed the danger of its Products, and thus the necessity of the recall, by describing the recall as a "precautionary measure and that the levels detected are not expected to cause adverse health consequences in consumers."⁴²

⁴² <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene>; *see also* <https://www.tinactin.com/spray-recall> and <https://www.lotrimin.com/spray-recall>.

- h. Bayer has not compensated consumers for the cost of medical monitoring based on their use of Products contaminated by a known carcinogen.

IV. PLAINTIFFS' ALLEGATIONS

A. Darrell Stewart

123. Plaintiff Darrell Stewart is a resident of Lewes, Delaware and has an intent to remain there, and is therefore a citizen of Delaware. During the Class Period, Mr. Stewart purchased:

- a. Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray;
- b. Lotrimin Anti-Fungal Jock Itch (AFJI) Powder Spray; Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray;
- c. Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; Tinactin Athlete's Foot Deodorant Powder Spray;
- d. Tinactin Athlete's Foot Powder Spray; and
- e. Tinactin Athlete's Foot Liquid Spray.

124. When purchasing the Products, Mr. Stewart reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Lotrimin and Tinactin were properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate and Tolnaftate. Mr. Stewart relied on these representations and warranties in deciding to purchase the Lotrimin and Tinactin manufactured and sold by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin and Tinactin from Defendants if he had known that it was not, in fact,

properly manufactured, free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate and Tolnaftate.

125. Mr. Stewart was injured in multiple ways as a result of his purchase of Lotrimin and Tinactin. First, Mr. Stewart bargained for Lotrimin and Tinactin that were properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. However, Mr. Stewart received Lotrimin and Tinactin that were not properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Mr. Stewart bargained for. Second, as a result of the benzene contamination, Mr. Stewart Products were adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Stewart still had a portion of his Products remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Stewart did not use and was unable to use the remaining portion of his Lotrimin and Tinactin products, and therefore wasted a portion of his Products as a result of the benzene contamination. And fourth, Mr. Stewart was forced to buy a replacement product, boric acid, to treat his athlete's foot as a result of the benzene contamination in his Lotrimin and Tinactin product. Mr. Stewart would not have purchased this replacement product but for the contamination of his Products, which rendered his Products adulterated, misbranded, unsafe to use, and worthless.

B. Juan Huertas

126. Plaintiff Juan Huertas is a resident of Levittown, New York and has an intent to remain there, and is therefore a citizen of New York. In or about August 2021, Mr. Huertas purchased a canister of Bayer's Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray with the lot number TN009K7 from a CVS in Freeport, New York. Mr. Huertas used the

Product as directed on the label. According to Bayer's recall notice, Mr. Huertas's cannister of Lotrimin contained benzene. However, Mr. Huertas never received notice of the recall from Bayer for his contaminated Lotrimin product. When purchasing the Product, Mr. Huertas reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Lotrimin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. Mr. Huertas relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin from Defendants if he had known that it was, in fact, not properly manufactured, not free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate.

127. Mr. Huertas was injured in multiple ways as a result of his purchase of Lotrimin. First, Mr. Huertas bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. However, Mr. Huertas received Lotrimin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate, and was therefore worth less than what Mr. Huertas bargained for. Second, as a result of the benzene contamination, Mr. Huertas's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Huertas still had a portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Huertas did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination. And fourth, Mr. Huertas was forced to buy a replacement product, boric acid, to treat his athlete's foot as a

result of the benzene contamination in his Lotrimin product. Mr. Huertas would not have purchased this replacement product but for the contamination of his Lotrimin product, which rendered his Product adulterated, misbranded, unsafe to use, and worthless.

C. Eva Mistretta

128. Plaintiff Eva Mistretta is a resident of East Elmhurst, New York and has an intent to remain there, and is therefore a citizen of New York. In or about July 2021, Ms. Mistretta purchased a canister of Bayer's Tinactin Athlete's Foot Liquid Spray with the lot number CV01E2X from a Walgreens in Queens, New York. Ms. Mistretta used the Product as directed on the label. According to Bayer's recall notice, Ms. Mistretta's canister of Tinactin contained benzene. However, Ms. Mistretta never received notice of the recall from Bayer for her contaminated Tinactin product. When purchasing the Product, Ms. Mistretta reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Tinactin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Tolnaftate. Ms. Mistretta relied on these representations and warranties in deciding to purchase the Tinactin manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased the Tinactin from Defendants if she had known that it was not, in fact, properly manufactured, free from defects, not safe for its intended use, and not equivalent to Tolnaftate.

129. Ms. Mistretta was injured in multiple ways as a result of her purchase of Tinactin. First, Ms. Mistretta bargained for Tinactin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Tolnaftate. However, Ms. Mistretta received Tinactin that was not properly manufactured, free from defects, safe for

its intended use, and the brand-name equivalent of uncontaminated Tolnaftate, and was therefore worth less than what Ms. Mistretta bargained for. Second, as a result of the benzene contamination, Ms. Mistretta's Tinactin was adulterated, misbranded, illegal to sell, and therefore worthless. Third, Ms. Mistretta still had a portion of her Tinactin product remaining when she learned of the benzene contamination. As a result of this contamination, Ms. Mistretta did not use and was unable to use the remaining portion of her Tinactin product, and therefore wasted a portion of her Tinactin product as a result of the benzene contamination.

D. Jose Villarreal

130. Plaintiff Jose Villarreal is a resident of Boone County, Missouri and has an intent to remain there, and is therefore a citizen of Missouri. Between September 2018 and September 2021, Mr. Villarreal Bayer's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray in Missouri. Mr. Villarreal used the Product as directed on the label. Mr. Villarreal's Lotrimin contained benzene. For each product he purchased, Mr. Villarreal reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Lotrimin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. Mr. Villarreal relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin from Defendants if he had known that it was not, in fact, properly manufactured, free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate.

131. Mr. Villarreal was injured in multiple ways as a result of his purchase of Lotrimin. First, Mr. Villarreal bargained for Lotrimin that was properly manufactured, free from defects,

safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. However, Mr. Villarreal received Lotrimin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate, and was therefore worth less than what Mr. Villarreal bargained for. Second, as a result of the benzene contamination, Mr. Villarreal's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Villarreal still had a portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Villarreal did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination.

E. Mike Poovey

132. Plaintiff Mike Poovey is a resident of Horry County, South Carolina and has an intent to remain there, and is therefore a citizen of South Carolina. Between September 2018 and September 2021, Mr. Poovey purchased Bayer's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray in South Carolina. Mr. Poovey used the Product as directed on the label. According to Bayer's recall notice, Mr. Poovey's cannister of Lotrimin contained benzene. For each product he purchased, Mr. Poovey reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the Lotrimin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. Mr. Poovey relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendant, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin from Defendants if he had known that it was not, in

fact, properly manufactured, free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate.

133. Mr. Poovey was injured in multiple ways as a result of his purchase of Lotrimin. First, Mr. Poovey bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. However, Mr. Poovey received Lotrimin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate, and was therefore worth less than what Mr. Poovey bargained for. Second, as a result of the benzene contamination, Mr. Poovey's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Poovey still had a portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Poovey did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination.

F. Christopher Cadorette

134. Plaintiff Christopher Cadorette is a resident of Essex County, Massachusetts and has an intent to remain there, and is therefore a citizen of Massachusetts. Between September 2018 and September 2021, Mr. Cadorette purchased canisters of Bayer's Lotrimin products in Massachusetts, including

- a. Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray; and
- b. Lotrimin Anti-Fungal Jock Itch (AFJI) Powder Spray.

135. Mr. Cadorette used the Products as directed on the labels. Mr. Cadorette's canisters of Lotrimin contained benzene. When purchasing the Products, Mr. Cadorette reviewed the accompanying labels and disclosures, and understood them as representations and

warranties by the manufacturers, distributors, and pharmacy that the Lotrimin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. Mr. Cadorette relied on these representations and warranties in deciding to purchase the Lotrimin products manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin products from Defendants if he had known that they were not, in fact, properly manufactured, free from defects, not safe for their intended use, and not equivalent to Miconazole Nitrate.

136. Mr. Cadorette was injured in multiple ways as a result of his purchase of Lotrimin. First, Mr. Cadorette bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. However, Mr. Cadorette received Lotrimin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate, and was therefore worth less than what Mr. Cadorette bargained for. Second, as a result of the benzene contamination, Mr. Cadorette's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Cadorette still had a portion of his Lotrimin products remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Cadorette did not use and was unable to use the remaining portion of his Lotrimin products, and therefore wasted a portion of his Lotrimin products as a result of the benzene contamination.

G. Sean Steinwedel

137. Plaintiff Sean Steinwedel is a resident of Sussex County, Delaware and has an intent to remain there, and is therefore a citizen of Delaware. Between September 2018 and

September 2021, Mr. Steinwedel purchased canisters of Bayer's Products in Delaware, including:

- a. Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray;
- b. Lotrimin Anti-Fungal Jock Itch (AFJI) Powder Spray;
- c. Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray;
- d. Tinactin Jock Itch (JI) Powder Spray; and
- e. Tinactin Athlete's Foot Deodorant Powder Spray.

138. Mr. Steinwedel used the Products as directed on the labels. Mr. Steinwedel's canisters of the Products contained benzene. When purchasing the Products, Mr. Steinwedel reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Products were properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. Mr. Steinwedel relied on these representations and warranties in deciding to purchase the Products manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Products from Defendants if he had known that they were not, in fact, properly manufactured, free from defects, safe for their intended uses, and not equivalent to Miconazole Nitrate and Tolnaftate.

139. Mr. Steinwedel was injured in multiple ways as a result of his purchase of the Products. First, Mr. Steinwedel bargained for Lotrimin and Tinactin that were properly manufactured, free from defects, safe for their intended use, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. However, Mr. Steinwedel received Lotrimin and Tinactin that were not properly manufactured, free from defects, safe for their intended uses,

and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Mr. Steinwedel bargained for. Second, as a result of the benzene contamination, Mr. Steinwedel's Products were adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Steinwedel still had a portion of his Products product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Steinwedel did not use and was unable to use the remaining portion of his Products, and therefore wasted a portion of his Products as a result of the benzene contamination.

H. Don Penales, Jr.

140. Plaintiff Don Penales, Jr. is a resident of California and has an intent to remain there, and is therefore a citizen of California. Between September 2018 and September 2021, Mr. Penales purchased canisters of Bayer's Products in California, including:

- a. Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray;
- b. Lotrimin AF Athlete's Foot Liquid Spray;
- c. Tinactin Athlete's Foot Powder Spray and
- d. Tinactin Athlete's Foot Liquid Spray.

141. Mr. Penales used the Products as directed on the labels. Mr. Penales's canisters of the Products contained benzene. When purchasing the Products, Mr. Penales reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Products were properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. Mr. Penales relied on these representations and warranties in deciding to purchase the Products manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Products

from Defendants if he had known that they were not, in fact, properly manufactured, free from defects, safe for their intended uses, and not equivalent to Miconazole Nitrate and Tolnaftate.

142. Mr. Penales was injured in multiple ways as a result of his purchase of the Products. First, Mr. Penales bargained for Lotrimin and Tinactin that were properly manufactured, free from defects, safe for their intended use, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. However, Mr. Penales received Lotrimin and Tinactin that were not properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Mr. Penales bargained for. Second, as a result of the benzene contamination, Mr. Penales's Products were adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Penales still had a portion of his Products product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Penales did not use and was unable to use the remaining portion of his Products, and therefore wasted a portion of his Products as a result of the benzene contamination.

I. Jonathan Martin

143. Plaintiff Jonathan Martin is a resident of Contra Costa County, California and has an intent to remain there, and is therefore a citizen of California. Between September 2018 and September 2021, Mr. Martin purchased Bayer's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray in California.

144. Mr. Martin used the Product as directed on the label. Mr. Martin's Lotrimin contained benzene. For each Product he purchased, Mr. Martin reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Lotrimin was properly manufactured, free

from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. Mr. Martin relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin from Defendants if he had known that it was not, in fact, properly manufactured, free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate.

145. Mr. Martin was injured in multiple ways as a result of his purchase of Lotrimin. First, Mr. Martin bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. However, Mr. Martin received Lotrimin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate, and was therefore worth less than what Mr. Martin bargained for. Second, as a result of the benzene contamination, Mr. Martin's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. Third, Mr. Martin still had a portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Martin did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination.

CLASS ACTION ALLEGATIONS

146. Plaintiffs Huertas, Villarreal, Wyant, Poovey, Cadorette, Steinwedel, Penales, Martin, and Stewart seek to represent a class defined as:

All persons in the United States who purchased the following Lotrimin spray products between September 2018 and September 2021 (the "Lotrimin Class"): (1) Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray; (2) Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray; (3) Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder

Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray.

147. Plaintiffs Mistretta, Wyant, Steinwedel, Penales and Stewart seek to represent a class defined as:

All persons in the United States who purchased the following Tinactin spray products between September 2018 and September 2021 (the "Tinactin Class") (collectively with the Lotrimin Class, the "Nationwide Classes"): (1) Tinactin® Jock Itch (JI) Powder Spray; (2) Tinactin® Athlete's Foot Deodorant Powder Spray; (3) Tinactin® Athlete's Foot Powder Spray; and (4) Tinactin® Athlete's Foot Liquid Spray.

148. Plaintiff Huertas also seeks to represent the following subclass:

All Lotrimin Class members who purchased the Lotrimin products in New York (the "Lotrimin New York Subclass").

149. Plaintiff Villarreal also seeks to represent the following subclass:

All Lotrimin Class members who purchased the Lotrimin products in Missouri (the "Lotrimin Missouri Subclass").

150. Plaintiff Wyant also seeks to represent the following subclass:

All Lotrimin Class members who purchased the Lotrimin products in Indiana (the "Lotrimin Indiana Subclass").

151. Plaintiff Poovey also seeks to represent the following subclass:

All Lotrimin Class members who purchased the Lotrimin products in South Carolina (the "Lotrimin South Carolina Subclass").

152. Plaintiff Cadorette also seeks to represent the following subclass:

All Lotrimin Class members who purchased the Lotrimin products in Massachusetts (the "Lotrimin Massachusetts Subclass").

153. Plaintiffs Steinwedel and Stewart also seek to represent the following subclass:

All Lotrimin Class members who purchased the Lotrimin products in Delaware (the "Lotrimin Delaware Subclass").

154. Plaintiffs Penales and Martin also seek to represent the following subclass:

All Lotrimin Class members who purchased the Lotrimin products in California (the “Lotrimin California Subclass”).

155. Plaintiff Mistretta also seeks to represent the following subclass:

All Tinactin Class members who purchased the Tinactin products in New York (the “Tinactin New York Subclass”).

156. Plaintiff Wyant also seeks to represent the following subclass:

All Lotrimin Class members who purchased the Tinactin products in Indiana (the “Tinactin Indiana Subclass”).

157. Plaintiffs Steinwedel and Stewart also seek to represent the following subclass:

All Tinactin Class members who purchased the Tinactin products in Delaware (the “Tinactin Delaware Subclass”).

158. Plaintiff Penales also seeks to represent the following subclass:

All Tinactin Class members who purchased the Tinactin products in California (the “Tinactin California Subclass”).

159. The various state subclasses shall be collectively referred to as the “Subclasses.”

160. The Nationwide Classes and the Subclasses shall collectively be referred to as the “Classes.”

161. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Classes may be expanded or narrowed by amendment to the complaint or narrowed at class certification.

162. Specifically excluded from the Classes are Defendants, Defendants’ officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and Defendants’ heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants officers and/or directors, the judge assigned to this action, and any member of the judge’s immediate family.

163. **Numerosity.** The members of the proposed Classes are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are hundreds of thousands of individuals that are members of the proposed Classes. Although the precise number of proposed members are unknown to Plaintiffs, the true number of members of the Classes are known by Defendants. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendants and third-party retailers and vendors.

164. **Typicality.** The claims of the representative Plaintiffs are typical of the claims of the Classes in that the representative Plaintiffs, like all members of the Classes, purchased the Products, which were worthless due to the presence of benzene, a harmful and carcinogenic chemical impurity, and were forced to discard the remainder of their Products due to this contamination. The representative Plaintiffs, like all members of the Classes, have been damaged by Defendants' misconduct in the very same way as the members of the Classes. Further, the factual bases of Defendants' misconduct are common to all members of the Classes and represent a common thread of misconduct resulting in injury to all members of the Classes.

165. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Classes and predominate over any questions affecting only individual members of the Classes. These common legal and factual questions include, but are not limited to, the following:

- a. whether the Products contain, or had a material risk of containing, benzene;

- b. whether Defendants knew or should have known that the Products contained, or had a material risk of containing, benzene;
- c. whether Defendants had a duty to disclose, and wrongfully failed to disclose, that the Products contained, or had a material risk of containing, benzene;
- d. whether Defendants misrepresented and/or wrongfully failed to disclose material facts in connection with the manufacturing, packaging, labeling, marketing, advertising, distribution, and sale of the Products;
- e. whether Bayer's representations and omissions in connection with the labeling of Products were likely to mislead, deceive, confuse or confound consumers acting reasonably;
- f. whether Bayer represented to consumers that the Products have characteristics, benefits, or qualities that they do not have;
- g. whether Defendants had inadequate testing and safety standards, and had a duty to disclose, and wrongfully failed to disclose same;
- h. whether Defendants had knowledge that the representations and omissions in connection with the Products were false, deceptive and misleading;
- i. whether Bayer breached express and/or implied warranties;
- j. whether Defendants engaged in fraudulent, deceptive, misleading, unlawful, and/or unfair trade practices;
- k. whether Bayer made fraudulent and/or negligent misrepresentations and/or omissions, and/or engaged in fraudulent concealment;

- l. whether Plaintiffs and members of the Classes are entitled to actual, statutory, and/or punitive damages;
- m. whether Bayer unjustly retained benefits;
- n. whether Plaintiffs and the Classes have sustained monetary loss and the proper measure of that loss;
- o. whether Plaintiffs and the Classes are entitled to declaratory and injunctive relief; and
- p. whether Plaintiffs and the Classes are entitled to restitution and disgorgement from Defendants.

166. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Classes. Plaintiffs have retained counsel who are highly experienced in complex consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Classes. Plaintiffs have no interests that are antagonistic to those of the Classes.

167. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by members of the Classes are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for members of the Classes, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Classes could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of

adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

168. In the alternative, the Classes may be certified because:

- a. the prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudication with respect to individual members of the Classes that would establish incompatible standards of conduct for the Defendants;
- b. the prosecution of separate actions by individual members of the Classes would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Classes not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or
- c. Defendants have acted or refused to act on grounds generally applicable to the Classes as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CLAIMS FOR RELIEF

CLAIM 1

BREACH OF EXPRESS WARRANTY (AGAINST DEFENDANT BAYER ON BEHALF OF PLAINTIFF STEWART AND THE CLASSES)

169. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

170. Plaintiff Stewart brings this claim individually and on behalf of the members of the Classes against Defendant Bayer.

171. In connection with the sale of the Products, Defendant Bayer, as the designer, manufacturer, marketer, distributor, and/or seller, issued written warranties by representing that the Products were antifungal medications that contained only those active and inactive ingredients listed on the Products' labels and were safe and appropriate for human use. Those active and inactive ingredients listed on the Products' labels do not include benzene, a known human carcinogen dangerous to humans. Bayer further expressly warranted that the Products are antifungal medications used for the treatment of certain infections and are equivalent to the formulation of the Products as approved by the FDA, rather than adulterated antifungal products containing dangerous chemicals that are not equivalent to their generic forms. Further, Bayer expressly warranted that the Products were the brand-name equivalents of Miconazole Nitrate and Tolnaftate. Finally, Bayer provided instructions for repeated daily use for a period of weeks.

172. Bayer made these express warranties regarding the Products' quality and fitness for use in writing through its website, advertisements, marketing materials, and on the Products' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff Stewart and the Classes entered upon purchasing the Products. The affirmations of fact and/or promises became part of the basis of the bargain, and the contract, that Plaintiff Stewart and the Classes entered into with Bayer upon purchasing the Products.

173. Bayer's advertisements, warranties, and representations were made in connection with the sale of the Products to Plaintiff Stewart and the Classes. Plaintiff Stewart and the Classes relied on Bayer's advertisements, warranties, and representations regarding Bayer Products in deciding whether to purchase Bayer's products.

174. Bayer's Products do not conform to Bayer's affirmations of fact and promises, in that they are not safe, healthy, and appropriate for human use.

175. Bayer therefore breached its express warranties by placing Products into the stream of commerce and selling them to consumers, when their use had dangerous effects and was unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Bayer. These associated health effects substantially impair the use, value, and safety of the Bayer Products.

176. Bayer was aware, or should have been aware, of the presence of the human carcinogen benzene in the Bayer Products and therefore was aware or should have been aware of the toxic or dangerous health effects of the use of the Bayer Products, but nowhere on the package labeling, on Bayer's websites, or other marketing materials did Bayer warn Plaintiff Stewart and members of the Classes of the presence of benzene, or risk of benzene, in the Bayer Products or the dangers it posed.

177. Instead, Bayer concealed the presence of benzene in the Bayer Products and deceptively represented that the Bayer Products were safe, healthy, and appropriate for human use. Bayer thus utterly failed to ensure that the material representations it was making to consumers were true.

178. Benzene was present in the Bayer Products when they left Bayer's possession or control and were sold to Plaintiff Stewart and members of the Classes. The dangers associated with use of the Bayer Products were undiscoverable by Plaintiff Stewart and members of the Classes at the time of purchase of the Products.

179. Bayer is the manufacturer, marketer, advertiser, distributor, labeler, and seller of the Bayer Products and thus had exclusive knowledge and notice of the fact that the Bayer Products did not conform to the affirmations of fact and promises.

180. In addition, or in the alternative, to the formation of an express contract, Bayer made each of the above-described representations to induce Plaintiff Stewart and members of the Classes to rely on such representations.

181. Bayer's affirmations of fact and promises were material, and Plaintiff Stewart and members of the Classes reasonably relied upon such representations in purchasing the Bayer Products.

182. All conditions precedent to Bayer's liability for its breach of express warranty have been performed by Plaintiff Stewart and members of the Classes.

183. As a direct and proximate cause of Bayer's breach of express warranty, Plaintiff Stewart and the Classes have been injured and harmed because they did not receive the Products as warranted by Bayer and would not have purchased the Products on the same terms if they knew that the Products contained benzene, are not generally recognized as safe, and are not equivalent to their generic forms.

184. On or about August 9, 2023 and August 16, 2023, prior to filing this action, Defendant Bayer was served with pre-suit notice letters on behalf of Plaintiff Stewart (and applicable Classes) that complied in all respects with U.C.C. §§ 2-313 and 2-607 and 6 Del. C. §§ 2-313 and 2-607. Plaintiff Stewart's counsel sent Defendant Bayer a letter advising Bayer that it breached an express warranty and demanded that Bayer cease and desist from such breaches and make full restitution by refunding the monies received therefrom. True and correct copies of Plaintiffs' counsel's letters are attached hereto as Exhibit 1.

185. Plaintiff Stewart and the Classes seek all applicable damages, declaratory relief, injunctive relief, and all other just and proper relief based on Bayer's breaches of express warranty.

CLAIM 2

**BREACH OF IMPLIED WARRANTY
(AGAINST DEFENDANT BAYER ON BEHALF OF
PLAINTIFF STEWART AND THE CLASSES)**

186. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

187. Plaintiff Stewart brings this claim individually and on behalf of the members of the Classes against Defendant Bayer.

188. Plaintiffs Stewart and the Classes are consumers who purchased the Products manufactured, marketed, and sold by Bayer throughout the United States.

189. An implied warranty that the Products were merchantable arose by operation of law as part of the sale of the Products.

190. Bayer, as the designer, manufacturer (until at least mid-2019), marketer, distributor, and/or seller, impliedly warranted that the Products (i) would not contain elevated levels of benzene and (ii) are generally recognized as safe for human use and were of merchantable quality and fit for their ordinary and intended use.

191. Bayer breached the warranty implied in the contract for the sale of the defective Products because they could not pass without objection in the trade under the contract description, the Products were not of fair or average quality within the description, and the Products were unfit for their intended and ordinary purpose because the Products manufactured, distributed, and sold by Bayer were defective in that they contained elevated levels of

carcinogenic and toxic benzene, and as such are not generally recognized as safe for human use. As a result, Plaintiffs and members of the Classes did not receive the goods as impliedly warranted by Bayer to be merchantable.

192. Bayer had exclusive knowledge of the material facts concerning the defective nature of the Products.

193. Plaintiffs and members of the Classes purchased the Products in reliance upon Bayer's skill and judgment and the implied warranties of fitness for the purpose.

194. Benzene existed in the Products when the Products left Bayer's possession or control and were sold to Plaintiff Stewart and members of the Classes. The presence of benzene in the Products was undiscoverable by Plaintiff Stewart and members of the Classes at the time of their purchases.

195. The Products were not altered by Plaintiff Stewart or members of the Classes.

196. The Products were defective when they left the exclusive control of Bayer.

197. Bayer knew or had reason to know of the specific use for which the Products were purchased, and that the Products would be purchased and used without additional testing by Plaintiffs and members of the Classes.

198. Privity exists because Bayer impliedly warranted to Plaintiff Stewart and members of the Classes through the warranting, packaging, advertising, marketing, and labeling that Products were safe and suitable for use and made no mention of the attendant health risks associated with use of the Products.

199. Further, Plaintiff Stewart members of the Classes were at all material times the intended third-party beneficiaries of Bayer and its agents in the distribution of the sale of its Products. Bayer exercises substantial control over the outlets that sell the Products, which are the

same means by which Plaintiff Stewart and members of the proposed Classes purchased the Products. Bayer's warranties are not intended to apply to distributors but are instead intended to apply to consumers, including Plaintiff Stewart and members of the proposed Classes, to whom Bayer directly markets through labels and product packaging, and who review the labels and product packaging in connection with their purchases. As a result, the warranties are designed and intended to benefit the consumers, including Plaintiff Stewart and members of the proposed Classes, who purchase the Products. Privity therefore exists based on the foregoing and because Bayer impliedly warranted to Plaintiff Stewart and members of the proposed Classes through the packaging that the Products were safe and suitable for human use.

200. The Products were defectively manufactured and unfit for their intended purpose, and Plaintiffs and members of the Classes did not receive the goods as warranted.

201. As a direct and proximate cause of Bayer's breach of the implied warranty, Plaintiffs and members of the Classes have been injured and harmed because: (a) they would not have purchased the Products on the same terms if they knew that the Products contained harmful levels of benzene, and are not generally recognized as safe for human use; and (b) the Products do not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

202. On or about August 9, 2023 and August 16, 2023, prior to filing this action, Defendant Bayer was served with pre-suit notice letters on behalf of Plaintiff Stewart (and applicable Classes) that complied in all respects with U.C.C. §§ 2-314 and 2-607 and 6 Del. C. §§ 2-314 and 2-607. Plaintiff Stewart's counsel sent Defendant Bayer a letter advising Bayer that it breached an implied warranty and demanded that Bayer cease and desist from such breaches and make full restitution by refunding the monies received therefrom. True and correct copies of Plaintiff Stewart's counsel's letters are attached hereto as Exhibit 1.

203. Plaintiff Stewart and the Classes seek all applicable damages, declaratory relief, injunctive relief, and all other just and proper relief based on Bayer's breaches of implied warranty.

CLAIM 3

**FRAUD
(AGAINST DEFENDANT BAYER ON BEHALF OF
PLAINTIFF STEWART AND THE CLASSES)**

204. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

205. Plaintiff Stewart brings this claim individually and on behalf of the members of the Classes against Defendant Bayer.

206. Bayer committed both fraudulent misrepresentation and fraudulent omission. Specifically, Bayer (i) misrepresented that the Products were the brand-name equivalents of Miconazole Nitrate and Tolnaftate when they were not, and (ii) failed to disclose the presence of benzene in the Products.

207. Bayer had a duty to disclose material facts to Plaintiffs and the Classes given their relationship as contracting parties and intended users of the Products. Bayer also had a duty to disclose material facts to Plaintiffs and the Classes, namely that it was in fact manufacturing, distributing, and selling harmful products unfit for human use, because Defendant had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

208. Bayer knew or should have known that the Products were contaminated with benzene but continued to manufacture them, nonetheless. Bayer was required to engage in impurity testing to ensure that harmful impurities such as benzene were not present in the Products. Had Bayer undertaken proper testing measures, it would have been aware that the

Products contained dangerously high levels of benzene. Further, Bayer's recall stretches back to September 2018, meaning Bayer has known or should have known its Products were contaminated with benzene for years. During this time, Plaintiff Stewart and members of the Classes were using the Products without knowing it contained dangerous levels of benzene.

209. Bayer failed to discharge its duty to disclose these material facts.

210. In so failing to disclose these material facts to Plaintiffs and the Classes, Bayer intended to hide from Plaintiff Stewart and the Classes that they were purchasing and using the Products with harmful defects that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

211. Plaintiffs and the Classes reasonably relied on Bayer's failure to disclose insofar as they would not have purchased the defective Products manufactured and sold by Bayer had they known they contained unsafe levels of benzene.

212. As a direct and proximate cause of Bayer's fraud and fraudulent concealment, Plaintiff Stewart and the Classes suffered damages in the amount of monies paid for the defective Products and other damages, including the need for medical monitoring, attorneys' fees, and costs.

213. As a result of Bayer's willful and malicious conduct, punitive damages are warranted.

CLAIM 4

UNJUST ENRICHMENT (AGAINST DEFENDANT BAYER ON BEHALF OF PLAINTIFF STEWART AND THE CLASSES)

214. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

215. Plaintiff Stewart brings this claim individually and on behalf of the members of the Classes against Bayer.

216. Plaintiff Stewart and the Classes conferred a benefit on Bayer in the form of monies paid to purchase Bayer's defective and worthless Products.

217. Bayer knowingly and voluntarily accepted and retained this benefit.

218. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for products unfit for human use, it would be unjust and inequitable for Bayer to retain the benefit without paying the value thereof.

219. As a direct and proximate result, Plaintiff Stewart and the Classes are entitled to recover from Bayer all amounts wrongfully collected and improperly retained by Bayer, plus interest.

220. Plaintiff Stewart and the Classes seek restitution, disgorgement, imposition of a constructive trust, all appropriate declaratory and injunctive relief, and any other just and proper relief available.

CLAIM 5

NEGLIGENT MISREPRESENTATION (AGAINST DEFENDANT BAYER ON BEHALF OF PLAINTIFF STEWART AND THE CLASSES)

221. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

222. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant Bayer.

223. Bayer had a duty to Plaintiffs and the Classes to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of Products.

224. Bayer breached its duty to Plaintiffs and the Classes by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiffs and the Classes that did not have the qualities, characteristics, and suitability for use as advertised by Bayer and by failing to promptly remove Products from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Products.

225. Bayer knew or should have known that the qualities and characteristics of the Products were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Bayer, yet continued selling the Products.

226. Specifically, Bayer knew or should have known that: (1) the manufacturing process used to produce the Products resulted in the presence of benzene in the Products and (2) the Products were otherwise not as warranted and represented by Bayer.

227. As a direct and proximate result of Bayer's conduct, Plaintiffs and the Classes have suffered actual damages in that they purchased Products that were worth less than the price they paid and that they would not have purchased at all had they known they contained the carcinogen benzene that is known to cause the benzene-caused cancers, which does not conform to the Products' labels, packaging, advertising, and statements.

228. Plaintiffs and the Classes also suffered actual damages in that they were forced to discard the leftover portions of their contaminated Products and/or purchase replacement products upon learning of the contamination in the Products.

229. Plaintiffs and the Classes seek actual and all applicable damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available.

CLAIM 6

**VIOLATION OF THE DELAWARE CONSUMER FRAUD ACT,
6 DEL. C. §§ 2511, *ET SEQ.*
(AGAINST DEFENDANT BAYER ON BEHALF OF PLAINTIFF
STEWART AND THE DELAWARE SUBCLASSES)**

230. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

231. Plaintiff Stewart brings this claim individually and on behalf of the members of the Lotrimin Delaware Subclass and Tinactin Delaware Subclass (collectively, the “Delaware Subclasses”) against Defendant Bayer.

232. The Delaware Consumer Fraud Act (“DCFA”) prohibits any “act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice.” 6 Del. C. § 2513(a).

233. At all relevant times, Plaintiff Stewart, members of the Delaware Subclasses, and Bayer were each a “person” within the meaning of 6 Del. C. § 2511(7), defined to include any “individual, corporation, government, or governmental subdivision or agency, statutory trust, business trust, estate, trusts, partnership, unincorporated association ... or other legal or commercial entity.”

234. Bayer willfully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of “merchandise” (as defined in the Delaware

Consumer Fraud Act, 6 Del. C., § 2511(6)) in violation of 6 Del. C. § 2513(a), as described in the allegations above, including but not limited to:

- a. Failing to detect the presence of carcinogens in Propellant A-31 and the Products;
- b. Knowingly or recklessly making a false representation as to the characteristics and use of Products;
- c. Misrepresenting that Products are safe for use; and
- d. Failing to disclose the material information that Recalled Sprays contained unsafe Benzene and that Recalled Sprays users were at risk of suffering adverse health effects.

235. Plaintiff Stewart and members of the Delaware Subclasses relied on Bayer's misrepresentations and omissions in the sale of the Products detailed above.

236. Bayer's misrepresentations and omissions in the sale of the Products detailed above are acts or practices in the conduct of trade or commerce.

237. Bayer's misrepresentations and omissions in the sale of the Products detailed above impacts the public interest.

238. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair (as defined by 6 Del. C § 2511(9)) because they were likely to cause and did actually cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition, and inequitably enriched Bayer at the expense of Plaintiff Stewart and members of the Delaware Subclasses.

239. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they offend public policy, and were so oppressive that Plaintiff Stewart and members of the Delaware Subclasses had little alternative but to submit, which caused consumers substantial injury.

240. Bayer's misrepresentations and omissions in the sale of the Products detailed above are unfair in that they violate the well-established public policies of protecting consumers from avoidable dangers and that the manufacturer of medical devices, such as Bayer's Lotrimin and Tinactin, is responsible for ensuring that they are safe for human use.

241. Plaintiff Stewart and members of the Delaware Subclasses have suffered economic injury as a direct and proximate result of Bayer's conduct.

242. Plaintiff Stewart and members of the Delaware Subclasses were deceived by Bayer's deceptive and unfair acts and practices in that had they known the truth they would not have purchased Bayer's Products or would have paid less for the Products.

243. Instead, as a result of Bayer's misrepresentation, Plaintiff Stewart and members of the Delaware Subclasses suffered monetary losses in that (1) the actual value of the merchandise they received was less than the value of the merchandise as represented denying them of the benefit of their bargain; (2) Plaintiff Stewart and members of the Delaware Subclasses paid more than the fair market value of the merchandise they received causing them out-of-pocket damages; and (3) Plaintiff Stewart and members of the Delaware Subclasses were forced to discard their leftover Product and/or purchase a replacement product as a result of the contamination.

244. As a direct and proximate result of the foregoing acts and practices, Bayer received, or will receive, income, profits, and other benefits which Bayer would not have received if Bayer had not engaged in the violations described in this Complaint.

245. As a result, Plaintiff Stewart and members of the Delaware Subclasses seek relief including, *inter alia*, refund of amounts recovered by Bayer for the Products, injunctive and/or declaratory relief, damages, and all other just and proper relief.

CLAIM 7

**VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT,
N.J. STAT. §§ 56:8-1, *ET SEQ.*
(AGAINST DEFENDANT BAYER ON BEHALF OF
PLAINTIFF STEWART AND THE CLASSES)**

246. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

247. Plaintiff Stewart brings this claim individually and on behalf of the members of the Classes against Defendant Bayer.

248. The New Jersey Consumer Fraud Act, N.J. Stat. §§ 56:8-1 (“NJCFA”) prohibits any “act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.” *See* N.J. Stat. § 56:8-2.

249. At all relevant times, Plaintiff Stewart, members of the Classes, and Bayer were “persons” within the meaning of the NJCFA. *See* N.J. Stat. § 56:8-1(d).

250. Bayer willfully and purposefully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts

they intended others to rely upon in connection with the sale of the merchandise as defined by N.J. Stat. § 56:8-1(c) in violation of N.J. Stat. § 56:8-2 as described in the allegations above.

251. Bayer's misrepresentations and omissions in the sale of the Products detailed above were acts or practices in the conduct of trade or commerce.

252. Bayer's misrepresentations and omissions in the sale of the Products detailed above impact the public interest.

253. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they inequitably enriched Bayer at the expense of Plaintiff Stewart and members of the Classes.

254. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they offended public policy, and were so oppressive that Plaintiff Stewart and members of the Classes had little alternative but to submit, which caused consumers substantial injury.

255. Bayer's misrepresentations and omissions in the sale of the Products were unfair in that they violated the well-established public policies of protecting consumers from avoidable dangers and that the manufacturer of products is responsible for ensuring that they are fit for human use.

256. Plaintiff Stewart and members of the Classes have suffered ascertainable loss as a direct and proximate result of Bayer's conduct because (i) Plaintiff Stewart and members of the Classes did not receive Products that were properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Plaintiff Stewart and members of the Classes' bargained for, (ii) as a result of the benzene contamination, Plaintiff Stewart's and

members of the Classes' Products were adulterated, misbranded, illegal to sell, and therefore worthless, and (iii) Plaintiff Stewart and members of the Classes were forced to discard the remaining portion of their contaminated Products and/or purchase a replacement product as a result of the contamination, which made the Products unusable.

257. As a direct and proximate result of the foregoing acts and practices, Bayer has received, or will receive, income, profits, and other benefits which it would not have received if it had not engaged in the violations described in this Complaint.

258. As a result, Plaintiff Stewart and members of the Classes seek relief including, *inter alia*, refund of amounts recovered by Bayer for the Products, injunctive relief, damages, treble damages, attorney's fees, and costs pursuant to N.J. Stat. §§ 56:8-2.11 and 56:8-19.

CLAIM 8

VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349 (AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF DEFENDANTS ON BEHALF OF PLAINTIFFS HUERTAS AND MISTRETTA AND THE NEW YORK SUBCLASSES)

259. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

260. Plaintiffs Huertas and Mistretta bring this claim individually and on behalf of the members of the Lotrimin New York Subclass and Tinctin New York Subclass (collectively, the "New York Subclasses") against Defendant Aeropres and the Beiersdorf Defendants.

261. New York General Business Law ("GBL") § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

262. In its sale of goods throughout the State of New York, Defendant Aeropres and the Beiersdorf Defendants conduct business and trade within the meaning and intendment of GBL § 349.

263. Plaintiffs and members of the New York Subclasses are consumers who purchased products manufactured by the Beiersdorf Defendants using components provided by Defendant Aeropres for their personal use.

264. By the acts and conduct alleged herein, Defendant Aeropres and the Beiersdorf Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the Products (i) would not contain dangerously high levels of benzene, (ii) are generally recognized as safe for human use, and (iii) are equivalent to the formulation of the Products as approved by the FDA (i.e., that the Products are the brand-name equivalents of Miconazole Nitrate and Tolnaftate).

265. Defendant Aeropres and the Beiersdorf Defendants also materially omitted key facts regarding the true nature of the Products, specifically that the Products contained dangerous levels of benzene, were adulterated, and were unsafe for use as an antifungal treatment.

266. Had Plaintiffs Huertas and Mistretta and members of the New York Subclasses been apprised of these facts, they would have been aware of them and would not have purchased the Products.

267. The foregoing deceptive acts and practices were directed at consumers.

268. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the Products to induce consumers to purchase the same. No reasonable consumer would knowingly purchase an antifungal product that may contain high levels of a known carcinogen and reproductive toxin and that was illegal to purchase or sell.

269. By reason of this conduct, Defendant Aeropres and the Beiersdorf Defendants engaged in deceptive conduct in violation of GBL § 349.

270. Defendant Aeropres' and the Beiersdorf Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiffs Huertas and Mistretta and members of New York Subclasses have sustained from having paid for and used Bayer's products, which were rendered unusable due to the presence of benzene. Further, Plaintiffs Huertas and Mistretta and members of the New York Subclasses were injured because, inter alia, they were forced to discard the remainder of their contaminated Products and/or buy a replacement product.

271. As a result of Defendant Aeropres' and the Beiersdorf Defendants' violations, Plaintiffs Huertas and Mistretta and members of the New York Subclasses have suffered damages because: (a) they paid a premium price in the amount of the full purchase price of the Products based on Bayer's deceptive conduct; (b) the Products do not have the characteristics, uses, benefits, or qualities as promised; and (c) Plaintiffs Huertas and Mistretta and members of the New York Subclasses were forced to discard the remainder of their contaminated Products and/or buy a replacement product.

272. On behalf of themselves and other members of the New York Subclasses, Plaintiffs Huertas and Mistretta seek to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

CLAIM 9

VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 350 (AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF DEFENDANTS ON BEHALF OF PLAINTIFFS HUERTAS AND MISTRETТА AND THE NEW YORK SUBCLASSES)

273. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

274. Plaintiffs Huertas and Mistretta bring this claim individually and on behalf of the members of the New York Subclasses against Defendant Aeropres and the Beiersdorf Defendants.

275. GBL § 350 prohibits “[f]alse advertising in the conduct of any business, trade, or commerce.” N.Y. Gen. Bus. Law § 350.

276. Pursuant to said statute, false advertising is defined as “advertising, including labeling, of a commodity ... if such advertising is misleading in a material respect.” N.Y. Gen. Bus. Law § 350-a(1).

277. Based on the foregoing, Defendant Aeropres and the Beiersdorf Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of GBL § 350.

278. Defendant Aeropres and the Beiersdorf Defendants knew consumers such as Plaintiffs Huertas and Mistretta and members of the New York Subclasses were purchasing the Products for personal use and therefore had a duty to ensure Propellant A-31, supplied by Defendant Aeropres to the Beiersdorf Defendants and used by the Beiersdorf Defendants in the manufacture of the Products, did not contain carcinogens such as benzene, and additionally had a duty to ensure the finished Products did not contain carcinogens such as benzene.

279. Defendant Aeropres and the Beiersdorf Defendants thus omitted material facts regarding the true nature of the Products, specifically that the Products contained dangerous levels of benzene, were adulterated, and were unsafe for use as antifungal medications. Had Plaintiffs Huertas and Mistretta and members of the New York Subclasses been apprised of these facts, they would have been aware of them and would not have purchased the Products.

280. As a result of Defendant Aeropres' and the Beiersdorf Defendants' false, misleading, and deceptive statements and representations of fact, Plaintiffs Huertas and Mistretta and members of the New York Subclasses have suffered and continue to suffer economic injury.

281. As a result of Defendant Aeropres' and Defendant Beiersdorf's violations, Plaintiffs Huertas and Mistretta and members of the New York Subclasses have suffered damages due to said violations because: (a) they paid a premium price in the amount of the full purchase price of the Products based on Defendant Aeropres' and the Beiersdorf Defendants' deceptive conduct; (b) the Products do not have the characteristics, uses, benefits, or qualities as promised; and (c) Plaintiffs Huertas and Mistretta and members of the New York Subclasses were forced to discard the remainder of their contaminated Products and/or buy a replacement product.

282. On behalf of themselves and other members of the New York Subclasses, Plaintiffs Huertas and Mistretta seek to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

CLAIM 10

**VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT,
MO. REV. STAT. ANN. §§ 407.010, *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF DEFENDANTS ON
BEHALF OF PLAINTIFF VILLARREAL AND THE LOTRIMIN MISSOURI
SUBCLASS)**

283. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

284. Plaintiff Villarreal brings this claim individually and on behalf of the members of the Lotrimin Missouri Subclass against Defendant Aeropres and the Beiersdorf Defendants.

285. Missouri’s Merchandising Practices Act, Mo. Rev. Stat. Ann. §§ 407.010, *et seq.* (“Missouri MPA”) prohibits any “act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose.” Mo. Rev. Stat. Ann. § 407.020

286. At all relevant times, Plaintiff Villarreal, members of the Missouri Lotrimin Subclass, Defendant Aeropres, and the Beiersdorf Defendants were “persons” within the meaning of the Missouri MPA. *See* Mo. Rev. Stat. § 407.010(5).

287. Defendant Aeropres and the Beiersdorf Defendants willfully and purposefully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts in connection with trade or commerce in violation of Mo. Rev. Stat. § 407.020 as described in the allegations above, including but not limited to:

- a. Failing to detect the presence of carcinogens in Propellant A-31 and the Products;
- b. Knowingly or recklessly making a false representation as to the characteristics and use of Products;
- c. Misrepresenting that Products are safe for use; and
- d. Failing to disclose the material information that Recalled Sprays contained unsafe Benzene and that Recalled Sprays users were at risk of suffering adverse health effects.

288. Defendant Aeropres’ and the Beiersdorf Defendants’ misrepresentations and omissions in the “advertisement” (as defined by Mo. Rev. Stat. § 407.010(1)) and sale (as

defined by Mo. Rev. Stat. § 407.010(6)) of the Products detailed above are acts or practices in the conduct of “trade” or “commerce” (as defined by Mo. Rev. Stat. § 407.010(7)).

289. At all relevant times, Plaintiff Villarreal and members of the Missouri Lotrimin Subclass acted as reasonable consumers would in light of all circumstances in purchasing the Products, which are “merchandise” as defined by Mo. Rev. Stat. § 407.010(4), primarily to be used for personal or household uses.

290. Defendant Aeropres’ and the Beiersdorf Defendants’ unlawful methods, acts, and practices as alleged would cause a reasonable person to enter into the transactions that resulted in damages.

291. At trial, Plaintiff Villarreal will present, both individually and on behalf of members of the Missouri Lotrimin Subclass, evidence that is sufficiently definitive and objective to allow the loss of individual damages to be calculated with a reasonable degree of certainty.

292. Defendant Aeropres’ and the Beiersdorf Defendants’ misrepresentations and omissions in the sale of the Products detailed above impact the public interest.

293. Defendant Aeropres’ and the Beiersdorf Defendants’ misrepresentations and omissions in the sale of the Products detailed above were unfair because they inequitably enriched Defendants at the expense of Plaintiff Villarreal and members of the Missouri Lotrimin Subclass.

294. Defendant Aeropres’ and the Beiersdorf Defendants’ misrepresentations and omissions in the sale of the Products detailed above were unfair because they contained harmful levels of benzene, illegal as sold and unsafe to human health, which offends public policy, and were so oppressive that the Plaintiff Villarreal and members the Missouri Lotrimin Subclass had

little alternative but to submit, because consumers had no reason to know of the presence of benzene in their Products, which caused consumers substantial injury.

295. Defendant Aeropres' and the Beiersdorf Defendants' misrepresentations and omissions in the sale of the Products detailed above were also unfair in that they violated the well-established public policies of protecting consumers from avoidable dangers and that the manufacturers of medical devices, such as Lotrimin and Tinactin, are responsible for ensuring that they are safe for human use.

296. Plaintiff Villarreal and members of the Missouri Lotrimin Subclass suffered economic injury as a direct and proximate result of Defendant Aeropres' and the Beiersdorf Defendants' conduct.

297. As a direct and proximate result of the foregoing acts and practices, Defendant Aeropres and the Beiersdorf Defendants received, or will receive, income, profits, and other benefits which they would not have received if they had not engaged in the violations described in this Complaint.

298. Plaintiff Villarreal brings this claim individually and on behalf of the members of the Lotrimin Missouri Subclass to seek all appropriate relief.

CLAIM 11

**VIOLATION OF THE INDIANA DECEPTIVE CONSUMER SALES ACT,
IND. CODE §§ 24-5-0.5-0.1, *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF
DEFENDANTS ON BEHALF OF PLAINTIFF WYANT
AND THE INDIANA SUBCLASSES)**

299. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

300. Plaintiff Wyant brings this claim individually and on behalf of the members of the Lotrimin Indiana Subclass and Tinactin Indiana Subclass (collectively, the “Indiana Subclasses”) against Defendant Aeropres and the Beiersdorf Defendants.

301. Plaintiff Wyant, the Indiana Subclasses, Defendant Aeropres and the Beiersdorf Defendants are each a “person” as defined by Ind. Code § 24-5-0.5-2(a)(2).

302. Defendant Aeropres and the Beiersdorf Defendants are each a “supplier” as defined by Ind. Code § 24-5-0.5-2(a)(3).

303. The sale by Bayer, as supplied by Defendant Aeropres and the Beiersdorf Defendants, to Plaintiff Wyant and members of the Indiana Subclasses, as well as purchases of the Recalled Sprays by Plaintiff Wyant and the Indiana Subclasses, constitute “consumer transactions” as that term is defined at Ind. Code § 24-5-0.5-2(a)(1).

304. As suppliers of the Products sold by Bayer, Defendant Aeropres and the Beiersdorf Defendants engaged in unfair and deceptive acts in violation of the Indiana Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1, *et seq.* (“IDCSA”), by the practices described above, and by knowingly and intentionally concealing the true nature of the Products from Plaintiff Wyant and members of the Indiana Subclasses. These acts and practices violate, *inter alia*, the following sections of the IDCSA:

- a. Ind. Code § 24-5-0.5-3(b)(1): a supplier representing, whether orally, in writing, or by electronic communication, that such subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses, or benefits it does not have which the supplier knows or should reasonably know it does not have, because the Propellant A-31 and the Products contained benzene and was unsafe for use;

- b. Ind. Code § 24-5-0.5-3(b)(2): a supplier representing, whether orally, in writing, or by electronic communication, that such subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not and if the supplier knows or should reasonably know that it is not, because the Propellant A-31 and the Products contained benzene and was unsafe for use.

305. Defendant Aeropres' and the Beiersdorf Defendants' unfair or deceptive acts or practices occurred repeatedly in Defendant Aeropres' and the Beiersdorf Defendants' trade or business and were capable of deceiving the purchasing public.

306. Defendant Aeropres and the Beiersdorf Defendants knew or should have known that the Products contained unsafe levels of the carcinogen benzene, making them susceptible to failure for their essential purpose, and that they would become useless and worthless as a result of reasonable and foreseeable use by consumers.

307. Defendant Aeropres and the Beiersdorf Defendants each owed a duty to Plaintiff Wyant and the Indiana Subclasses to disclose the presence of Benzene in the Recalled Sprays as well as the dangers posed by the Benzene in the Recalled Sprays because:

- a. Defendant Aeropres and the Beiersdorf Defendants were each in a superior position to know the true state of facts about the defect within the Recalled Sprays;
- b. Plaintiff Wyant and Indiana Economic Loss Subclass could not reasonably have been expected to learn or discover that the Recalled Sprays contained the carcinogen benzene and thus were not in accordance with Defendant

Aeropres' and the Beiersdorf Defendants' advertisements and representations;

- c. Defendant Aeropres and the Beiersdorf Defendants knew that Plaintiff Wyant and the Indiana Economic Loss Subclass could not reasonably have been expected to learn or discover the presence of or dangers posed by the dangerous levels of benzene in the Recalled Sprays; and
- d. Defendant Aeropres and the Beiersdorf Defendants actively concealed and failed to disclose the presence of and dangers posed by the levels of benzene within the Recalled Sprays from Plaintiff Wyant and Indiana Economic Loss Subclass.

308. By failing to disclose the presence of and dangers posed by the benzene in the Products at the time of sale, Defendant Aeropres and the Beiersdorf Defendants knowingly and intentionally concealed material facts and breached their duty not to do so.

309. The fact that Defendant Aeropres and the Beiersdorf Defendants concealed or did not disclose to Plaintiff Wyant and the Indiana Subclasses are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase the Recalled Sprays. Had Plaintiff Wyant and members of the Indiana Subclasses known of the presence of benzene in the Products and the dangers it posed, and that the Products were not the brand-name equivalents of Miconazole Nitrate and Tolnaftate, they would not have purchased the Recalled Sprays or would have paid less for the Recalled Sprays. Indeed, Plaintiff Wyant and members of the Indiana Subclasses could not have purchased the Products had this fact been properly represented or disclosed because the presence of benzene renders the Products adulterated, misbranded, and illegal to sell.

310. Plaintiff Wyant's and members of the Indiana Subclasses' injuries were proximately caused by Defendant Aeropres' and the Beiersdorf Defendants' fraudulent, unfair, and deceptive business practices.

311. Plaintiff Wyant provided notice of his claims (to the extent notice was required) to Defendant Aeropres and the Beiersdorf Defendants on or about August 9, 2023 by mailing a letter via certified mail, return receipt requested to Defendant Aeropres and the Beiersdorf Defendants. True and correct copies of the letters are attached hereto as Exhibit 2 and Exhibit 3. Because Defendant Aeropres and the Beiersdorf Defendants did not cure within 30 days, their conduct is "uncured." Therefore, Plaintiff Wyant and members of the Indiana Subclasses are entitled to damages and equitable relief under the IDCSA.

312. Alternatively, Defendant Aeropres' and the Beiersdorf Defendants' violations were willful and were done as part of a scheme, artifice, or device with intent to defraud or mislead, and therefore are incurable deceptive acts or omissions under the IDCSA.

313. The IDCSA provides that "[a] person relying upon an uncured or incurable deceptive act may bring an action for the damages actually suffered as a consumer as a result of the deceptive act or five hundred dollars (\$500), whichever is greater. The court may increase damages for a willful deceptive act in an amount that does not exceed the greater of: (1) three (3) times the actual damages of the consumer suffering the loss; or (2) one thousand dollars (\$1,000)." Ind. Code § 24-5-0.5-4(a).

314. The IDCSA further provides that "[a]ny person who is entitled to bring an action under subsection (a) on the person's own behalf against a supplier for damages for a deceptive act may bring a class action against such supplier on behalf of any class of persons of which that person is a member." Ind. Code § 24-5-0.5-4(b).

315. Plaintiff Wyant brings this claim individually and on behalf of the members of the Indiana Subclasses to seek all appropriate relief.

CLAIM 12

**VIOLATION OF SOUTH CAROLINA’S UNFAIR TRADE PRACTICES ACT,
S.C. CODE §§ 39-5-10, *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF
DEFENDANTS ON BEHALF OF PLAINTIFF POOVEY AND THE
LOTRIMIN SOUTH CAROLINA SUBCLASS)**

316. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

317. Plaintiff Poovey brings this claim individually and on behalf of the members of the Lotrimin South Carolina Subclass against Defendant Aeropres and the Beiersdorf Defendants.

318. At all relevant times, Plaintiff Poovey, members of the Lotrimin South Carolina Subclass, Defendant Aeropres, and the Beiersdorf Defendants were “persons” within the meaning of S.C. Code § 39-5-10(a). The South Carolina Unfair Trade Practices Act prohibits unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. See S.C. Code § 39-5-20.

319. Defendant Aeropres and the Beiersdorf Defendants willfully engaged in unfair, deceptive, and/or unlawful practices as described in the allegations above, including but not limited to:

- a. Failing to detect the presence of carcinogens in Propellant A-31 and the Products;
- b. Knowingly or recklessly making a false representation as to the characteristics and use of Products;

- c. Misrepresenting that Products are safe for use; and
- d. Failing to disclose the material information that Recalled Sprays contained unsafe Benzene and that Recalled Sprays users were at risk of suffering adverse health effects.

320. Defendant Aeropres' and the Beiersdorf Defendants' deceptive acts or practices, misrepresentations, omissions, and suppression of material information in the sale of the Products are acts or practices in the conduct or trade or commerce within the meaning of S.C. Code § 39-5-10(b).

321. Plaintiff Poovey and members of the Lotrimin South Carolina Subclass suffered loss of money as a direct and proximate result of Defendant Aeropres' and the Beiersdorf Defendants' unfair and deceptive practices.

322. The unfair and deceptive practices and acts by Defendant Aeropres and the Beiersdorf Defendants described above impact the public interest and are capable of repetition.

323. Defendant Aeropres' and the Beiersdorf Defendants' conduct was unfair because it was immoral, unethical, or oppressive in that Plaintiff Poovey and members of the Lotrimin South Carolina Subclass were unaware that the Products they were purchasing contained a harmful contaminant – benzene.

324. Defendant Aeropres' and the Beiersdorf Defendants' conduct was deceptive because it was likely to, and did actually, deceive reasonable consumers such as Plaintiff Poovey and members of the Lotrimin South Carolina Subclass, who relied on Defendant Aeropres' and the Beiersdorf Defendants' representations in that they would not have acquired the Products had they known that the Products contained the carcinogen benzene and the Products were not the brand-name equivalents Miconazole Nitrate and Tolnaftate.

325. As a direct and proximate result of the foregoing acts and practices, Defendant Aeropres and the Beiersdorf Defendants' received, or will receive, income, profits, and other benefits which they would not have received if they had not engaged in the violations described in this Complaint.

326. Plaintiff Poovey brings this claim individually and on behalf of the members of the South Carolina Lotrimin Subclass to seek all appropriate relief.

CLAIM 13

**VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT,
MASS. GEN. LAWS CH. 93, §§1, *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE
BEIERSDORF DEFENDANTS ON BEHALF OF PLAINTIFF
CADORETTE AND THE LOTRIMIN MASSACHUSETTS SUBCLASS)**

327. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

328. Plaintiff Cadorette brings this claim individually and on behalf of the members of the Lotrimin Massachusetts Subclass against Defendant Aeropres and the Beiersdorf Defendants.

329. Defendant Aeropres and the Beiersdorf Defendants are each a "person" as defined by Mass. Gen. Laws ch. 93A, § 1(a).

330. Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass are actual or potential consumers of the Products.

331. Defendant Aeropres and the Beiersdorf Defendants engaged in deceptive or unfair acts or practices in the conduct of any trade or commerce, in violation of Mass. Gen. Laws ch. 93A, § 2(a), including but not limited to the following:

- a. Failing to detect the presence of carcinogens in Propellant A-31;
- b. Failing to detect the presence of carcinogens in the Products;

- c. Knowingly or recklessly made a false representation as to the characteristics and use of Products, in violation of 93A, § 2(a);
- d. Misrepresenting that Products are safe for use, in violation of 93A, § 2(a);
and
- e. Failing to disclose the material information that Recalled Sprays contained unsafe Benzene and that Recalled Sprays users were at risk of suffering adverse health effects, in violation of 93A, § 2(a).

332. As detailed throughout this Complaint, Defendant Aeropres' and the Beiersdorf Defendants' deceptive trade practices significantly impacted the public, because there are millions of consumers of the Products, including Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass.

333. Defendants Aeropres' and the Beiersdorf Defendants' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to purchase the Products without being aware that the Products were unsafe to use and not the brand-name equivalents of Miconazole Nitrate and Tolnaftate.

334. Defendants Aeropres' and the Beiersdorf Defendants' representations and omissions also were unfair, immoral, unethical, oppressive, or unscrupulous because the presence of benzene in the Products is harmful to human health.

335. As a direct and proximate result of Defendants Aeropres' and the Beiersdorf Defendants' unfair and deceptive acts or practices, Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass suffered damages by purchasing the Products because (i) Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass did not receive Products that were properly manufactured, free from defects, safe for its intended use, and the

brand-name equivalent of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass bargained for, (ii) as a result of the benzene contamination, Plaintiff Cadorette's and members of the Lotrimin Massachusetts Subclass's Products were adulterated, misbranded, illegal to sell, and therefore worthless, and (iii) Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass were forced to discard the remaining portion of their contaminated Products and/or purchase a replacement product as a result of the contamination, which made the Products unusable.

336. Defendant Aeropres' and the Beiersdorf Defendants' deceptive trade practices caused injury in fact and actual damages to Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass in the form of the loss or diminishment of value of the Products Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass purchased, which allowed Defendant Aeropres and the Beiersdorf Defendants to profit at the expense of Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass. The injuries to Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass were to legally protected interests. The gravity of the harm of Defendant Aeropres' and the Beiersdorf Defendants' actions is significant and there is no corresponding benefit to consumers of such conduct.

337. Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass seek relief under 93A, § 9 including, not limited to, compensatory damages or statutory damages of \$25 per violation, whichever is greater, restitution, penalties, injunctive relief, and/or attorneys' fees and costs.

338. Plaintiff Cadorette and members of the Lotrimin Massachusetts Subclass provided noticed pursuant to Mass. Gen. Laws ch. 93A, § 9(3) to Defendant Aeropres and the Beiersdorf

Defendants on or about August 9, 2023 by mailing letters via certified mail, return receipt requested. True and correct copies of the letters are attached hereto as Exhibit 2 and Exhibit 3.

CLAIM 14

**VIOLATION OF THE DELAWARE CONSUMER FRAUD ACT,
6 DEL. C §§ 2511, *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF
DEFENDANTS ON BEHALF OF PLAINTIFF STEINWEDEL AND
PLAINTIFF STEWART AND THE DELAWARE SUBCLASSES)**

339. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

340. Plaintiff Stewart and Plaintiff Steinwedel bring this claim individually and on behalf of the members of the Lotrimin Delaware Subclass and Tinactin Delaware Subclass (collectively, the “Delaware Subclasses”) against Defendant Aeropres and the Beiersdorf Defendants.

341. Delaware’s Consumer Fraud Act, 6 Del. C. §§ 2511 *et seq.* (“DCFA”) prohibits any “act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice.”

342. At all relevant times, Plaintiff Stewart, Plaintiff Steinwedel, members of the Delaware Subclasses, Defendant Aeropres, and the Beiersdorf Defendants were each a “person” as defined by 6 Del. C. § 2511 (7), which includes individuals, corporations, governments, or governmental subdivisions or agencies, statutory trusts, business trusts, estates, trusts, partnerships, unincorporated associations or other legal or commercial entities.

343. Defendant Aeropres and the Beiersdorf Defendants willfully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of “merchandise” (as defined in the DCFA, 6 Del. C. § 2511(6)) in violation of 6 Del. C., § 2513(a)), as described in the allegations above, including but not limited to:

- a. Misrepresenting that the Products are safe for use, when they were not;
- b. Knowingly or recklessly making a false representation as to the characteristics and use of the Products; and
- c. Failing to disclose the material information that Recalled Sprays contained unsafe Benzene and that Recalled Sprays users were at risk of suffering adverse health effects.

344. Defendant Aeropres and the Beiersdorf Defendants intended for consumers such as Plaintiff Stewart, Plaintiff Steinwedel, and members of the Delaware Subclasses to rely on their misrepresentations or omissions, and Plaintiff Stewart, Plaintiff Steinwedel, and members of the Delaware Subclasses actually relied on Defendant Aeropres’ and the Beiersdorf Defendants’ misrepresentations and omissions in the sale of the Products detailed above.

345. Defendant Aeropres’ and the Beiersdorf Defendants’ misrepresentations and omissions in the manufacture and sale of the Products detailed above are acts or practices in the conduct of trade or commerce.

346. Defendant Aeropres’ and the Beiersdorf Defendants’ misrepresentations and omissions in the sale of the Products detailed above impact the public interest.

347. Defendant Aeropres and the Beiersdorf Defendants’ misrepresentations and omissions in the sale of the Products detailed above also were unfair (as defined by 6 Del. C. §

2511(9)) because they were likely to cause and did actually cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition, and they inequitably enriched Defendant Aeropres and the Beiersdorf Defendants at the expense of the Plaintiff Steinwedel and members of the Delaware Subclasses.

348. Defendant Aeropres' and the Beiersdorf Defendants' misrepresentations and omissions in the sale of the Products detailed above were further unfair because they offend public policy, and were so oppressive that Plaintiff Steinwedel and members of the Delaware Subclasses had little alternative but to submit, which caused consumers substantial injury.

349. Defendant Aeropres' and the Beiersdorf Defendants' misrepresentations and omissions in the sale of the Products detailed above are unfair in that they violate the well-established public policies of protecting consumers from avoidable dangers and that the manufacturer of medical devices is responsible for ensuring that they are safe for human use.

350. Plaintiff Stewart, Plaintiff Steinwedel, and members of the Delaware Subclasses have suffered economic injury as a direct and proximate result of Defendant Aeropres' and the Beiersdorf Defendants' conduct.

351. Plaintiff Stewart, Plaintiff Steinwedel, and members of the Delaware Subclasses were deceived by Defendant Aeropres' and the Beiersdorf Defendants' deceptive and unfair acts and practices in that had they known the truth they would not have purchased the Products or would have paid less for the Products.

352. Instead, as a result of Defendant Aeropres' and the Beiersdorf Defendants' material misrepresentations and omissions, Plaintiff Stewart, Plaintiff Steinwedel, and members of the Delaware Subclasses suffered monetary losses in that (1) the actual value of the

merchandise they received was less than the value of the merchandise as represented denying them of the benefit of their bargain; (2) Plaintiff Stewart, Plaintiff Steinwedel, and members of the Delaware Subclasses paid more than the fair market value of the merchandise they received causing them out-of-pocket damages; and (3) Plaintiff Stewart, Plaintiff Steinwedel, and members of the Delaware Subclasses were forced to discard their leftover Product and/or purchase a replacement product as a result of the contamination.

353. As a direct and proximate result of the foregoing acts and practices, Defendant Aeropres and the Beiersdorf Defendants received, or will receive, income, profits, and other benefits which Defendant Aeropres and the Beiersdorf Defendants would not have received if they had not engaged in the violations described in this Complaint.

354. Plaintiffs Stewart and Steinwedel bring this claim individually and on behalf of the members of the Delaware Subclasses to seek all appropriate relief.

CLAIM 15

**VIOLATION OF THE CALIFORNIA CONSUMER LEGAL REMEDIES ACT,
CAL. CIV. CODE §§ 1750 *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF
DEFENDANTS ON BEHALF OF PLAINTIFF MARTIN, PLAINTIFF
PENALES AND THE CALIFORNIA SUBCLASSES)**

355. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

356. Plaintiffs Martin and Penales bring this claim individually and on behalf of the members of the Lotrimin California Subclass and Tinactin California Subclass (collectively, the “California Subclasses”) against Defendant Aeropres and the Beiersdorf Defendants.

357. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses are “consumer[s]” as that term is defined in Cal. Civ. Code § 1761(d).

358. The Products are “goods,” as that term is defined in Cal. Civ. Code § 1761(a).

359. Defendant Aeropres and the Beiersdorf Defendants are each a “person” as that term is defined in Cal. Civ. Code § 1761(c).

360. Each purchase of a Product by Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses constituted a “transaction” as that term is defined in Cal. Civ. Code § 1761(e).

361. Defendant Aeropres’ and the Beiersdorf Defendants’ conduct alleged herein violates the California Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.* (“CLRA”), which prohibits unfair methods of competition and unfair or deceptive acts or practices, including specifically the following provisions of the CLRA:

- a. Cal. Civ. Code § 1770(a)(5), by negligently, recklessly, and/or intentionally representing that Propellant A-31 was safe for use in the manufacture and use of the Products when in fact it was not;
- b. Cal. Civ. Code § 1770(a)(5), by negligently, recklessly, and/or intentionally representing the Propellant A-31 and the Products were and are safe for use by individuals when in fact they contain an unsafe chemical, benzene;
- c. Cal. Civ. Code § 1770(a)(7), by negligently, recklessly, and/or intentionally representing that Propellant A-31 and the Products were of a particular standard, quality, or grade (i.e., that the Products are the brand-name equivalent of Miconazole Nitrate and Tolnaftate), when they were of another;

- d. Cal. Civ. Code § 1770(a)(9), by negligently, recklessly, and/or intentionally advertising the Propellant A-31 and the Products with intent not to sell them as advertised; and
- e. Cal. Civ. Code § 1770(a)(16), by representing that Propellant A-31 and the Products have been supplied in accordance with previous representations, when they have not.

362. Defendant Aeropres and the Beiersdorf Defendants, as manufacturers, producers, and/or distributors of Propellant A-31 and/or Products, had exclusive knowledge of the presence of benzene in the Products.

363. Plaintiffs Martin and Penales and members of the California Subclasses reasonably relied on the representations and omissions of Defendant Aeropres and the Beiersdorf Defendants when purchasing the Products.

364. As a direct and proximate result of these violations, Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses have been harmed by the misleading marketing and unfair and deceptive conduct described herein in any manner in connection with the advertising and sale of the Products.

365. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses seek relief for the injuries they have suffered as a result of Defendant Aeropres' and the Beiersdorf Defendants' practices, as provided by the CLRA and applicable law.

366. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses provided Defendant Aeropres and the Beiersdorf Defendants, via certified mail, return receipt requested, notice of the specific complaint and damages in accordance with Cal. Civ. Code §

1782 on or about August 9, 2023, thirty (30) days prior to the initiation of this claim. True and correct copies of the letters are attached hereto as Exhibit 2 and Exhibit 3.

CLAIM 16

**VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW,
CAL. BUS. & PROF. CODE §§ 17200 *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF
DEFENDANTS ON BEHALF OF PLAINTIFFS MARTIN AND
PENALES AND THE CALIFORNIA SUBCLASSES)**

367. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

368. Plaintiffs Martin and Penales bring this claim individually and on behalf of the members of the California Subclasses against Defendant Aeropres and the Beiersdorf Defendants.

369. The California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.* (“UCL”) prohibits any “unlawful, unfair or fraudulent business act or practice.” Cal. Bus. & Prof. Code §17200.

370. Defendant Aeropres’ and the Beiersdorf Defendants’ conduct was fraudulent in that they fraudulently represented that Propellant A-31 and the Products were and are properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. None of these representations were true because Propellant A-31 and the Products contained an unsafe chemical, benzene.

371. These material representations were likely to, and did actually, deceive members of the public, including Plaintiffs Martin and Penales and members of the California Subclasses, who would not have otherwise purchased the benzene-containing Products.

372. Defendant Aeropres' and the Beiersdorf Defendants' conduct also was "unlawful." In addition to violating the various consumer protection statutes and common law claims alleged in this Complaint, as alleged herein, Defendant Aeropres and the Beiersdorf Defendants have each committed "unlawful" acts by violating the Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875, *et seq.* (the "Sherman Act").

373. Specifically, the Sherman Act prohibits the sale of misbranded drugs and devices. "Any drug or device is misbranded if its labeling is false or misleading in any particular." Sherman Act, Health & Safety Code § 111330. Here, the Products fit within the definition of a "drug" and are "misbranded" because its labeling—specifically, the Products' representations that the Products are the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate—are false and misleading. Therefore, the marketing of Propellant A-31 and the Products is violative of the Sherman Act and the unlawful provision of the UCL by extension.

374. Defendant Aeropres' and the Beiersdorf Defendants' conduct with respect to the labeling, packaging, advertising, marketing, and sale of Propellant A-31 and the Products also was unfair because it was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

375. Furthermore, Defendant Aeropres' and the Beiersdorf Defendants' conduct with respect to the labeling, packaging, advertising, marketing, and sale of Propellant A-31 and the Products was unfair because the consumer injury is substantial, not outweighed by benefits to consumers or competition, and not one that consumers, themselves, can reasonably avoid because benzene is a harmful chemical and the ingredients in Propellant A-31 and the Products were within the exclusive knowledge of Defendant Aeropres and the Beiersdorf Defendants.

376. Defendant Aeropres' and the Beiersdorf Defendants' conduct also violates the FAL, see ¶¶ 402-413, which is a violation of the UCL.

377. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses seek an order requiring Defendant Aeropres and the Beiersdorf Defendants to immediately repair or replace the Products.

378. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses also seek an order for the restitution of all monies from the sale of the Products, which were unjustly acquired through acts of fraudulent, unfair, or unlawful competition.

379. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses have no adequate remedy at law for this claim. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses plead their claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

380. Alternatively, legal remedies available to Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluit*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view ... It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

381. Furthermore:

- a. To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses fail to sufficiently adduce evidence to support an award of damages.
- b. Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses seek such relief here.
- c. Legal claims for damages are not equally certain as restitution because claims under the UCL entail few elements. Further, the “unlawful” prong of the UCL is the only way for Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses to vindicate violations of the Sherman Act because the Sherman Act contains no private right of action.
- d. A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law.” RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

CLAIM 17

**VIOLATION OF THE CALIFORNIA FALSE ADVERTISING LAW,
CAL. BUS. & PROF. CODE §§ 17500 *ET SEQ.*
(AGAINST DEFENDANT AEROPRES AND THE BEIERSDORF
DEFENDANTS ON BEHALF OF PLAINTIFF MARTIN AND PLAINTIFF
PENALES AND THE CALIFORNIA SUBCLASSES)**

382. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

383. Plaintiffs Martin and Penales bring this claim individually and on behalf of the members of the California Subclasses against Defendant Aeropres and the Beiersdorf Defendants.

384. The California False Advertising Law, Cal. Bus. & Prof. Code §17500 *et seq.* (“FAL”) prohibits any statement in connection with the sale of goods “which is untrue or misleading.” Cal. Bus. & Prof. Code §17500.

385. As set forth herein, Defendant Aeropres and the Beiersdorf Defendants claimed the Products were and are properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. None of these representations were true because the Products contained an unsafe chemical, benzene.

386. Further, Defendant Aeropres and the Beiersdorf Defendants failed to disclose the presence of benzene in Propellant A-31 and the Products, which rendered Propellant A-31 and the Products not properly manufactured, not free from defects, not safe for their intended uses, and not the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate.

387. Defendant Aeropres and the Beiersdorf Defendants knew, or reasonably should have known, that all these claims were untrue or misleading, which constitute an unfair business practice and/or false advertising, because they fundamentally misrepresent the characteristics and quality of the Products to induce consumers to purchase the same. No reasonable consumer would knowingly purchase an antifungal product that may contain high levels of a known carcinogen and reproductive toxin and that was illegal to purchase or sell.

388. Plaintiffs Martin and Penales and members of the California Subclasses actually relied on the untrue and/or misleading statements of Defendant Aeropres and the Beiersdorf Defendants in purchasing the Products, and as a result, were economically injured because the Products that they purchased were not worth what they paid, were rendered unusable, and replacement products needed to be purchased.

389. Prospective injunctive relief is necessary given Defendant Aeropres' and the Beiersdorf Defendants' refusal to offer details as to how and when they intend to repair the Recalled Sprays.

390. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses are entitled to injunctive and equitable relief, and restitution in the amount they spent on the Products and replacement devices.

391. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses have no adequate remedy at law for this claim. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses plead their claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

392. Alternatively, legal remedies available to Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluit*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view ... It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

393. Furthermore:

- a. To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that

Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses fail to sufficiently adduce evidence to support an award of damages.

- b. Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff Martin, Plaintiff Penales, and members of the California Subclasses seek such relief here.
- c. Legal claims for damages are not equally certain as restitution because claims under the FAL entail few elements.
- d. A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law.” RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request, individually and on behalf of the alleged Classes, that the Court enter judgment in their favor and against Defendants as follows:

A. For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiffs as the representatives of the Classes, and naming Plaintiffs’ attorneys as Class Counsel to represent the Classes;

B. For an order declaring that Defendants’ conduct violates the causes of action referenced herein;

C. For an order finding in favor of Plaintiffs and the Classes on all counts asserted herein;

D. For compensatory, actual, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

- F. For an order of restitution and all other forms of equitable monetary relief;
- G. For injunctive relief as pleaded or as the Court may deem proper; and
- H. For an order awarding Plaintiffs and the Classes their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable as of right.

DATED: September 14, 2023

Respectfully Submitted,

FORDE O'MEARA LLP

By:

/s/Brian P. O'Meara

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