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**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF CALIFORNIA**

LAURA WILLIS ALBRIGO, on behalf of herself and all others similarly situated,

Plaintiff,

v.

HARRIS PHARMACEUTICAL, INC.

Defendant.

Case No. '24CV1098 BEN MSB

**CLASS ACTION COMPLAINT**

**DEMAND FOR JURY TRIAL**

Plaintiff Laura Willis Albrigo ("Plaintiff") individually and on behalf of herself and all others similarly situated, brings this class action lawsuit against Harris Pharmaceutical, Inc. ("Harris" or "Defendant") based upon personal knowledge as to herself, the investigation of her counsel, and on information and belief as to all other matters.

## INTRODUCTION

1. This is a class action lawsuit against Defendant regarding the manufacturing, distribution, advertising, marketing, and sale of Harris branded benzoyl peroxide ("BPO") acne treatment product (the "BPO Product")[1] that contains and/or degrades to form dangerously unsafe levels of benzene, a known human carcinogen.

[1] The BPO Product includes, but is not limited to, the Harris branded Benzoyl Peroxide 10% Acne Wash. Plaintiff reserves the right to amend this list if further investigation and/or discovery reveals that the list should be amended.

2. The BPO Product is used to treat acne vulgaris ("acne") and is formulated with BPO and other inactive ingredients to make treatments for acne in various forms such as creams, scrubs, washes, and bars.

3. Benzene is a known human carcinogen. The World Health Organization ("WHO") and the International Agency for Research on Cancer ("IARC") have classified benzene as a Group 1 compound thereby defining it as "carcinogenic to humans."[2] Similarly, the Department of Health and Human Services ("DHHS") has determined that benzene causes cancer in humans.[3] Benzene exposure has been linked with acute lymphocytic leukemia, chronic lymphocytic leukemia, multiple myeloma, and non-Hodgkin lymphoma.[4]

4. On March 5, 2024, Valisure LLC ("Valisure"), an independent laboratory that analyzes the safety of consumer products, filed a citizen petition (the "Valisure Petition") with the FDA detailing its findings that it detected high levels of benzene in BPO products, including Defendant's BPO Product.[5] Valisure called for the FDA to recall and suspend the sale of all products containing BPO, including Defendant's BPO Product. Valisure argued that the products containing BPO are adulterated under Section 301 of the Federal Drug and Cosmetics Act ("FDCA") in violation of 21 U.S.C. § 331 and misbranded under Section 502 of the FDCA in violation of 21 U.S.C. § 352, among various other FDCA violations.

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[2] *IARC Monographs on the Identification of Carcinogenic Hazards to Humans: List of Classifications*, INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, WORLD HEALTH ORGANIZATION, https://monographs.iarc.who.int/list-of-classifications (last visited June 24, 2024).

[3] *Facts About Benzene,* CENTERS FOR DISEASE CONTROL AND PREVENTION (April 4, 2018) https://emergency.cdc.gov/agent/benzene/basics/facts.asp (last visited June 24, 2024).

[4] *Benzene and Cancer Risk*, AMERICAN CANCER SOCIETY https://www.cancer.org/cancer/cancer-causes/benzene.html (last visited June 24, 2024).

[5] David Light, Wolfgang Hinz, PhD, and Kaury Kucera, PhD, *Valisure's FDA Citizen Petition on Benzoyl Peroxide Acne Products*, VALISURE (March 6, 2024), *available at:* https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide (last visited June 24, 2024).

5. Valisure's Petition detailed that products' containing BPO, including the BPO Product marketed and sold by Defendant, decomposed to form benzene under normal and expected use, handling, and storage, rendering them materially different than advertised, *i.e.*, by containing unsafe levels of benzene. Many of the BPO products that Valisure tested were found to contain benzene in many multiple times higher than allowed in any regulated drug.[6]

6. This led Valisure to conduct a stability study on a diverse market sweep of BPO products and formulations. Valisure's results show that on-market BPO products can form over ***800 times*** the conditionally restricted FDA concentration limit of 2 parts per million ("ppm") for benzene, suggesting this problem applies broadly to BPO products currently on the market.[7]

7. Incubation of Defendant's BPO Product at the temperature accepted by the pharmaceutical industry for performing accelerated stability standards (50°C), a temperature the BPO Product is expected to be exposed to through normal consumer and distributor handling, resulted in the detection of benzene up to approximately ***400 ppm***, well above the FDA's strict concentration limit of 2 ppm for a drug product when the use of benzene is "unavoidable".[8] Overall, the testing led Valisure to conclude that on-market BPO products appear to be fundamentally unstable and form unacceptably high levels of benzene.[9]

8. The presence of benzene, or the risk of benzene contamination via degradation of BPO, is not disclosed on the BPO Product's label. Therefore, Plaintiff, by use of reasonable care, could not have discovered that the BPO Product was contaminated with benzene and/or was at risk of benzene contamination via the degrading of BPO.

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[6] *Id.*
[7] *Valisure Discovers Benzoyl Acne Treatment Products are Unstable and Form Benzene*, VALISURE (March 6, 2024), https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide (last visited June 24, 2024).
[8] *Id.*
[9] *Id.*

9. Although BPO is known within the scientific community to degrade to form benzene, this fact is not known among consumers. Defendant knew or should have known the BPO Product contains benzene and/or degraded to form benzene when exposed to normal and expected consumer use, handling, and storage.

10. Plaintiff and Class Members purchased the BPO Product with the expectation that the product was safe, including free of carcinogens that are not listed on the label. Because Defendant sold products to consumers that contain dangerous levels of benzene and/or degrade to form benzene, Plaintiff and the Class Members were deprived of the benefit of their bargain.

11. Defendant is therefore liable to Plaintiff and Class members for misrepresenting and/or failing to disclose or warn that the BPO Product contains benzene and/or that the BPO Product degrades to form benzene under normal and expected usage/conditions.

12. As a result of Defendant's misconduct and consumer deception, Plaintiff, the Class, and the public, have been economically harmed. Plaintiff would not have purchased the BPO Product or would have paid less for it, had she known the truth.

13. Plaintiff seeks damages, reasonable attorneys' fees and costs, interest, restitution, other equitable relief, including an injunction and disgorgement of all benefits and profits Defendant received from misconduct.

## PARTIES

14. Plaintiff Laura Willis Albrigo is a resident and citizen of San Diego County, California. In October 2023, Plaintiff purchased Defendant's BPO Product, the Harris-branded Benzoyl Peroxide 10% Acne Wash. When purchasing the BPO Product, Plaintiff reviewed the accompanying labels and disclosures and understood them as representations and warranties by Defendant that the product was properly manufactured, free from defects, and safe for its intended use. Plaintiff relied on these representations and warranties in deciding to purchase the BPO

Product and these representations and warranties were part of the basis of the bargain in that she would not have purchased, or would have paid less for, the BPO Product, if she had known that the BPO Product was not, in fact, properly manufactured, free from defects, or safe for its intended use.

15. Defendant is a Florida corporation with its principal place of business at 9090 Park Royal Drive Ft Myers, Florida 33908. Defendant owns and operates the website https://www.harrispharmaceutical.org/ and markets and distributes dermatology products, including the BPO Product, in the U.S. market.

## JURISDICTION AND VENUE

16. 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, because at least one member of the Class, as defined below, is a citizen of a different state than at least one Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

17. This Court has personal jurisdiction over Defendant because Defendant directed its business via the sale of its BPO Product to consumers in California, including to Plaintiff.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because the act and transaction giving rise to this action occurred in this District, Defendant conducts substantial business in this District, and Plaintiff resides in this District.

## FACTUAL ALLEGATIONS

### The Dangers of Benzene

19. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the U.S. Department of Health and Human Services has determined that benzene causes cancer in humans. Similarly, the WHO and the IARC have

classified benzene as a Group 1 compound thereby defining it as "carcinogenic to humans."[10]

20. The National Institute for Occupational Safety and Health ("NIOSH") and CDC identify "exposure routes" for benzene to include: "inhalation, skin absorption, ingestion, skin and/or eye contact."[11]

21. The NIOSH and CDC identify "target organs" associated with human exposure to benzene to include: "eyes, skin, respiratory system, blood, central nervous system, bone marrow.[12]

22. The CDC warns that "[b]enzene works by causing cells not to work correctly. For example, it can cause bone marrow not to produce enough red blood cells, which can lead to anemia. Also, it can damage the immune system by changing blood levels of antibodies and causing the loss of white blood cells."[13]

23. As for "where benzene is found and how it is used," the CDC states that "[s]ome industries use benzene to make other chemicals that are used to make plastics, resins, and nylon and synthetic fibers. Benzene is also used to make some types of lubricants, rubbers, dyes, detergents, drugs, and pesticides."[14]

24. The CDC has stated that ways in which people "could be exposed to benzene" include:

a. Outdoor air contains low levels of benzene from tobacco smoke, gas stations, motor vehicle exhaust, and industrial emissions.

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[10] David Light, Wolfgang Hinz, PhD, and Kaury Kucera, PhD, *Valisure's FDA Citizen Petition on Benzoyl Peroxide Acne Products*, VALISURE (March 5, 2024), *available at:* https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide (last visited June 24, 2024).

[11] *NIOSH Pocket Guide to Chemical Hazards: Benzene*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/niosh/npg/npgd0049.html (last visited June 24, 2024).

[12] *Id.*

[13] *Facts About Benzene,* CENTERS FOR DISEASE CONTROL AND PREVENTION (April 4, 2018) https://emergency.cdc.gov/agent/benzene/basics/facts.asp (last visited June 24, 2024).

[14] *Id.*

b. Indoor air generally contains levels of benzene higher than those in outdoor air. The benzene in indoor air comes from products that contain benzene such as glues, paints, furniture wax, and detergents.

c. The air around hazardous waste sites or gas stations can contain higher levels of benzene than in other areas.

d. Benzene leaks from underground storage tanks or from hazardous waste sites containing benzene can contaminate well water.

e. People working in industries that make or use benzene may be exposed to the highest levels of it.

f. A major source of benzene exposure is tobacco smoke.[15]

25. A 2010 study titled "Advances in Understanding Benzene Health Effects and Susceptibility" summarized the epidemiological studies of the carcinogenic effects of benzene exposure and an overview of the hematotoxic effects of benzene.[16] The 2010 study concluded:

a. 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.

b. Exposure to benzene can lead to multiple alterations that contribute to the leukemogenic process, indicating a multimodal mechanism of action.

c. Benzene is a ubiquitous chemical in our environment that causes acute leukemia and probably other hematological cancers.

[15] *Id.*

[16] Martyn T. Smith, *Advances in Understanding Benzene Health Effects and Susceptibility*, ANNUAL REVIEWS, Vol. 31:133-148 (April 21, 2010) https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646 (last visited June 24, 2024).

26. The FDA currently recognizes the danger of benzene and, as a result, has claimed it should not be used in the manufacture of any component of a drug product due to its unacceptable toxicity effect.[17]

27. Where the use of benzene or other Class 1 solvents is unavoidable to produce a drug product with a significant therapeutic advance, the FDA has stated that the levels should be restricted, and benzene is restricted under such guidance to 2 ppm.[18]

28. Recognizing the risks of benzene, in December 2022, the FDA issued a statement alerting manufacturers to the risk of benzene contamination and warned that any drug product containing more than 2 ppm benzene was adulterated and should be recalled. This statement was updated on December 27, 2023, and still provides that drug manufacturers "should not release any drug product batch that contains benzene above 2 ppm" and "[i]f any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall[.]"[19]

29. Over the past three years alone, the FDA has announced over a dozen recalls of various drug and cosmetic products identified as containing "low levels" or even "trace levels" of benzene, including certain hand sanitizers and aerosol drug products like sunscreens and antiperspirants.[20]

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[17] David Light, Wolfgang Hinz, PhD, and Kaury Kucera, PhD, *Valisure's FDA Citizen Petition on Benzoyl Peroxide Acne Products*, VALISURE (March 5, 2024), *available at:* https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide (last visited June 24, 2024).

[18] *Id.*

[19] *FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs*, U.S. FOOD & DRUG ADMINISTRATION (Dec. 27, 2023) https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs (last visited June 24, 2024) (The FDA cannot force a drug manufacturer to recall a contaminated or adulterated drug); *Facts About the Current Good Manufacturing Practice (CGMP)*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp (last visited June 15, 2024) ("While FDA cannot force a company to recall a drug, companies usually will recall voluntarily or at FDA's request").

[20] *Johnson & Johnson Consumer Inc. Issues Voluntary Recall of Specific*

**Defendant's History in the Industry**

30. Defendant manufactures, markets, distributes, and sells a skin care product containing BPO, Harris-branded Benzoyl Peroxide 10% Acne Wash. For over 30 years, Defendant has and continues to distribute and sell its products through third party sellers, drug store chains and hospitals.[21] Defendant makes hundreds of generic prescriptions, over the counter, and generic topical dermatological products used by millions of Americans every year, including well known products such as Benzoyl Peroxide 10% Acne Wash. Defendant hires "healthcare veterans", such as clinicians, prescribers, and drug developers, to develop and manufacture FDA-approved prescription products.[22]

31. BPO is an active ingredient in Defendant's BPO Product.

32. Defendant's BPO Product systematically degrades to form benzene. As noted below, this is supported by testing of acne treatment products containing benzoyl peroxide, all of which tested positive for benzene at various levels ranging from 2,000 ppm to 1.8 ppm.

33. Defendant's BPO Product is widely marketed, available, sold, and used by children, teenagers, and adults throughout the United States and the world.

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*NEUTROGENA® and AVEENO® Aerosol Sunscreen Products Due to the Presence of Benzene*, U.S. FOOD & DRUG ADMINISTRATION (July 14, 2021) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-issues-voluntary-recall-specific-neutrogenar-and-aveenor-aerosol (last visited June 24, 2024); *Edgewell Personal Care Issues Voluntary Nationwide Recall of Banana Boat Hair & Scalp Sunscreen Due to the Presence of Benzene*, U.S. FOOD & DRUG ADMINISTRATION (July 29, 2022) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edgewell-personal-care-issues-voluntary-nationwide-recall-banana-boat-hair-scalp-sunscreen-due (last visited June 24, 2024); *P&G Issues Voluntary Recall of Specific Old Spice and Secret Aerosol Spray Antiperspirants and Old Spice Below Deck Aerosol Spray Products Due to Detection of Benzene*, U.S. FOOD & DRUG ADMINISTRATION (Nov. 23, 2021) https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pg-issues-voluntary-recall-specific-old-spice-and-secret-aerosol-spray-antiperspirants-and-old-spice (last visited June 24, 2024).

[21] *Products*, HARRIS PHARMACEUTICAL, https://www.harrispharmaceutical.org/-products last visited June 24, 2024).

[22] *About Us*, HARRIS PHARMACEUTICAL, https://www.harrispharmaceutical.org/about-us (last visited June 24, 2024).

The acne treatment industry is a highly competitive billion-dollar market. To that end, Defendant promotes the BPO Product directly to consumers.

34. Defendant makes promises to consumers such as affirming that the BPO Product is manufactured in facilities with "stellar FDA and cGMP reputations" so that consumers can feel confident in the product.[23] Defendant affirms that dermatology is its foundation, making it capable of producing safe and effective products while providing savings to its customers.[24]

**The Valisure Petition Identified High Levels of Benzene in Defendant's BPO Product**

35. Valisure is an accredited independent laboratory who has developed validated analytical methods[25] to test drugs and consumer products to address rising concerns about public safety. Valisure has tested a wide variety of drugs and products for benzene including hand sanitizers, sunscreens, antiperspirants, and dry shampoos. Their work has led to widely publicized product recalls protecting the public from dangerous and carcinogenic consumer products.

36. On March 5, 2024, Valisure submitted a public citizens petition to the FDA requesting a recall and suspension of sales of products containing benzoyl peroxide from the U.S. market. The petition was based on testing conducted by Valisure in 2023 that found common acne treatment products formulated with BPO are not only contaminated with benzene but have levels dangerous to public health.

37. Valisure tested 175 finished acne treatment products to determine whether any had benzene. Of the 175 products tested, 99 were formulated with

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[23] *Products*, HARRIS PHARMACEUTICAL, https://www.harrispharmaceutical.org/-products last visited June 24, 2024).

[24] *About Us*, HARRIS PHARMACEUTICAL, https://www.harrispharmaceutical.org/about-us (last visited June 24, 2024).

[25] Valisure's test methods largely mirror those utilized by FDA's own "Drug Quality Sampling and Testing" ("DQST") Program. *See Valisure FDA Citizen's Petition on Benzoyl Peroxide* at 4.

BPO.[26] 83 of the BPO products were purchased over the counter from major retailers and 16 were prescription products purchased from licensed wholesalers.[27] The BPO products tested by Valisure included various popular products such as Harris Pharmaceutical's Benzoyl Peroxide 10% Acne Wash, Target Up & Up 2.5% BPO Cream, Equate Beauty 10% BPO Cream, Equate BPO Cleanser, Neutrogena 10% BPO Cleanser, Clearasil 10% BPO Cream, CVS Health 10% BPO Face Wash, Walgreens 10% BPO Cream, La Roche Posay BPO Cream, and Clean & Clear 10% BPO Lotion.

38. To evaluate the effects of common distributor and consumer use, handling, and storage conditions on benzene formation, Valisure used three incubation temperatures: (1) 37°C/98.6°F was used for human body temperature, (2) 50°C/122°F was used to evaluate shelf-life performance as an accelerated stability testing temperature used by the pharmaceutical industry,[26] and (3) 70°C/158°F to model storage in a hot vehicle.

39. The BPO products that Valisure tested were incubated at 50°C for 18 days and benzene concentration was measured at day 0, 4, 10, 14, and 18 using industry standard gas chromatography and detection by mass spectrometry ("GC-MS") instrumentation. These BPO containing products included creams, lotions, gels, washes, liquids, and bars, and included analysis of Defendant's BPO Product.[28] The results below were submitted to the FDA in Valisure's Petition on Benzoyl Peroxide:

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[26] *See Valisure's FDA Citizen Petition on Benzoyl Peroxide Acne Products*, VALISURE (March 5, 2024), *available at:* https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide (last visited June 24, 2024)..

[27] *Id.*

[28] *Valisure Petition* at 15-16

**Figure 4A**

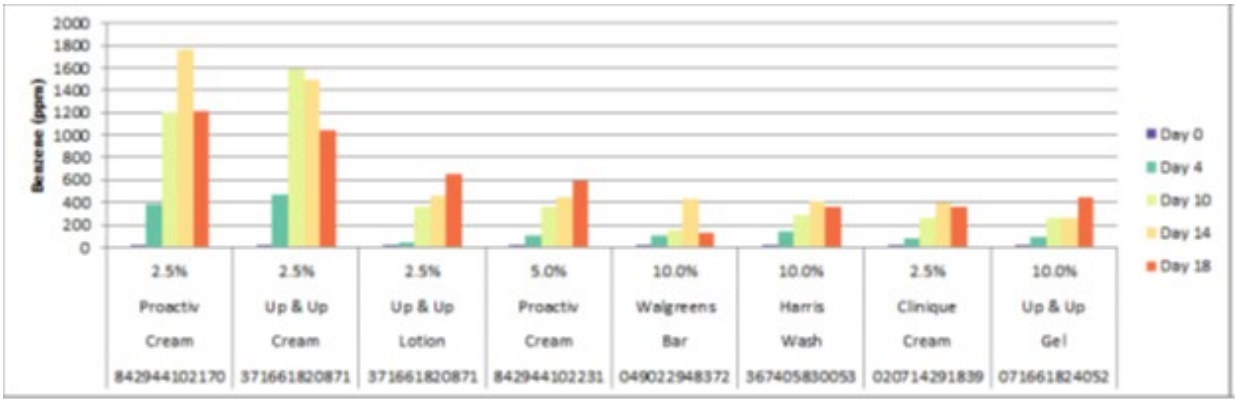



**Figure 4B**

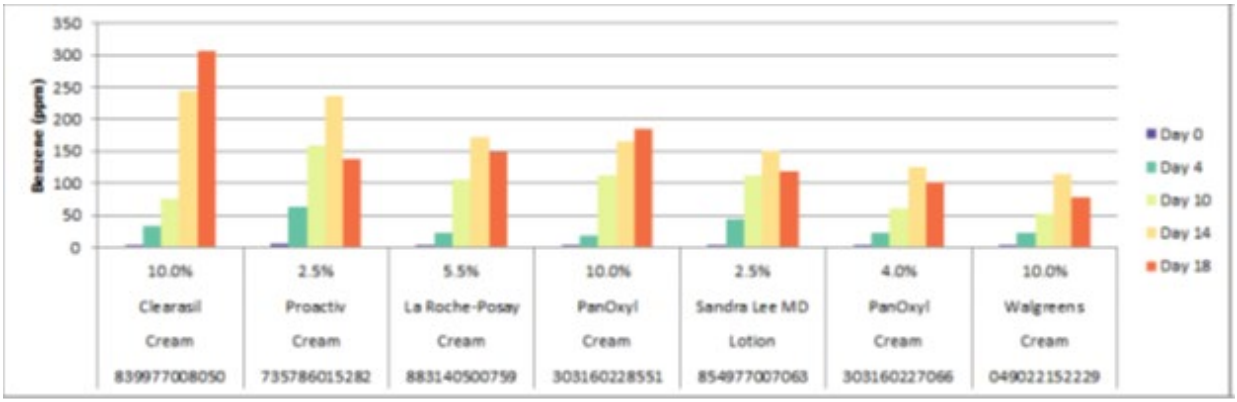



**Figure 4C**

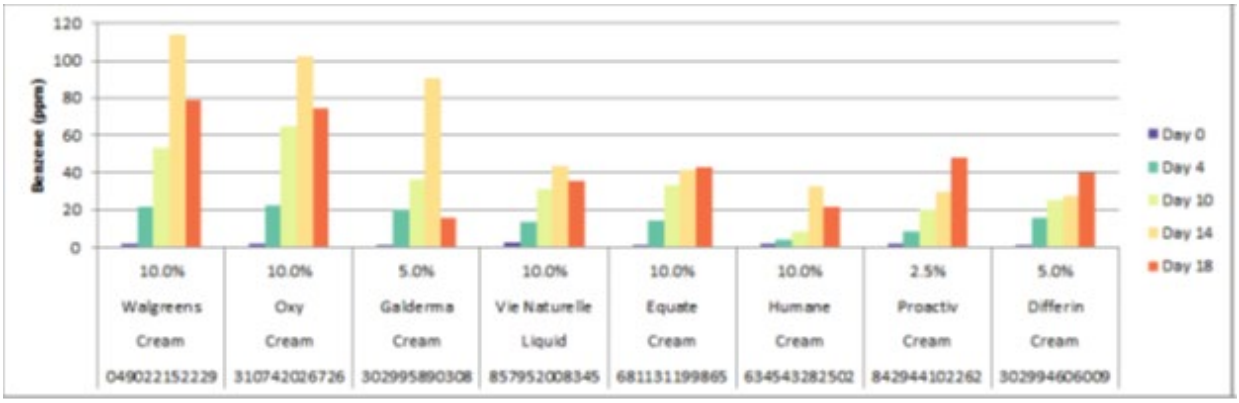


**Figure 4D**

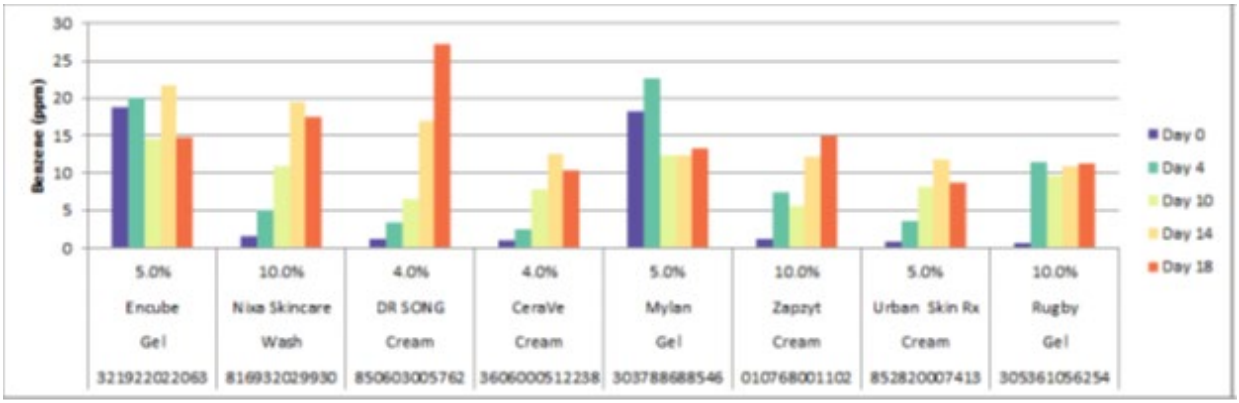



**Figure 4E**

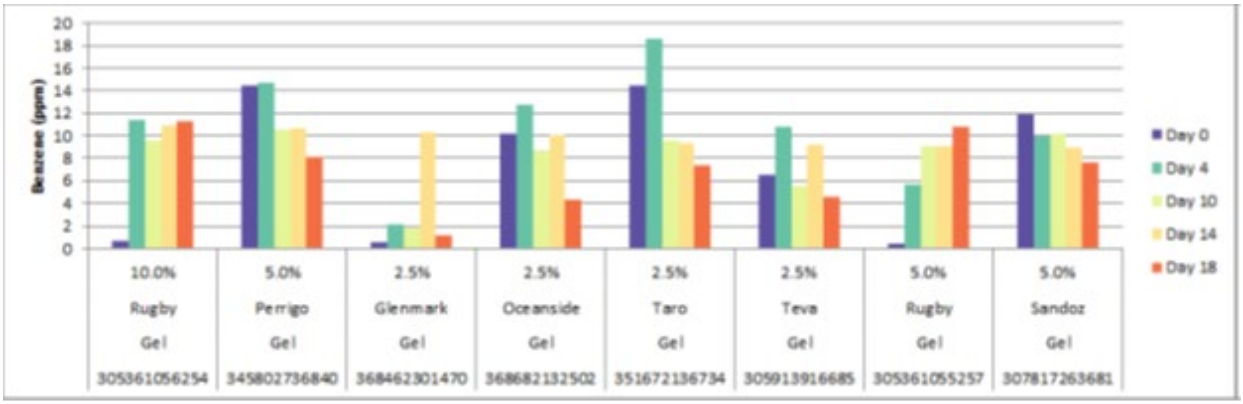



**Figure 4F**

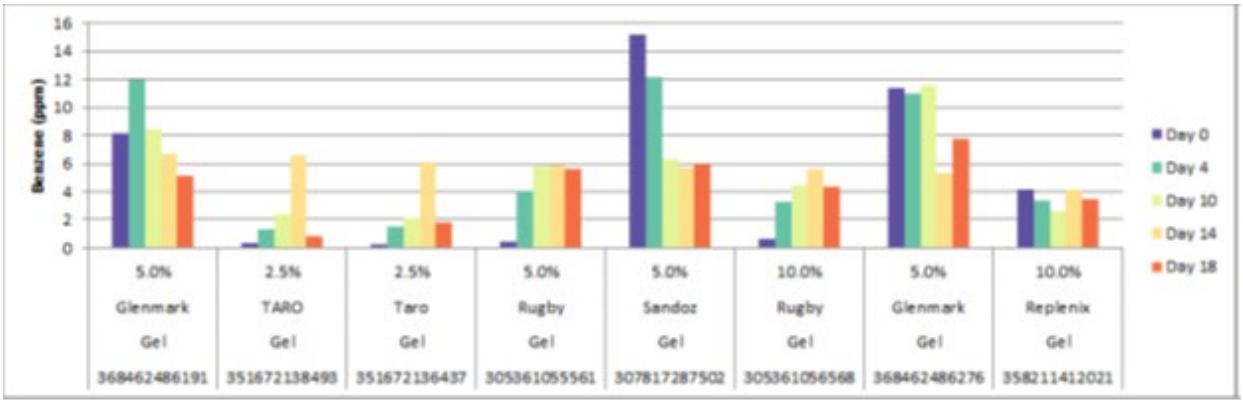


**Figure 4G**

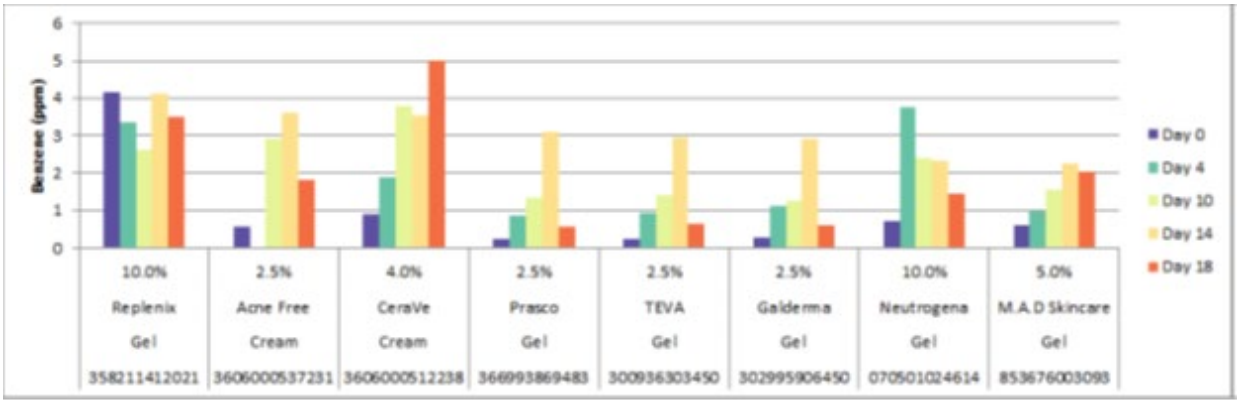
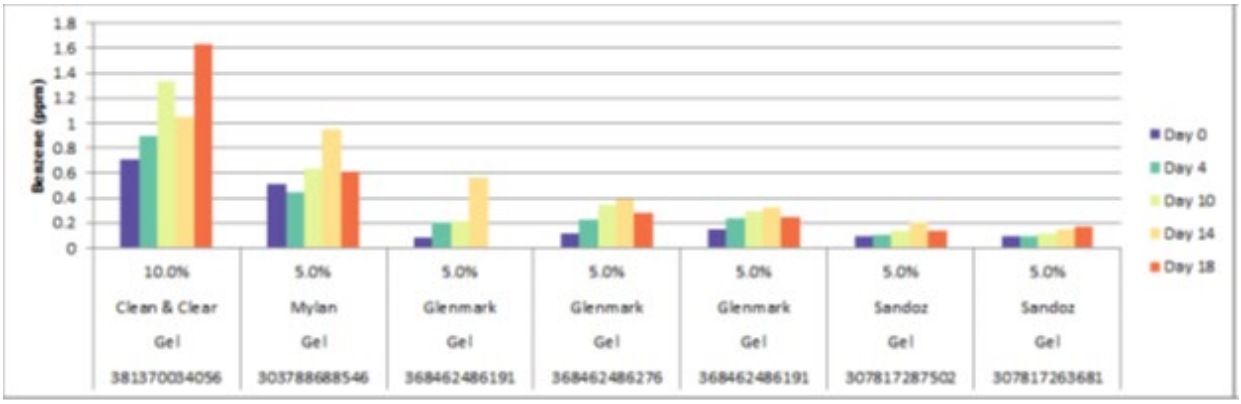



**Figure 4H**


**Figure 4I**




40. As demonstrated in the above charts, results from the 50°C stability testing showed that every one of the tested BPO products, including Defendant's

BPO Product contained and/or degraded to form, dangerous levels of benzene well over 2ppm, the maximum amount allowed in any U.S. regulated drug when the use of benzene is unavoidable.[29] In fact, Defendant's BPO Product consistently topped the charts for benzene levels over 2 ppm which reached as high as approximately ***400 ppm.***

41. Valisure's Petition concluded that all on-market BPO acne formulations seem to be fundamentally unstable and form unacceptably high levels of benzene under normal use, handling, and storage temperatures. Importantly, no such evidence was observed for acne treatment products not formulated with BPO.

**Defendant's Failure to Warn Consumers About BPO Degradation**

42. It is well known among the scientific community that BPO degrades to form benzene when exposed to heat over time and was first reported as early as 1936.[30]

43. The BPO Product is not designed to contain benzene.

44. Defendant holds itself out to be experts in generic dermatological products and employs "healthcare veterans", such as clinicians, prescribers, and drug developers, to develop and manufacture FDA-approved prescription products for public use.

45. Defendant, with these resources and expertise knew, or should have known, of the well-known chemical processes that degrade the BPO in products to form benzene when exposed to common use temperatures and conditions.

46. Defendant's BPO Product lists the ingredients of the BPO Product on its label, including benzoyl peroxide. What Defendant fails to disclose on the BPO Product's labeling or anywhere in its marketing is that the BPO Product contains

[29] *Valisure FDA Citizen's Petition* at 16-18.
[30] H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden,* HELVETICA, Vol. 19, Issue 1, 338-342 (1936) https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153 (last visited June, 24, 2024).

benzene and/or that the BPO in the BPO Product degrades to form benzene even under normal and expected use, handling, and storage.

47. Defendant should have known through its own research, development, formulation, manufacturing, and testing that the BPO Product was not chemically and physically stable. Defendant was required to make sure it adequately tested its BPO Product for safety and stability before selling it to the public, as well as monitor its internal practices, processes, and specifications to make sure its processes and procedures met current and emerging scientific methodologies. This means that during expiration and stability studies examining the "shelf life" of the BPO Product, Defendant knew or should have known that the chemical changes in BPO to benzene took place during normal and expected use and storage conditions.

48. Moreover, Defendant knew or should have known the BPO Product would be handled, used, and stored by distributors, sellers, and consumers under various temperatures that affect chemical stability. For example, Defendant knew or should have known the BPO Product would travel by commercial carriers and distributors in varying storage conditions. Defendant knew or should have known that the BPO Product would be stored by consumers in bathrooms, showers, and in vehicles during warm months where the BPO Product would be exposed to heat.

49. The use, handling, and storage conditions were known or should have been known to Defendant prior to the BPO Product being marketed and sold to Plaintiff and the Class. Defendant knew, or should have known, that under these normal use, handling, and storage conditions by consumers, that the BPO in the BPO Product would degrade to form benzene, exposing consumers to the dangerous carcinogen. Regardless of this fact, Defendant still sold the BPO Product to Plaintiff, the Class, and the public anyway, without warning of the risk of exposure.

## CLASS ACTION ALLEGATIONS

50. Plaintiff brings this action pursuant to Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, individually and on behalf of the following Class:

> All persons who purchased one or more of Defendant's BPO Product in the United States for personal/household use within any applicable limitations period (the "Nationwide Class").

51. Plaintiff brings this action individually and on behalf of the following California Subclass:

> All persons who purchased one or more of Defendant's BPO Product in the state of California for personal/household use within any applicable limitations (the "California Subclass").

52. Excluded from the Class and Subclass are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendant, Defendant's subsidiaries, parents, successors, predecessors, and any entities in which Defendant or its parents and any entities in which Defendant has a controlling interest and its current or former employees, officers, and directors; and (3) individuals who allege personal bodily injury resulting from the use of the BPO Product.

53. **Numerosity (Rule 23(a)(1)):** The exact number of Class Members is unknown and currently unavailable to Plaintiff, but joinder of individual members herein is impractical. The Class is likely comprised of thousands of consumers. The precise number of Class Members, and their addresses, is unknown to Plaintiff at this time, but can be ascertained from Defendant's records and/or retailer records. The Class Members may be notified of the pendency of this action by mail or email, Internet postings and/or publications, and supplemented (if deemed necessary or appropriate by the Court) by published notice.

54. **Predominant Common Questions (Rule 23(a)(2) and (b)(3)):** The Class's claims present common questions of law and fact, and those questions

predominate over any questions that may affect individual Class Members. The common and legal questions include, but are not limited to, the following:

a. Whether the BPO Product contains and/or degrades to form benzene;
b. Whether Defendant knew or should have known that the BPO Product contains and/or degrades to form benzene;
c. Whether Defendant's representations and omissions, in its marketing, advertising, labeling, and packaging of the BPO Product, are misleading;
d. Whether Defendant's representations and omissions, in its marketing, advertising, labeling, and packaging of the BPO Product are reasonably likely to deceive;
e. Whether Defendant engaged in false and misleading advertising;
f. Whether Defendant's internal testing showed that its products contained and/or degraded to form benzene;
g. Whether Defendant violated the state consumer protection statutes alleged herein;
h. Whether Defendant breached its implied warranties;
i. Whether Defendant was unjustly enriched;
j. The nature of relief, including damages and equitable relief, to which Plaintiff and Class Members are entitled.

55. **Typicality of Claims (Rule 23(a)(3)):** Plaintiff's claims are typical of the claims of the Class because Plaintiff, like all other Class Members, purchased the BPO Product, suffered damages as a result of that purchase, and seeks the same relief as the proposed Class Members.

56. **Adequacy of Representation (Rule 23(a)(4)):** Plaintiff adequately represents the Class because her interests do not conflict with the interests of the Class Members, and she has retained counsel competent and experienced in

complex class action and consumer litigation. Plaintiff and her counsel will fairly and adequately protect the interest of the Class Members.

57. **Superiority (Rule 23(b)(3)):** A class action is superior to other available means of adjudication for this controversy. It would be impracticable for Class Members to individually litigate their own claims against Defendant because the damages suffered by Plaintiff and the Class Members are relatively small compared to the cost of individually litigating their claims. Individual litigation would create the potential for inconsistent judgments and delay and expenses to the court system. A class action provides an efficient means for adjudication with fewer management difficulties and comprehensive supervision by a single court.

58. **Declaratory Relief (Fed. R. Civ. P. 23(b)(1) and (2)):** In the alternative, this action may properly be maintained as a class action because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudication with respect to individual Class Members, which would establish incompatible standards of conduct for the Defendant; or the prosecution of separate actions by individual Class Members would create a risk of adjudications with respect to individual Class Members which would, as a practical matter, be dispositive of the interests of other Class Members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; or Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or corresponding declaratory relief with respect to the Class as a whole.

## CAUSES OF ACTION

### COUNT I
### CALIFORNIA UNFAIR COMPETITION LAW
### Cal. Bus. & Prof. Code §§ 17200, *et seq*.
### (On behalf of Plaintiff and the California Subclass)

59. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above in paragraphs 1 through 13 and paragraphs 19 through 57 as though fully set forth herein.

60. Defendant is a "person" as defined by Cal. Bus. & Prof. Code § 17201.

61. Defendant violated Cal. Bus. & Prof. Code §§ 17200, *et seq*. ("UCL") by engaging in unlawful, unfair, misleading, and deceptive business acts and practices.

62. Defendant misrepresented its BPO Product in advertising, labels, and containers and misled Plaintiff and Class about the ingredients, characteristics, quality, approval, and safety of its BPO Product. Defendant led Plaintiff and Class Members to believe its BPO Product was safe.

63. Defendant knew or should have known the BPO Product formulated benzene under normal and expected consumer use, handling, and storage conditions, and that consumers would be exposed to benzene. Defendant was specifically reminded by the FDA of its obligation to ensure the safety and quality of its BPO Product[31], including testing it for benzene before selling it to the public, but reneged on its duties and continued to market and sell the BPO Product without substantiating its safety, or warning Plaintiff, the Class, and the public about benzene.

64. Defendant omitted material health and safety information regarding benzene from its BPO Product's advertising, label, container, and warnings.

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[31] *FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs*, U.S. FOOD & DRUG ADMINISTRATION (Dec. 27, 2023) https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs (last visited June 24, 2024).

Defendant failed to inform Plaintiff and the Class members that its BPO Product would subject them to benzene, a human carcinogen, during normal and expected handling, use and storage of the BPO Product.

65. Defendant's acts and omissions were likely to deceive reasonable consumers and the public. Reasonable consumers expect to be informed about all ingredients in the BPO Product. Furthermore, reasonable consumers expect disclosure of carcinogens contained in the BPO Product. Furthermore, reasonable consumers expect that the BPO Product be free of carcinogens, unless told otherwise.

66. Had Defendant disclosed in its advertising, labeling, packaging, and online statements about benzene in the BPO Product, or the risk of contamination, and the risk of cancer, Plaintiff and the Class members would not have bought the BPO Product.

67. Defendant's misrepresentations and omissions were material because they were likely to deceive reasonable consumers about the safety of Defendant's BPO Product.

68. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent acts and practices, Plaintiff and Class Members were injured and suffered monetary and non-monetary damages, as described herein.

69. Defendant acted intentionally, knowingly, and maliciously to violate California's Unfair Competition Law.

70. Plaintiff and Class Members seek all monetary and non-monetary relief allowed by law, including restitution of all profits stemming from Defendant's unfair, unlawful, and fraudulent business practices; declaratory relief; reasonable attorneys' fees and costs under California Code of Civil Procedure § 1021.5; injunctive relief; and other appropriate equitable relief.

**COUNT II**
**CALIFORNIA FALSE ADVERTISING LAW**
**Cal. Bus. & Prof. Code §§ 17500 *et seq.***
**(On Behalf of Plaintiff and California Subclass)**

71. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above in paragraphs 1 through 13 and paragraphs 19 through 57 as though fully set forth herein.

72. California's False Advertising Law prohibits untrue or misleading statements or omissions in connection with the sale of goods.[1]

73. Defendant's failure to adequately disclose the presence of benzene in its BPO Product, as set forth herein, is likely to deceive the public.

74. Defendant knew, or should have known, that the BPO Product contained benzene and had a duty to disclose its presence to consumers.

75. Defendant's failure to alert consumers to the presence of benzene, misled consumers. Defendant knew, or should have known, that its omissions would result in misleading reasonable consumers.

76. Defendant continues to omit the presence of benzene from its representations and labeling concerning the BPO Product. Prospective injunctive relief is necessary to cure Defendant's conduct.

77. Plaintiff and Class Members are entitled to injunctive and equitable relief, and restitution in the form of a full refund for the amount spent on the BPO Product.

**COUNT III**
**NEGLIGENCE**
**(On behalf of Plaintiff and Nationwide Class)**

78. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above in paragraphs 1 through 13 and paragraphs 19 through 57 as though fully set forth herein.

79. Defendant owed a duty of reasonable care to Plaintiff and the Class Members in the labeling, manufacturing, sale, and distribution of its BPO Product.

80. Defendant also had a duty to exercise reasonable care in properly and accurately representing the safety of its BPO Product to consumers, including Plaintiff and the Class Members.

81. Defendant failed to exercise ordinary care when making the misrepresentations and/or omissions in its marketing and labeling, claiming that its BPO Product was safe.

82. Defendant negligently and falsely misrepresented facts regarding the safety of its BPO Product to Plaintiff and the Class Members.

83. Defendant knew or should have known that the misrepresentations regarding the safety of its BPO Product were misleading. Defendant knew or should have known that these misrepresentations would induce Plaintiff and the Class Members to purchase the BPO Product in reliance of Defendant's claims.

84. As a direct and proximate cause of Defendant's negligent misrepresentations, Plaintiff and the Class Members have suffered harm.

85. Defendant's misrepresentations were material and substantial factors in Plaintiff and Class Members purchasing and paying for the BPO Product.

86. Defendant intended, or had reckless disregard, to induce Plaintiff and Class Members to purchase its BPO Product based on its misrepresentations of safety. Plaintiff and Class Members reasonably relied on the misrepresentations made by Defendant.

87. As a direct and proximate result thereof, Plaintiff and Class Members are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the BPO Product.

**COUNT IV**
**BREACH OF IMPLIED WARRANTY**
**(On behalf of Plaintiff and Nationwide Class)**

88. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above in paragraphs 1 through 15 and paragraphs 19 through 57 as though fully set forth herein.

89. Defendant, as manufacturers and sellers of the BPO Product, made implied warranties including warranting the BPO Product was of the same quality and purity represented on the labels, in advertising, and on Defendant's websites and in advertising. Defendant represented the BPO Product was fit for the ordinary purpose and conformed to the promises made on the containers, labels, advertising, and websites that all ingredients were listed, and all warnings given.

90. Defendant advertised its BPO Product as safe, when it knew, or should have known, that the BPO in the PBO Product degraded to form benzene. Defendant did not list benzene as an ingredient or contaminant anywhere on the BPO Product's or advertising. Defendant did not list proper storage procedures anywhere on the BPO Product or advertising to limit the risk of BPO degradation into benzene. The BPO Product is not of the quality and purity represented by Defendant because the BPO in the BPO Product degrades to form benzene under normal use, handling, and storage conditions.

91. Defendant failed to disclose to Plaintiff and Class Members the BPO Product was not fit for its ordinary use because the BPO Product, as advertised and sold by Defendant, degraded to form benzene under normal and expected handling, use, and storage.

92. Plaintiff and Class Members purchased the BPO Product in reasonable reliance on Defendant's statements, affirmations, and omissions of material health and safety information.

93. Defendant's acts and omissions are ongoing and continuing to cause harm.

94. As a result of Defendant's misconduct, Plaintiff and Class Members seek recovery of actual damages, injunctive relief, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and the actual damages can be measured and returned to consumers who bought Defendant's BPO Product.

**COUNT V**
**UNJUST ENRICHMENT**
**(On behalf of Plaintiff and Nationwide Class)**

95. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above in paragraphs 1 through 13 and paragraphs 19 through 57 as though fully set forth herein.

96. Plaintiff and Class Members conferred benefits upon Defendant. Plaintiff and Class Members paid money for Defendant's worthless and defective BPO Product.

97. Defendant has unjustly retained the benefits conferred upon it by Plaintiff and Class Members.

98. Defendant retained those benefits under circumstances that make it inequitable for Defendant to retain such benefits. Specifically, Defendant retained those benefits even though Defendant's BPO Product contains and/or degrades to form benzene through normal and expected handling, use, and storage and are unfit and unsafe for human use. If Plaintiff and Class Members had known the true nature of Defendant's BPO Product, they would not have purchased the BPO Product or would have paid less for it. Plaintiff and Class Members are therefore entitled to disgorgement and/or restitution as prayed for hereunder.

99. Since Defendant's retention of the non-gratuitous benefits conferred on it by Plaintiff and Class Members is unjust and inequitable, Defendant must pay

restitution to Plaintiff and Class Members for its unjust enrichment, as ordered by the Court.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff, on behalf of herself and the proposed Classes, prays for relief and judgment against Defendant as follows:

a. Certifying the Classes pursuant to Rule 23 of the Federal Rules of Civil Procedure, appointing Plaintiff as representative of the Class, and designating Plaintiff's counsel as Class Counsel;

b. Awarding Plaintiff and the Classes compensatory damages, in an amount exceeding $5,000,000, to be determined by proof;

c. Awarding Plaintiff and the Classes appropriate relief, including but not limited to actual damages;

d. For declaratory and equitable relief, including restitution and disgorgement;

e. For an order enjoining Defendant from continuing to engage in the wrongful acts and practices alleged herein;

f. Awarding Plaintiff and the Classes the costs of prosecuting this action, including expert witness fees;

g. Awarding Plaintiff and the Classes reasonable attorneys' fees and costs as allowable by law;

h. Awarding pre-judgment and post-judgment interest; and

i. Granting any other relief as this Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury of all claims so triable.

Dated: June 25, 2024

Respectfully submitted,

**LEVI & KORSINSKY, LLP**
*/s/ Adam M. Apton*
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