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10 **UNITED STATES DISTRICT COURT**
NORTHERN DISTRICT OF CALIFORNIA

11 **LINDSEY DAUGHERTY, TUAN**
12 **NGUYEN, and COLE SCROGGS,**
13 **individually, and on behalf of all others**
similarly situated,

14
15 **Plaintiffs,**

16 **v.**

17
18 **PADAGIS ISRAEL PHARMACEUTICALS**
19 **LIMITED; PADAGIS US LLC; PADAGIS,**
20 **LLC; and PERRIGO COMPANY PLC,**

21 **Defendants.**

CASE NO. 3:24-cv-2066

CLASS ACTION COMPLAINT FOR:

- 22 **1. UNFAIR COMPETITION IN VIOLATION OF BUSINESS AND PROFESSIONS CODE §17200, et seq.**
- 23 **2. FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS AND PROFESSIONS CODE §17500, et seq.**
- 24 **3. VIOLATION OF MISSOURI MERCHANDISING PRACTICES ACT § 407.010, et seq.**
- 25 **4. FRAUD/MISREPRESENTATION**
- 26 **5. NEGLIGENT MISREPRESENTATION**
- 27 **6. UNJUST ENRICHMENT/QUASI CONTRACT**

DEMAND FOR JURY TRIAL

28 **CLASS ACTION COMPLAINT**

Lindsey Daugherty, Tuan Nguyen, and Cole Scroggs (“Plaintiffs”), individually, and on

1 behalf of all others similarly situated, by and through their attorneys, bring this class action
2 complaint against Defendants Padagis Israel Pharmaceuticals Limited (“Padagis Ltd.”), Padagis
3 US LLC (“Padagis US”), Padagis, LLC (“Padagis LLC”), and Perrigo Company PLC
4 (“Perrigo”) (collectively “Defendants”). Plaintiffs allege the following based upon personal
5 knowledge as well as investigation by counsel, and as to all other matters, upon information and
6 belief. Plaintiffs further believe that substantial evidentiary support will exist for the allegations
7 set forth herein after a reasonable opportunity for discovery.

8 **NATURE OF THE ACTION**

9 1. This is a class action lawsuit regarding Defendant’s manufacturing, distribution,
10 advertising, marketing, and sale of Perrigo® branded benzoyl peroxide products¹ (the “BPO
11 Products”) that contain dangerously high levels of benzene, a carcinogen that has been linked to
12 leukemia and other blood cancers.

13 2. Throughout this Complaint, references to federal law and Food and Drug
14 Administration (“FDA”) regulations are merely to provide context and are not intended to raise a
15 federal question of law. All claims alleged herein arise out of violations of Missouri and
16 California law, which in no way conflict, interfere with, or impose obligations that are materially
17 different than those imposed by federal law.

18 3. Prior to placing the BPO Products into the stream of commerce and into the hands
19 of consumers to use on their skin, Defendants knew or should have known that the BPO Products
20 contained benzene, but misrepresented, omitted, and concealed this fact to consumers, including
21 Plaintiffs and Class members, by not including benzene on the BPO Products’ labels or
22 otherwise warning consumers about its presence.

23 4. Plaintiffs and Class members reasonably relied on Defendants’ representations
24 that the BPO Products were safe, unadulterated, and free of any carcinogens that are not listed on

25 _____
26 ¹ The BPO Products refer to Perrigo® Benzoyl Peroxide Acne Treatment Gel 10% BPO, Perrigo® Benzoyl Peroxide Acne Treatment Gel 5% BPO, Perrigo® Benzoyl Peroxide Acne
27 Treatment Gel 2.5% BPO, Perrigo® Benzoyl Peroxide Acne Medication Wash 10% BPO, and Perrigo® Benzoyl Peroxide Acne Medication Wash 5% BPO.
28

1 the label.

2 5. Plaintiffs and Class members purchased the BPO Products, which contain harmful
3 levels of benzene.

4 6. The BPO Products are worthless because they contain benzene at levels which
5 render the BPO Products adulterated, misbranded, and illegal to sell under federal law and
6 California and Missouri state law.

7 7. Defendants are therefore liable to Plaintiffs and Class members for
8 misrepresenting and/or failing to disclose or warn that the BPO Products contain benzene or that
9 the Products degrade into benzene.

10 **PARTIES**

11 8. Plaintiff Lindsey Daugherty is a resident and citizen of Ukiah, California, located
12 in Mendocino, California. Within the applicable class period, including within the past three
13 years, Plaintiff purchased Defendant's Perrigo® brand Benzoyl Peroxide Acne Treatment Gel
14 2.5% BPO from Riteaid in Mendocino County. When purchasing the BPO Products, Plaintiff
15 reviewed the accompanying labels and disclosures, and understood them as representations and
16 warranties by the manufacturer that the BPO Products were properly manufactured, free from
17 defects, safe for their intended use, and not adulterated or misbranded. Plaintiff relied on these
18 representations and warranties in deciding to purchase the BPO Products manufactured by
19 Defendants, and these representations and warranties were part of the basis of the bargain. Had
20 Plaintiff known that benzene was contained in the Products at the time of purchase or that the
21 Products degraded to form benzene, Plaintiff would not have purchased and used the Products at
22 all or would have paid significantly less for them. Plaintiff would have never paid a premium for
23 BPO Products that contain the carcinogen benzene.

26 9. Plaintiff Tuan Nguyen is a resident and citizen of Fountain Valley, California,
27 located in Orange County. Plaintiff has purchased and used Defendant's Perrigo® brand Benzoyl
28

1 Peroxide Acne Treatment Gel 10% BPO regularly since 2018. Plaintiff most recently purchased
2 the BPO Product in 2024 from BT Pharmacy in Westminster, California. When purchasing the
3 BPO Products, Plaintiff reviewed the accompanying labels and disclosures, and understood them
4 as representations and warranties by the manufacturer that the BPO Products were properly
5 manufactured, free from defects, safe for their intended use, and not adulterated or misbranded.
6 Plaintiff relied on these representations and warranties in deciding to purchase the BPO Products
7 manufactured by Defendants, and these representations and warranties were part of the basis of
8 the bargain. Had Plaintiff known that benzene was contained in the Products at the time of
9 purchase or that the Products degraded to form benzene, Plaintiff would not have purchased and
10 used the Products at all or would have paid significantly less for them. Plaintiff would have
11 never paid a premium for BPO Products that contain the carcinogen benzene.
12

13
14 10. Plaintiff Cole Scroggs is a resident and citizen of Novinger, Missouri, located in
15 Adair County. For the past several years, including from 2020 through 2023, Plaintiff purchased
16 Defendant's Perrigo® brand Benzoyl Peroxide Acne Medication Wash 10% BPO from retail
17 outlets such as Walmart in Missouri and online at Amazon.com. When purchasing the BPO
18 Products, Plaintiff reviewed the accompanying labels and disclosures, and understood them as
19 representations and warranties by the manufacturer that the BPO Products were properly
20 manufactured, free from defects, safe for their intended use, and not adulterated or misbranded.
21 Plaintiff relied on these representations and warranties in deciding to purchase the BPO Products
22 manufactured by Defendants, and these representations and warranties were part of the basis of
23 the bargain. Had Plaintiff known that benzene was contained in the Products at the time of
24 purchase or that the Products degraded to form benzene, Plaintiff would not have purchased and
25 used the Products at all or would have paid significantly less for them. Plaintiff would have
26
27
28

1 never paid a premium for BPO Products that contain the carcinogen benzene.

2 11. Standing is satisfied by alleging economic injury. Here, Plaintiffs suffered
3 economic injury when they spent money to purchase BPO Products they would not otherwise
4 have purchased, or paid less for, absent Defendants' misconduct, as alleged herein. Members of
5 the putative class have likewise suffered economic injuries in that they have spent money to
6 purchase BPO Products they would not otherwise have purchased, or paid less for, absent
7 Defendants' misconduct, as alleged herein.
8

9 12. Defendant Padagis Israel Pharmaceuticals Limited is a corporation organized and
10 existing under the laws of Israel, with its principal place of business at 1 Rakefet Street, Shoham,
11 Israel 6085001. Upon information and belief, Defendant Padagis Israel Pharmaceuticals Limited
12 is a wholly owned subsidiary of Defendant Padagis LLC.
13

14 13. Defendant Padagis US LLC is a Delaware limited liability company. Padagis US
15 LLC's sole member is Padagis Acquisition Holding Company LLC, with a principal place of
16 business at 1251 Lincoln Road, Allegan, Michigan 49010. Padagis Acquisition Holding
17 Company LLC's sole member is Amethyst Cederholm, Executive Vice President and General
18 Counsel of Padagis LLC, whose address is 1251 Lincoln Road, Allegan, Michigan 49010. Thus,
19 Padagis US LLC is a citizen of Michigan.
20

21 14. Defendant Padagis LLC is a Delaware limited liability company. Padagis LLC's
22 sole member is Padagis Acquisition Holding Company LLC, with a principal place of business at
23 1251 Lincoln Road, Allegan, Michigan 49010. Padagis Acquisition Holding Company LLC's
24 sole member is Amethyst Cederholm, Executive Vice President and General Counsel of Padagis
25 LLC, whose address is 1251 Lincoln Road, Allegan, Michigan 49010. Thus, Padagis LLC is a
26 citizen of Michigan.
27
28

1 15. Upon information and belief, Padagis LLC directs the operations, management,
 2 and activities of Defendants Padagis Israel Pharmaceuticals Ltd. and Padagis US LLC in the
 3 United States.

4 16. Defendant Perrigo Company PLC is a Delaware corporation with its principal
 5 place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Upon information and
 6 belief, Parrigo Company PLC is a distributor of the BPO Products, including the specific BPO
 7 Products purchased by Plaintiffs.
 8

9 17. Upon information and belief, Defendants engage in the manufacture, marketing,
 10 distribution and sale of over-the-counter drug products (including the BPO Products at issue)
 11 throughout the United States, including in California and Missouri. The BPO Products, including
 12 those purchased by Plaintiffs and Class members, are available for sale on third party websites
 13 like Amazon (www.amazon.com) and are sold by various retailers such as Walmart, both online
 14 and in their brick-and-mortar stores throughout the United States. Defendants authorized the
 15 false, misleading, and deceptive marketing, advertising, distribution, and sale of its BPO
 16 Products.
 17

18 **JURISDICTION AND VENUE**

19 18. This Court has original jurisdiction over all causes of action asserted herein under
 20 the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because the matter in controversy
 21 exceeds the sum or value of \$5,000,000 exclusive of interest and costs and is a class action in
 22 which there are more than 100 class members and many members of the class are citizens of a
 23 state different than Defendant.
 24

25 19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because Plaintiffs
 26 suffered injury as a result of Defendants’ acts in this district, many of the acts and transactions
 27
 28

1 giving rise to this action occurred in this district, Defendants conduct substantial business in this
2 district, Defendants have intentionally availed themselves of the laws and markets of this district,
3 and Defendants are subject to personal jurisdiction in this district.

4 **FACTUAL ALLEGATIONS**

5
6 ***I. Defendants' History in the Industry***

7 20. Defendants manufacturer, market, distribute, and/or sell various skin care
8 products, including the BPO Products.

9 21. Benzoyl peroxide is an active ingredient in all the BPO Products.

10 22. All of Defendants BPO Products are manufactured in the same manner.

11 23. All lots of Defendants' BPO Products contain and/or or systematically degrade to
12 form benzene. As noted below, this is supported by testing of 66 acne treatment products
13 containing benzoyl peroxide, all of which tested positive for benzene at various levels ranging
14 from 2,000 ppm to 1.8 ppm. Defendants' Perrigo® Benzoyl Peroxide Acne Treatment Gel 5%
15 BPO, in particular, was tested and found to contain over 14 ppm benzene. These results have
16 been published in peer-reviewed literature.²

17 24. The rates of degradation and benzene impurities in the BPO Products occur at a
18 systematic rate.

19 ***II. Evidence of Benzene's Danger***

20 25. Benzene is used primarily as a solvent in the chemical and pharmaceutical
21 industries, as a starting material and intermediate in the synthesis of numerous chemicals, and in
22 gasoline. The major United States source of benzene is petroleum. The health hazards of benzene
23 have been recognized for over one hundred years.

24
25 _____
26 ² Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light DY. Benzoyl Peroxide Drug Products Form Benzene. Environ Health Perspect. 2024
27 Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID:
28 PMC10939128.

1 26. “Human exposure to benzene has been associated with a range of acute and long-
2 term adverse health effects and diseases, including cancer and haematological effects.”³

3 27. A toxicity assessment by the Centers for Disease Control and Prevention has
4 shown benzene can harm the central nervous system and may affect reproductive organs.⁴

5 28. According to the World Health Organization, “Benzene is a genotoxic carcinogen
6 in humans and no safe level of exposure can be recommended.”⁵

7 29. According to the National Cancer Institute, “[e]xposure to benzene increases the
8 risk of developing leukemia and other blood disorders.”⁶

9 30. According to the National Toxicology Program, benzene is “known to be a human
10 carcinogen based on sufficient evidence of carcinogenicity from studies in humans.”⁷

11 31. Benzene has also been “found to be carcinogenic to humans” by the International
12 Agency for Research on Cancer (“IARC”). Benzene was “[f]irst evaluated by IARC in 1974 . . .
13 and was found to be carcinogenic to humans (Group 1), a finding that has stood since that
14 time.”⁸ As noted by the IARC:

15
16 In the current evaluation, the Working Group again confirmed the carcinogenicity
17 of benzene based on *sufficient evidence* of carcinogenicity in humans, *sufficient*
18 *evidence* of carcinogenicity in experimental animals, and *strong* mechanistic
19 evidence. . . . The Working Group affirmed the strong evidence that benzene is
20 genotoxic, and found that it also exhibits many other key characteristics of
21 carcinogens, including in exposed humans. In particular, benzene is metabolically
22 activated to electrophilic metabolites; induces oxidative stress and associated
23 oxidative damage to DNA; is genotoxic; alters DNA repair or causes genomic
24 instability; is immunosuppressive; alters cell proliferation, cell death, or nutrient
25 supply; and modulates receptor-mediated effects.⁹

26 32. The FDA also recognizes that “[b]enzene is a carcinogen that can cause cancer in

24 ³ <https://www.who.int/publications/i/item/WHO-CED-PHE-EPE-19.4.2>.

25 ⁴ <https://www.atsdr.cdc.gov/toxprofiles/tp3.pdf>.

26 ⁵ WHO Guidelines for Indoor Air Quality: Selected Pollutants (2010).

27 ⁶ <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene>.

28 ⁷ <http://ntp.niehs.nih.gov/go/roc/content/profiles/benzene.pdf> (emphasis in original).

⁸ Benzene / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2017: Lyon, France), at p. 33.

⁹ *Id.* at 34.

1 humans”¹⁰ and classifies benzene as a “Class 1” solvent that should be “avoided” in drug
2 manufacturing.¹¹ FDA guidance provides: “Solvents in Class 1 [e.g. benzene] should not be
3 employed in the manufacture of drug substances, excipients, and drug products because of [its]
4 unacceptable toxicity.”¹²

5 33. In July 2021, the FDA conducted a “Health Hazard Evaluation” on “Multiple
6 Aerosol Sunscreen Products” manufactured by Johnson & Johnson.¹³ The evaluation was
7 requested following testing which showed benzene levels ranging “from 11.2 to 23.6 ppm” in
8 Johnson & Johnson’s aerosol sunscreen products. Specifically, the agency requested “an
9 evaluation of the likelihood and risks associated with using aerosol sunscreens that contain
10 benzene 11.2 to 23.6 ppm,” which “levels exceed the guideline value provided by ICH [Q3C]¹⁴
11 and USP¹⁵” limits, states the report. The evaluation concluded that serious adverse effects,
12 including potential for “life-threatening” issues or “permanent impairment of a body function”
13 were “likely to occur” at exposure levels within that range. In addition, the evaluation stated that
14 “individuals with altered skin absorption (i.e., infants, elderly, broken skin) and individuals who
15 are exposed to benzene from other sources . . . may be at greater risk.”

16 34. On December 27, 2023, in response to reports of benzene contamination in
17 various drug products, the FDA issued an “Alert,” stating: “Drug manufacturers with a risk for
18 benzene contamination should test their drugs accordingly and should not release any drug
19 product batch that contains benzene above 2 ppm[.] . . . If any drug product batches with benzene
20 above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the
21

22 ¹⁰ [https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-
23 and-other-beverages#q1](https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-and-other-beverages#q1).

24 ¹¹ <https://www.fda.gov/media/71737/download>.

25 ¹² *Id.*

26 ¹³ [https://article.images.consumerreports.org/prod/content/dam/CRO-Images-
27 2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment](https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment).

28 ¹⁴ The term “ICH” refers to The International Conference on Harmonization (ICH) Q3C
Impurities: Residual Solvents guidance (December 1997), at
<https://www.fda.gov/media/71736/download?attachment>.

¹⁵ The term “USP” refers to United States Pharmacopeia (USP) Residual Solvents, at
https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf.

1 voluntary initiation of a recall[.]”¹⁶

2 35. “Even in trace amounts, benzene is known to pose a health risk from exposure
3 routes that include inhalation, ingestion, dermal absorption, and skin or eye contact.”¹⁷

4 36. As with other topically applied products, such as sunscreen, the application of
5 BPO Products specifically increases the absorption rate of benzene through the skin, thereby
6 increasing the risk of harm.¹⁸ Indeed, “[d]irect exposure of the eyes, skin, or lungs to benzene
7 can cause tissue injury and irritation.”¹⁹ Accordingly, The National Institute for Occupational
8 Safety and Health (“NIOSH”) recommends protective equipment be worn by workers exposed or
9 expecting to be exposed to benzene at concentrations of 0.1 ppm and defines “inhalation, skin
10 absorption, ingestion, skin and/or eye contact” as exposure routes or paths.²⁰

11 37. The Environmental Protection Agency (“EPA”) similarly recognizes the cancer
12 risks of benzene, noting that “Benzene is classified as a ‘known’ human carcinogen (Category A)
13 under the Risk Assessment Guidelines of 1986.”²¹ “[B]enzene is characterized as a known
14 human carcinogen for all routes of exposure based on convincing human evidence as well as
15 supporting evidence from animal studies.”²²

16 38. EPA has set 0.0005 ppm as the maximum permissible level of benzene in
17 drinking water, with a stated goal of “zero.”²³

18 39. In its review of non-cancer adverse health effects of benzene, the EPA cited
19

20 ¹⁶ [https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-
21 risk-benzene-contamination-certain-drugs](https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs).

22 ¹⁷ Hudspeth, A., et al., Independent Sun Care Product Screening for Benzene Contamination, Environmental Health Perspectives, 130:3, Online Publication 29 March 2022.

23 ¹⁸ *Valisure Detects Benzene in Sunscreen*, VALISURE BLOG (May 25, 2021),
<https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/>.

24 ¹⁹ *Facts About Benzene*, CENTERS FOR DISEASE CONTROL AND PREVENTION,
<https://emergency.cdc.gov/agent/benzene/basics/facts.asp>.

25 ²⁰ *NIOSH Pocket Guide to Chemical Hazards - Benzene*, THE NATIONAL INSTITUTE FOR
OCCUPATIONAL SAFETY AND HEALTH (NIOSH),
<https://www.cdc.gov/niosh/npg/npgd0049.html>.

26 ²¹ https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?substance_nmbr=276.

27 ²² *Id.*

28 ²³ [https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-
regulations](https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations).

1 epidemiologic evidence that “support a threshold of benzene hematotoxicity²⁴ in humans in the
 2 5-19 ppm range[.]”²⁵ As noted in the EPA’s review, “[c]learly, if a significantly elevated risk of
 3 benzene poisoning is an indication of hematotoxicity, then certainly exposures to benzene at 5-19
 4 ppm are hematotoxic.”²⁶

5 *III. Discovery of Benzene in the BPO Products*

6 40. On March 5, 2024, Valisure LLC (“Valisure”) submitted a public citizens petition
 7 to the FDA requesting a recall and suspension of sales of benzoyl peroxide from the U.S. market.
 8 The petition was based on Valisure’s findings that numerous BPO products contained elevated
 9 levels of benzene, a known human carcinogen.²⁷

10 41. “Valisure operates an analytical laboratory that is accredited under International
 11 Organization for Standardization (‘ISO/IEC’) 17025:2017 standards for chemical testing (PJLA
 12 Accreditation Number 94238),” and it “is registered with the Drug Enforcement Administration
 13 (License # RV0484814).”²⁸ As an industry leader in independent chemical testing of
 14 medications, Valisure works with large private health care systems like Kaiser Permanente and
 15 governmental healthcare systems like the Military Health System through the U.S. Department
 16 of Defense.²⁹

17 42. In its citizens petition, Valisure reported its testing results for benzene in various
 18 types of BPO drug products, mostly utilizing gas chromatography and detection by mass
 19

20
 21 ²⁴ The term “hematotoxic” means “poisonous to the blood and to the organs and tissues involved
 22 in the production of blood, such as the bone marrow.”

<https://clinicalinfo.hiv.gov/en/glossary/hematotoxic>.

²⁵ EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38.

https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf.

²⁶ *Id.*

²⁷ [https://assets-global.website-](https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf)

[files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf](https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf).

²⁸ *Id.*

26 ²⁹ Valisure Signs Agreement with Department of Defense to Independently Test & Quality Score
 27 Drugs. (August 8, 2023). PR Newswire. ([https://www.prnewswire.com/newsreleases/valisure-](https://www.prnewswire.com/newsreleases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs301895301.html)
 28 [signs-agreement-with-department-of-defense-to-independently-test--quality-score-](https://www.prnewswire.com/newsreleases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs301895301.html)
[drugs301895301.html](https://www.prnewswire.com/newsreleases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs301895301.html)).

1 spectrometry (“GC-MS”) instrumentation that allows mass spectral separation and utilizing
2 selected ion chromatograms, along with Selected Ion Flow Tube-Mass Spectrometry (“SIFT-
3 MS”) for detection of benzene released into the air around certain BPO products. Valisure also
4 used other orthogonal approaches for confirmation of a few select products.³⁰

5 43. GC-MS “is generally considered one of the most accurate analyses available.”³¹
6 Indeed, the FDA used the same method to test for impurities like benzene in hand sanitizers.³²

7 44. “The GC-MS method described in [Valisure’s] petition utilized body temperature
8 (37°C) for oven incubation. 40°C has been previously used for benzene analysis from liquid
9 pharmaceuticals and beverages, and reduced false positive results compared with higher-
10 temperature incubation.”³³

11 45. As reported, Valisure analyzed 66 different BPO containing drug products, both
12 prescription and over-the-counter (“OTC”) for the presence of benzene. Valisure acquired the
13 products and incubated the products at 50°C³⁴ for 18 days, with samples measured at day 0, 4,
14 10, 14, and 18. These BPO containing products represented creams, lotions, gels, washes,
15 liquids, and bars, and included analysis of Defendant’s Equate® Beauty Acne Wash 10% BPO
16 cream.³⁵ As demonstrated below, results from this 50°C stability showed that every one of the 66
17 products, including Defendants’ Perrigo® Benzoyl Peroxide Acne Treatment Gel 5% BPO,
18 contained some level of benzene ranging from a maximum of 2,000 ppm to 1.8 ppm.³⁶

19 46. Valisure’s findings with respect to its benzene testing of the BPO Product has
20

21
22 ³⁰ *Id.* at 10.

³¹ *GC/MS Analysis*, Element, <https://www.element.com/materials-testing-services/chemical-analysis-labs/gcms-analysis-laboratories>.

23 ³² *Direct Injection Gas Chromatography Mass Spectrometry (GC-MS) Method for the Detection*
24 *of Listed Impurities in Hand Sanitizers*, FDA (Aug. 24, 2020),
<https://www.fda.gov/media/141501/download>.

³³ *Valisure Citizen Petition* at 10-11 (citations omitted).

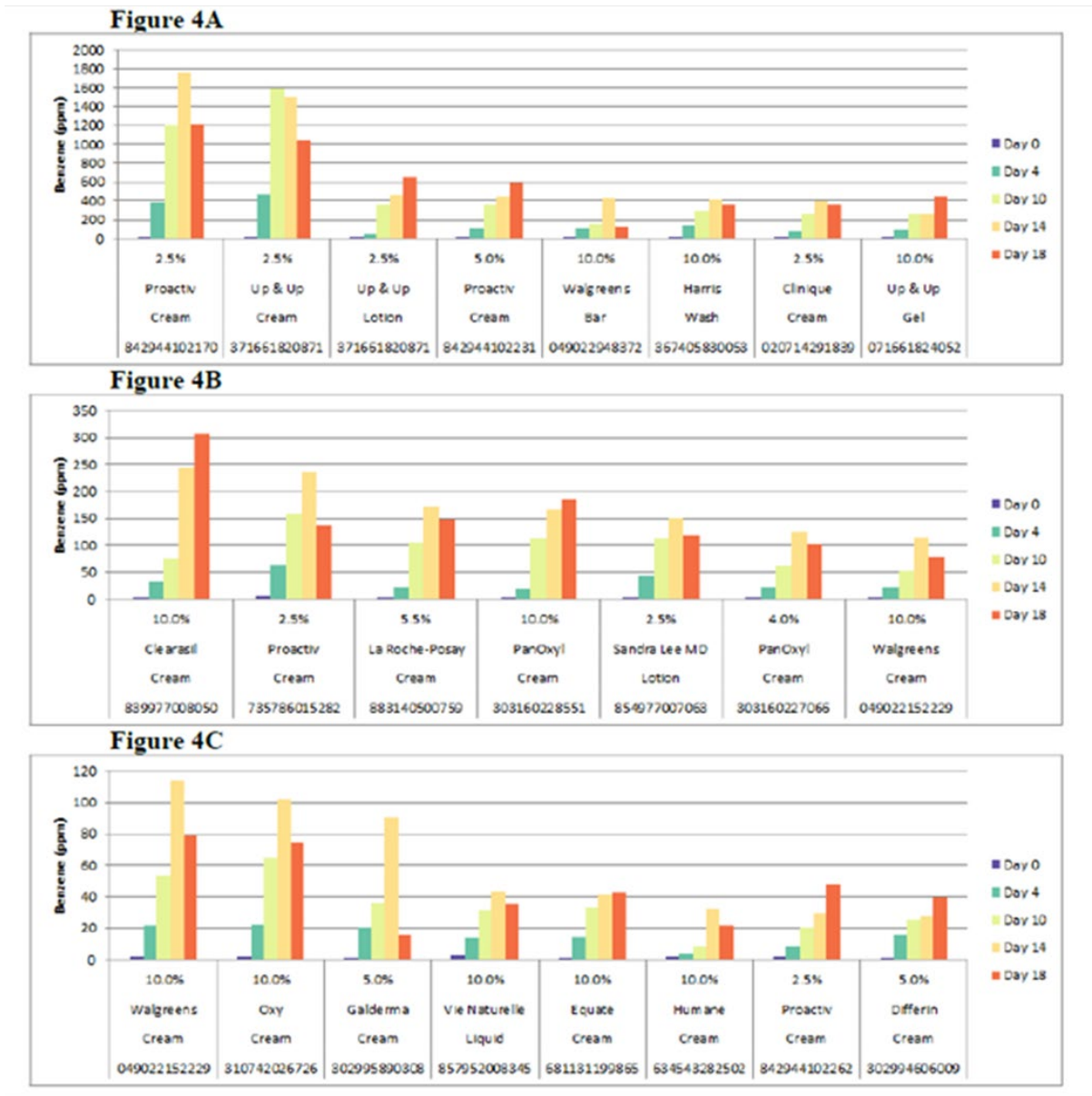
25 ³⁴ “50°C (122°F) is not only a reasonable temperature that ‘the product may be exposed to during
26 distribution and handling by consumers’ but is an accepted incubation temperature used by the
pharmaceutical industry for performing accelerated stability studies with a duration of at least 3
27 months.” *Id.* at 18-19 (citations omitted).

³⁵ *Id.* at 16, 23.

³⁶ *Id.* at 16-18.

1 been published in peer-reviewed literature.³⁷

2 47. As noted in the chart below, testing conducted on Defendants’ Perrigo® Benzoyl
 3 Peroxide Acne Treatment Gel 5% BPO, in particular, revealed benzene levels over 14 ppm.³⁸



25 ³⁷ Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light
 26 DY. Benzoyl Peroxide Drug Products Form Benzene. Environ Health Perspect. 2024
 27 Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID:
 28 PMC10939128.

³⁸ Valisure Citizen Petition at 16. The Universal Product Code (“UPC”) for the test conducted on
 PanOxyl® Acne Foaming Wash 10% BPO is identified as 303160228551.

Figure 4G

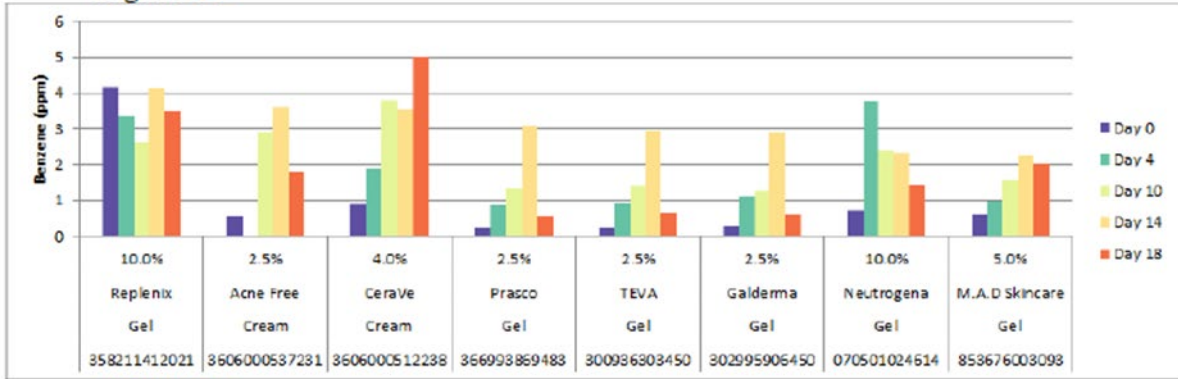


Figure 4H

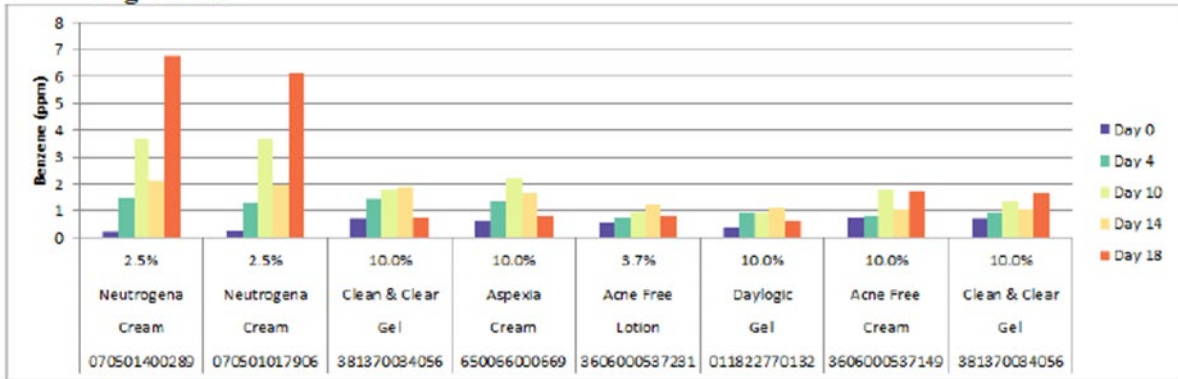
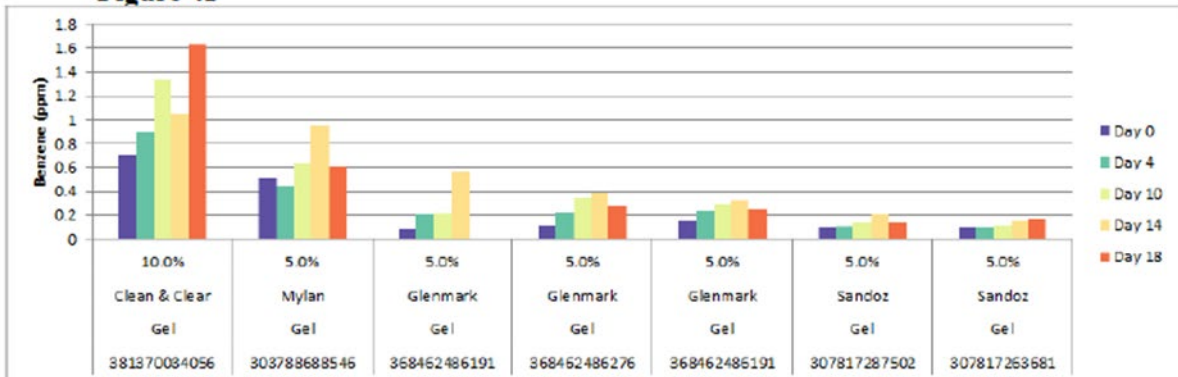


Figure 4I



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1 48. The BPO Products are not designed to contain benzene, and no amount of
2 benzene is acceptable in acne treatment products such as the BPO Products manufactured,
3 distributed, and sold by Defendant. Further, although Defendants lists the ingredients on the BPO
4 Products' labels, Defendants fail to disclose on the Products' labeling or anywhere in its
5 marketing that the BPO Products contain benzene or that the Products can degrade to form
6 benzene.
7

8 49. Despite its knowledge that the BPO Products contain benzene, Defendants have
9 failed to issue a voluntary recall of the BPO Products.
10

11 ***IV. Benzene Renders the BPO Products Adulterated, Misbranded, and Illegal to***
12 ***Sell***

13 50. The BPO Products are “drugs” used to treat acne (i.e., *acne vulgaris*), formulated
14 with a chemical called benzoyl peroxide, along with other inactive ingredients, to make acne
15 treatment creams, washes, scrubs, and bars. Before being sold to the public, the BPO Products
16 must be made in conformity with current good manufacturing practices and must conform to
17 quality, safety, and purity specifications. Under the FDCA, a drug is adulterated “if it is a drug
18 and the methods used in, or the facilities or controls used for, its manufacture, processing,
19 packaging, or holding do not conform to or are not operated or administered in conformity with
20 current good manufacturing practice...”³⁹
21

22 51. Benzene is restricted by the FDA to 2 ppm where its use in manufacturing “is
23 unavoidable in order to produce a drug product with a significant therapeutic advance.”⁴⁰ Except
24 in such “limited cases,” Class 1 solvents such as benzene should not be employed in the
25

26
27 ³⁹ 21 U.S.C. § 351(a)(2)(B).

28 ⁴⁰ 2018 ICH Q3C guidance, at p. 5. US FDA, June 2017 (available at <https://www.fda.gov/media/71737/download>).

1 manufacture of drug substances or drug products “because of their unacceptable toxicity.”⁴¹
2 Defendants’ BPO Products do not meet this safe harbor exception. This is because the use of
3 benzene in the manufacture of the BPO Products is not “unavoidable,” nor does the use of
4 benzene in BPO Products provide a “significant therapeutic advance.” That is why, in December
5 2022, the FDA issued a statement alerting manufacturers to the risk of benzene contamination
6 and warned that any drug product containing more than 2 ppm benzene was adulterated and
7 should be recalled. This statement was updated on December 27, 2023, and still provides that
8 drug manufacturers “should not release any drug product batch that contains benzene above 2
9 ppm,” and further provides, “[i]f any drug product batches with benzene above 2 ppm are
10 already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation
11 of a recall[.]”⁴²
12

13
14 52. It is therefore illegal under federal law to manufacture and distribute drug
15 products in the United States that contain benzene above 2 ppm.⁴³ Hence, within the past three
16 years alone, the FDA has announced over a dozen recalls of various drug and cosmetic products
17 identified as containing “low levels” or even “trace levels” of benzene, including certain hand
18 sanitizers and aerosol drug products like sunscreens and antiperspirants.⁴⁴
19

20
21 ⁴¹ *Reformulating Drug Products That Contain Carbomers Manufactured With Benzene*;
22 *Guidance for Industry – Final Guidance*. US FDA, December 27, 2023 (citing 2018 ICH Q3C
guidance at p. 5) (available at <https://www.regulations.gov/document/FDA-2023-D-5408-0002>).

23 ⁴² [https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-
24 risk-benzene-contamination-certain-drugs](https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs). The FDA cannot force a drug manufacturer to recall a
contaminated or adulterated drug. [https://www.fda.gov/drugs/pharmaceutical-quality-
25 resources/facts-about-current-good-manufacturing-practice-cgmp](https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp) (“While FDA cannot force a
company to recall a drug, companies usually will recall voluntarily or at FDA’s request”).

26 ⁴³ 21 U.S.C. § 351(a)(2)(B).

27 ⁴⁴ [https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-
28 consumer-inc-issues-voluntary-recall-specific-neutrogena-and-aveenor-aerosol](https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-issues-voluntary-recall-specific-neutrogena-and-aveenor-aerosol);
[https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edgewell-personal-care-
issues-voluntary-nationwide-recall-banana-boat-hair-scalp-sunscreen-due-0](https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edgewell-personal-care-issues-voluntary-nationwide-recall-banana-boat-hair-scalp-sunscreen-due-0);

1 53. It is also illegal to distribute benzene contaminated drug products under California
 2 and Missouri law. For example, in Missouri, “[a] drug ... shall be deemed to be adulterated: (1)
 3 If it consists in whole or part of any filthy, putrid, or decomposed substance; or (2) It has been
 4 produced, prepared, packed, or held under insanitary conditions whereby it may have been
 5 contaminated with filth, or whereby it may have been rendered injurious to health; or ... (6) If
 6 [its] purity or quality falls below [] that which it purports or is represented to possess.”⁴⁵

8 54. Because all of Defendants’ BPO Products contain benzene above 2 ppm, the
 9 Products (1) consist of a filthy, putrid, and/or decomposed substance (i.e. benzene), (2) have
 10 been produced under conditions whereby it is injurious to health (i.e. benzene exposure), (3)
 11 have a purity or quality that falls below that which it purports or is represented to possess. As a
 12 result, it is illegal under Missouri law for Defendants to distribute any of its BPO Products in the
 13 State of Missouri.

14 55. As alleged herein, Defendants’ BPO Products contain more than 2 ppm benzene
 15 and have been distributed to residents of the states of California and Missouri, including
 16 Plaintiffs, in violation of Missouri and California law.

17 56. The manufacture of any misbranded or adulterated drug is prohibited under
 18 federal law⁴⁶ and California⁴⁷ and Missouri⁴⁸ and state law.

19 57. The introduction into commerce of any misbranded or adulterated drug is
 20

21 [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#:~:text=The%20Procter%20%26%20Gamble%20Company%20\(NYSE,level%20due%20to%20the%20presence.](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#:~:text=The%20Procter%20%26%20Gamble%20Company%20(NYSE,level%20due%20to%20the%20presence.)

24 ⁴⁵ Mo. Rev. Stat. § 196.095 (1), (2), (6).

24 ⁴⁶ 21 U.S.C. §331(g).

25 ⁴⁷ Cal. Health & Safety Code § 111250 (“It is unlawful for any person to manufacture, sell,
 26 deliver, hold, or offer for sale any drug or device that is adulterated.”); [Cal. Health & Safety Code § 111330](#) (“Any drug or device is misbranded if its labeling is false or misleading in any particular.”).

27 ⁴⁸ Mo. Rev. Stat. § 196.015(1) (“The following acts and the causing thereof within the state of Missouri are hereby prohibited: (1) The manufacture, sale, or delivery, holding or offering for sale any ... drug ... that is adulterated or misbranded”).

1 similarly prohibited.⁴⁹

2 58. The receipt in interstate commerce of any adulterated or misbranded drug is also
3 unlawful.⁵⁰

4 59. Among the ways a drug may be adulterated are:

5 If it consists in whole or in part of any filthy, putrid, or
6 decomposed substance; or . . . whereby it may have been rendered
injurious to health;⁵¹

7 60. Among the ways a drug may be misbranded include:

- 8 (1) The dissemination of any false advertisement.⁵²
9 (2) The using, on the labeling of any drug or in any advertising
10 related to such drug, of any representation or suggestion that ...
such drug complies with the provisions of such section.⁵³

11 61. Defendants could have avoided any potential for benzene contamination in the
12 BPO Products by changing the manufacturing process or raw ingredients, and the BPO Products
13 could have been sold with absolutely no benzene in them. Specifically, BPO as a raw material is
14 known to be thermally stable at purities as high as 75% up to temperatures of 98°C.⁵⁴ Valisure
15 also evaluated pure BPO reference powder in its GC-MS analytical system and found no
16

17 ⁴⁹Mo. Rev. Stat. § 196.015(1); Cal. Health & Safety Code § 111305 (“It is unlawful for any
18 person to receive in commerce any drug or device that is adulterated or to deliver or proffer for
delivery any drug or device.”).

19 ⁵⁰Mo. Rev. Stat. § 196.015(3); Cal. Health & Safety Code § 111305 (“It is unlawful for any
20 person to receive in commerce any drug or device that is adulterated or to deliver or proffer for
delivery any drug or device.”).

21 ⁵¹ 21 U.S.C. §351(a)(2)(B). *See also* Mo. Rev. Stat. § 196.095(1) (“A drug or device shall be
deemed to be adulterated: (1) If it consists in whole or part of any filthy, putrid, or decomposed
22 substance”); Cal. Health & Safety Code § 111250 (“Any drug or device is adulterated if it
consists, in whole or in part, of any filthy, putrid, or decomposed substance.”); Cal. Health &
23 Safety Code § 111255 (“Any drug or device is adulterated if it has been produced, prepared,
packed, or held under conditions whereby it may have been contaminated with filth, or whereby
it may have been rendered injurious to health.”).

24 ⁵² Mo. Rev. Stat. § 196.015(5); [Cal. Health & Safety Code § 111330](#) (“Any drug or device is
misbranded if its labeling is false or misleading in any particular.”).

25 ⁵³ Mo. Rev. Stat. § 196.015(11); [Cal. Health & Safety Code § 111355\(a\)](#) (“Any drug is
26 misbranded unless its label bears . . . all of the following information:... (3) For nonprescription
drugs, the quantity or proportion of each active ingredient and the established name of each
27 inactive ingredient in accordance with Sections 502(e)(1)(A)(ii) and (iii) of the federal act (21
U.S.C. 352(e)(1)(A)(ii) and (iii)).”).

28 ⁵⁴ *Valisure Citizens Petition* at 25 (citation omitted).

1 evidence of the instability and formation of benzene seen in formulated final products of BPO
2 containing acne treatments.⁵⁵ Thus, if BPO is inherently stable as a pure, crystalline powder, a
3 reformulated product that focuses on substantially reducing or entirely preventing the
4 degradation of BPO into benzene could potentially be developed.⁵⁶

5 62. The mere presence of benzene in the BPO Products renders the Products
6 adulterated, misbranded, and illegal to sell. As such, the BPO Products have no economic value
7 and are worthless. Worse, as manufactured, the levels of benzene contained in the BPO
8 Products—over 14 ppm—"render [them] injurious to health" under the conditions of use
9 prescribed in the labeling and advertising.⁵⁷

10 63. As the FDA's July 2021 Health Hazard Evaluation concluded, serious adverse
11 effects, including potential for "life-threatening" issues or "permanent impairment of a body
12 function" were "likely to occur" at exposure levels of between 11.2 to 23.6 ppm benzene.⁵⁸

13 64. Similarly, in its review of the non-cancer effects of benzene, the EPA cites to
14 studies in the medical literature which "support a threshold of benzene hematotoxicity in humans
15 in the 5-19 ppm range, in broad agreement with the emerging exposure-response range that is
16 apparent from the epidemiologic studies[.]"⁵⁹

17 65. Defendants engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful
18 conduct stemming from its misrepresentations and omissions regarding benzene in its BPO
19 Products.

20 66. If Defendants had disclosed to Plaintiffs and putative Class members that the BPO
21 Products contain benzene or would degrade into benzene, Plaintiffs and putative Class members

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23 ⁵⁵ *Id.*

24 ⁵⁶ *See id.* at 25-26.

25 ⁵⁷ Mo. Rev. Stat. § 196.095(2); *see also* Cal. Health & Safety Code § 111255 ("Any drug or
26 device is adulterated if it has been produced, prepared, packed, or held under conditions whereby
27 it may have been contaminated with filth, or whereby it may have been rendered injurious to
28 health.").

26 ⁵⁸ [https://article.images.consumerreports.org/prod/content/dam/CRO-Images-
2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment](https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment).

27 ⁵⁹ EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38.
28 https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf.

1 would not have purchased the BPO Products.

2 67. As manufacturers, distributors, and sellers of acne treatment products, Defendants
3 had and have a duty to ensure that their BPO Products did not and do not contain excessive (or
4 any) level of benzene, including through regular testing, especially before injecting the BPO
5 Products into the stream of commerce for consumers to use on their skin.⁶⁰ This includes testing
6 of raw materials and finished product batches prior to release to ensure they meet appropriate
7 specifications for identity, strength, quality, and purity.⁶¹ But Defendants made no reasonable
8 effort to test their BPO Products for the presence of benzene or test whether the Products could
9 degrade into benzene over the course of the shelf-life of the Products. Nor did Defendants
10 disclose to Plaintiffs in any advertising or marketing that their BPO Products contained benzene
11 or would degrade into benzene. To the contrary, Defendants represented the BPO Products were
12 of merchantable quality, safe to use as prescribed, complied with federal and state law, and did
13 not contain carcinogens or other impurities such as benzene.

14
15 ***V. Defendants' Knowledge, Misrepresentations, Omissions, and Concealment of Material
Facts Deceived Plaintiffs and Reasonable Consumers***

16 68. It is well known that BPO degrades to benzene when exposed to heat over time.
17 This process was first reported in scientific literature as early as 1936.⁶²

18 69. The issue of BPO decomposition into benzene has been previously identified and
19 acted upon in industries other than in the acne treatment product industry.

20 70. For example, at least one patent application was filed by the chemical company
21 Akzo Nobel N.V. in 1997 which “relates to a method for reducing the rate of free benzene and/or
22 benzene derivative formation in BPO formulations based on organic plasticizers, such as pastes,
23
24

25 _____
26 ⁶⁰ 21 CFR 211.84; 21 CFR 211.160.

27 ⁶¹ 21 CFR 211.165.

28 ⁶² H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden*,
HELU. CHIM. ACTA, 19, 338 (1936),
<https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153>.

1 emulsions, suspensions, dispersions and the like.”⁶³

2 71. In the polymer manufacturing industry, BPO’s decomposition into benzene has
3 been studied and concern was raised specifically regarding the carcinogenic implications of the
4 presence of benzene. In 1994, a paper was published⁶⁴ by researchers at Denmark’s Department
5 of Environmental Chemistry titled “Formation of benzene by hardeners containing benzoyl
6 peroxide and phthalates” and stated:

7
8 Recently, during the investigation of benzene residues in chemical products
9 (Rastogi 1993a),⁶⁵ it was observed that the benzene content in benzoyl peroxide
10 containing hardeners of two component repair-sets (fillers, elastomers) were >2 %
11 (w/w) [20,000 ppm]. Benzene is carcinogenic (IARC 1982), and its use in
12 consumer and industrial products is generally avoided.

13 72. The study continues with heating of various BPO-containing products at 34°C,
14 50°C and 80°C, finding substantial benzene formation at elevated temperatures, even exceeding
15 levels found in Valisure’s March 2024 public citizens petition. Furthermore, similar to Valisure’s
16 results, Rastogi finds that only formulations of BPO are unstable, while BPO alone is relatively
17 stable:

18
19 Even heating of BPO-phthalate mixtures at 50°C produced significant amounts of
20 benzene (approximately 0.3% [3,000 ppm]), while no benzene production was
21 detected when benzoyl peroxide was heated alone at this temperature (Table 2).⁶⁶

22
23 73. The referenced 1993 Rastogi article above, titled “Residues of Benzene in
24 Chemical Products,” has also been flagged by the EPA as part of its Health & Environmental
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⁶³ Borys F. Schafran Bryce Milleville (1997). “Reduction of benzene formation in dibenzoyl peroxide formulations.” Akzo Nobel N.V. Worldwide application, WO1997032845A1. (<https://patents.google.com/patent/WO1997032845A1/en>)

⁶⁴ Rastogi SC. Formation of benzene by hardeners containing benzoyl peroxide and phthalates. *Bull Environ Contam Toxicol*. 1994 Nov;53(5):747-52. doi: 10.1007/BF00196949. PMID: 7833612.

⁶⁵ Rastogi, S.C. Residues of benzene in chemical products. *Bull. Environ. Contam. Toxicol*. 50, 794-797 (1993). <https://doi.org/10.1007/BF00209940>.

⁶⁶ *Id.*

1 Research Online (“HERO”) system.⁶⁷

2 74. Chemical evidence of carcinogenicity has been reported since at least 1981.⁶⁸
 3 Multiple studies in the 1980s were conducted using animal models that suggested carcinogenic
 4 potential of benzoyl peroxide, including the use of commercial drug formulations of BPO like
 5 that of PanOxyl Gel.⁶⁹

6 75. In 1991, FDA posted an amendment to the monograph for OTC topical acne drug
 7 products because, “the agency became aware of a 1981 study by Slage, et al. ([FDA] Ref. 1) that
 8 raised a safety concern regarding benzoyl peroxide as a tumor promoter in mice and a 1984 study
 9 by Kurokawa, et al. ([FDA] Ref. 2) that reported benzoyl peroxide to have tumor initiation
 10 potential,” leading FDA to determine that “further study is necessary to adequately assess the
 11 tumorigenic potential of benzoyl peroxide.”⁷⁰

12 76. By 2010, FDA published a final monograph on benzoyl peroxide along with
 13 summarizing results from further studies on the potential carcinogenicity of benzoyl peroxide
 14 and actions of the FDA Advisory Committee. This final monograph stated, “The Committee
 15 recommended, by a four-to-three vote (with one abstention), that the known safety data
 16 regarding the tumor promoting potential of benzoyl peroxide should be communicated to
 17 _____

18 ⁶⁷ US Environmental Protection Agency. Health & Environmental Research Online (HERO).
 19 “Residues of Benzene in Chemical Products.” HERO ID 2894703
 (http://hero.epa.gov/hero/index.cfm/reference/details/reference_id/2894703).

20 ⁶⁸ Slaga TJ, Klein-Szanto AJ, Triplett LL, Yotti LP, Trosko KE. Skin tumor-promoting activity
 of benzoyl peroxide, a widely used free radical-generating compound. *Science*. 1981 Aug
 28;213(4511):1023-5. doi: 10.1126/science.6791284. PMID: 6791284.

21 ⁶⁹ Kurokawa Y, Takamura N, Matsushima Y, Imazawa T, Hayashi Y. *Studies on the promoting
 and complete carcinogenic activities of some oxidizing chemicals in skin carcinogenesis*. *Cancer*
 22 *Lett*. 1984 Oct;24(3):299-304. doi: 10.1016/0304-3835(84)90026-0. PMID: 6437666; Pelling JC,
 Fischer SM, Neades R, Strawhecker J, Schweickert L. *Elevated expression and point mutation of
 23 the Ha-ras proto-oncogene in mouse skin tumors promoted by benzoyl peroxide and other
 promoting agents*. *Carcinogenesis*. 1987 Oct;8(10):1481-4. doi: 10.1093/carcin/8.10.1481.
 24 PMID: 3115617; 81 O'Connell JF, Klein-Szanto AJ, DiGiovanni DM, Fries JW, Slaga TJ.
*Enhanced malignant progression of mouse skin tumors by the free-radical generator benzoyl
 25 peroxide*. *Cancer Res*. 1986 Jun;46(6):2863-5. PMID: 3084079; 82 Iversen OH. *Carcinogenesis
 studies with benzoyl peroxide (Panoxyl gel 5%)*. *J Invest Dermatol*. 1986 Apr;86(4):442-8. doi:
 26 10.1111/1523-1747.ep12285787. PMID: 3091706.

27 ⁷⁰ Food and Drug Administration. *Proposed Rule: Reclassifies benzoyl peroxide from GRASE to
 Category III*. (August 7, 1991) Federal Register, 56FR37622. pp 37622 - 37635
 (https://cdn.loc.gov/service/ll/fedreg/fr056/fr056152/fr056152.pdf#page=178).

1 consumers. Because this data was inconclusive, the Committee unanimously agreed that the
2 word, “cancer” should not be included in the labeling of acne drug products containing benzoyl
3 peroxide. The Committee was concerned that the word “cancer” would cause consumers to avoid
4 using these products (even though the data were inconclusive).⁷¹

5 77. In 2020, the FDA started working with companies to identify benzene in products,
6 which resulted in product recalls of hand sanitizers, sunscreens, and deodorants. In 2021, an
7 independent chemical analysis by Valisure of hundreds of sunscreens and after-sun care products
8 from 69 brands found 27% of the batches had significant levels of benzene above 2 ppm.⁷²

9 78. Thus, by 2021, Defendants were well-aware of benzene contamination issues in
10 their BPO Products and in products of their competitors.

11 79. Further, Defendants, which markets themselves as merchandisers of quality acne
12 treatment products that and employs high-level scientists, chemists, and researchers to formulate
13 and/or decide which drug products to label and sell for public use, were aware of the well-known
14 chemical processes that degrade their BPO Products into benzene when exposed to commonly
15 used temperatures and conditions.

16 80. Defendants, as large, sophisticated corporations in the business of manufacturing,
17 distributing, and selling products containing BPO, knew or should have known the BPO
18 Products were contaminated with excess levels of benzene and that testing the BPO Products for
19 benzene was necessary to protect Plaintiffs and Class members from harmful levels of benzene
20 exposure.

21 81. Defendants’ use of BPO put it on notice of the excessive levels of benzene in the
22 BPO Products.

23 82. Notwithstanding this knowledge, Defendants failed to appropriately and
24 adequately test their BPO Products for the presence of benzene to protect Plaintiffs and Class

25 _____
26 ⁷¹ Food and Drug Administration. Final Monograph. (March 4, 2010) Federal Register,
27 75FR9767. (<https://www.gpo.gov/fdsys/pkg/FR-2010-03-04/pdf/2010-4424.pdf>).

28 ⁷² Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products, May 24,
2021.

1 members from dangerous levels of benzene exposure.

2 83. Defendants sold, and continue to sell, BPO Products during the class period
3 despite their knowledge of the risk of benzene contamination.

4 84. Benzene is not listed on the BPO Products' labels as an ingredient, nor is there
5 any warning about the inclusion (or even potential inclusion) of benzene in the BPO Products.
6 The following image shows an example:



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1 85. Plaintiffs have standing to represent members of the putative Class because there
2 is sufficient similarity between the specific BPO Product purchased by Plaintiffs and the other
3 BPO Products not purchased by Plaintiffs. Specifically, each and every one of the BPO Products
4 (i) are marketed in substantially the same way – as an acne treatment— and (ii) fail to include
5 labeling indicating to consumers that the BPO Products contain benzene or degrade into benzene.
6 Accordingly, the misleading effect of all the BPO Products’ labels are substantially the same.

7 86. Defendants have engaged in deceptive, untrue, and misleading advertising by
8 making representations by failing to warn about the presence of benzene in the BPO Products.

9 87. As alleged, the presence of benzene in the BPO Products renders the BPO
10 Products misbranded and adulterated and therefore illegal and unfit for sale in trade or
11 commerce. Plaintiffs would not have purchased the BPO Products had they been truthfully and
12 accurately labeled.

13 88. Had Defendants adequately tested its BPO Products for benzene and other
14 carcinogens and impurities, it would have discovered its BPO Products contained benzene – at
15 levels above 2 ppm, making the BPO Products illegal to distribute, market, and sell.

16 89. Accordingly, Defendants knowingly, recklessly, or at least negligently, introduced
17 the contaminated, adulterated, and misbranded BPO Products into the U.S. market.

18 90. Defendants’ concealment was material and intentional because people are
19 concerned with what is contained in the products they are putting onto and into their bodies.
20 Consumers such as Plaintiffs and Class members make purchasing decisions based on the
21 representations made on the BPO Products’ labeling, including the ingredients listed.

22 ***VI. Injuries to Plaintiffs and Class Members***

23 91. When Plaintiffs purchased Defendants’ BPO Products, Plaintiffs did not know,
24 and had no reason to know, that Defendants’ BPO Products contained or would degrade into the
25 harmful carcinogen benzene. Not only would Plaintiffs not have purchased Defendants’ BPO
26 Products had they known the Products contained or would degrade into benzene, but they would
27

1 also not have been capable of purchasing them if Defendants had done as the law required and
2 tested the BPO Products for benzene and other carcinogens and impurities.

3 92. Consumers lack the ability to test or independently ascertain or verify whether a
4 product contains unsafe substances, such as benzene, especially at the point of sale, and therefore
5 must rely on Defendants to truthfully and honestly report on the BPO Products' packaging and
6 labeling what the Products contain.

7 93. Further, given Defendants' position as a leader in the acne treatment market,
8 Plaintiffs and reasonable consumers trusted and relied on Defendants' representations and
9 omissions regarding the presence of benzene in the BPO Products.

10 94. Defendants' false and misleading omissions and deceptive misrepresentations
11 regarding the presence of benzene in the BPO Products are likely to continue to deceive and
12 mislead reasonable consumers and the public, as it has already deceived and misled Plaintiffs
13 and the Class members.

14 95. Plaintiffs and Class members bargained for products free of contaminants and
15 dangerous substances. Plaintiffs and Class members were injured by the full purchase price of
16 the BPO Products because the Products are worthless, as they are adulterated and contain
17 harmful levels of benzene, and Defendants failed to warn consumers of this fact. Such illegally
18 sold products are worthless and have no value.

19 96. As a proximate result thereof, Plaintiffs and Class members are entitled to
20 statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems
21 just and proper.

22 97. All conditions precedent to the prosecution of this action have occurred, and/or
23 have been performed, excused, or otherwise waived.

24
25 **CLASS ALLEGATIONS**

26 98. Plaintiffs, individually and on behalf of all others similarly situated, bring this
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28

1 class action pursuant to Fed. R. Civ. P. 23.

2 99. Plaintiffs seeks to represent classes defined as:

3
4 **California Class**

5 All persons who purchased the BPO Products in the State of
6 California for personal or household use within the applicable
7 limitations period.

8 **Missouri Class**

9 All persons who purchased the BPO Products in the State of
10 Missouri for personal or household use within the applicable
11 limitations period.

12 100. Excluded from the Class are: (1) any Judge or Magistrate presiding over this
13 action and any members of their families; (2) Defendants, Defendants' subsidiaries, parents,
14 successors, predecessors, and any entities in which Defendants or their parents and any entities in
15 which Defendants have a controlling interest and their current or former employees, officers, and
16 directors; and (3) individuals who allege personal bodily injury resulting from the use of the
17 BPO Products.

18 101. Plaintiffs reserve the right to modify, change, or expand the definitions of the
19 Class based upon discovery and further investigation.

20 102. *Numerosity*: The Class is so numerous that joinder of all members is
21 impracticable. The Class likely contains hundreds of thousands of members based on publicly
22 available data. The Class is ascertainable by records in Defendants' possession.

23 103. *Commonality*: Questions of law or fact common to the Class include:

- 24 a. Whether the BPO Products contain benzene;
25
26 b. Whether a reasonable consumer would consider the presence of benzene in the
27 BPO Products to be material;

- 1 c. Whether Defendants knew or should have known that the BPO Products contains
2 benzene;
- 3 d. Whether Defendants misrepresented that the BPO Products contain or degrade
4 into benzene;
- 5 e. Whether Defendants failed to disclose that the BPO Products contain or degrade
6 into benzene;
- 7 f. Whether Defendants concealed that the BPO Products contain or degrade into
8 benzene;
- 9 g. Whether Defendants engaged in unfair or deceptive trade practices;
- 10 h. Whether Defendants violated the state consumer protection statutes alleged
11 herein;
- 12 i. Whether Defendants were unjustly enriched; and
- 13 j. Whether Plaintiffs and Class members are entitled to damages.

14
15
16 104. *Typicality*: Plaintiffs' claims are typical of the claims of Class members. Plaintiffs
17 and Class members were injured and suffered damages in substantially the same manner, have
18 the same claims against Defendants relating to the same course of conduct, and are entitled to
19 relief under the same legal theories.

20
21 105. *Adequacy*: Plaintiffs will fairly and adequately protect the interests of the Class
22 and has no interests antagonistic to those of the Class. Plaintiffs have retained counsel
23 experienced in the prosecution of complex class actions, including actions with issues, claims,
24 and defenses similar to the present case. Counsel intends to vigorously prosecute this action.

25 106. *Predominance and superiority*: Questions of law or fact common to Class
26 members predominate over any questions affecting individual members. A class action is
27
28

1 superior to other available methods for the fair and efficient adjudication of this case because
2 individual joinder of all Class members is impracticable and the amount at issue for each Class
3 member would not justify the cost of litigating individual claims. Should individual Class
4 members be required to bring separate actions, this Court would be confronted with a
5 multiplicity of lawsuits burdening the court system while also creating the risk of inconsistent
6 rulings and contradictory judgments. In contrast to proceeding on a case-by-case basis, in which
7 inconsistent results will magnify the delay and expense to all parties and the court system, this
8 class action presents far fewer management difficulties while providing unitary adjudication,
9 economies of scale and comprehensive supervision by a single court. Plaintiffs are unaware of
10 any difficulties that are likely to be encountered in the management of this action that would
11 preclude its maintenance as a class action.
12

13
14 107. Accordingly, this class action may be maintained pursuant to Fed. R. Civ. P.
15 23(b)(3).

16 **COUNT I – Violations of the Unfair Competition Law (the “UCL”), Cal. Bus. & Prof. Code**
17 **§ 17200, *Et Seq.***
18 **(On Behalf of Plaintiffs Daugherty and Nguyen and the California Class)**

19 108. Plaintiffs incorporate by reference and re-allege each and every allegation
20 contained above, as though fully set forth herein.

21 109. Plaintiffs bring this Count I individually and on behalf of the California Class
22 members against Defendants.

23 110. The UCL prohibits any “unlawful, unfair or fraudulent business act or practice
24 and unfair, deceptive, untrue or misleading advertising....” Cal. Bus. & Prof. Code § 17200.

25 111. Any business act or practice that is likely to deceive members of the public
26 constitutes a fraudulent business act or practice under the UCL. Similarly, any advertising that is
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28

1 deceptive, untrue or misleading constitutes a fraudulent business act or practice under the UCL.

2 112. Defendants have engaged, and continue to engage, in conduct that is likely to
3 deceive members of the public. This conduct includes representing in their labels that its BPO
4 Products are safe and effective when used as directed, which is untrue, and by failing to make
5 any mention that the BPO Products contain benzene or degrade to form benzene.
6

7 113. By committing the acts alleged above, Defendants have engaged in fraudulent
8 business acts and practices, which constitute unfair competition within the meaning of Business
9 & Professions Code §17200.

10 114. Defendants' conduct also violates Cal. Health & Safety Code § 111730, which
11 prohibits the sale of any misbranded product. The BPO Products are "false and misleading in any
12 particular" in violation of Health & Safety Code § 111730 because the labeling for the BPO
13 Products does not mention that the Products contain benzene or degrade to form benzene.
14

15 115. By violating the Cal. Health and Safety Code § 111730, Defendants have engaged
16 in unlawful business acts and practices which constitute unfair competition within the meaning
17 of Cal. Bus. & Prof. Code § 17200.

18 116. Any business practice that offends an established public policy or is immoral,
19 unethical, oppressive, unscrupulous, or substantially injurious to consumers constitutes an
20 "unfair" practice under the UCL.
21

22 117. Defendants have engaged, and continue to engage, in unfair business practices.
23 This conduct includes representing that the BPO do not contain benzene and/or do not degrade
24 into benzene when in fact they do.

25 118. Moreover, Defendants' conduct has caused, and continues to cause, substantial
26 injury to consumers because consumers, including Plaintiffs, would not have paid for BPO
27
28

1 Products containing benzene or that degrade into benzene but for Defendants’ false labeling,
2 advertising, and promotion. Thus, Plaintiffs and the Class have “lost money or property” as
3 required for UCL standing, and such an injury is not outweighed by any countervailing benefits
4 to consumers or competition.

5
6 119. Indeed, no benefit to consumers or competition results from Defendants’ conduct.
7 As alleged, the BPO Products are illegal to sell because of the level of benzene contained in the
8 Products (i.e. over 2 ppm). Moreover, since consumers reasonably rely on Defendants’
9 representation of the ingredients contained in the BPO Products’ labels and injury resulted from
10 ordinary use of the BPO Products, consumers could not have reasonably avoided such injury.

11 120. By committing the acts described above, Defendants have engaged in unfair
12 business acts and practices which constitute unfair competition within the meaning of the UCL.

13 121. As a result of the conduct described above, Defendants have been unjustly
14 enriched at the expense of the Plaintiffs and the putative Class.

15 122. An action for injunctive relief and restitution is specifically authorized under Cal.
16 Bus. & Prof. Code 17203.

17 123. In accordance with California Business & Professions Code section 17203,⁷³
18 Plaintiffs seek an order enjoining Defendants from continuing to conduct business through
19 fraudulent or unlawful acts and practices and to commence a corrective advertising campaign.
20 Defendants’ conduct is ongoing and continuing, such that prospective injunctive relief is
21 necessary.
22

23 124. On behalf of Plaintiffs and the Class, Plaintiffs also seek an order for the
24 restitution of all monies spent on the BPO Products, which were acquired through acts of
25

26 _____
27 ⁷³ “Any person who engages, has engaged, or proposes to engage in unfair competition may be
28 enjoined in any court of competent jurisdiction.” Cal. Bus. & Prof. Code § 17203.

1 fraudulent, unfair, or unlawful competition.⁷⁴ In addition, because the BPO Products contain
2 benzene and/or degrade to form benzene, a known human carcinogen, the measure of restitution
3 should be rescission and full refund insofar as the BPO Products and their associated labels are
4 illegal to sell, and thus, worthless. But for Defendants’ misrepresentations and omissions,
5 Plaintiffs would have paid nothing for the BPO Products. Indeed, there is no discernible
6 “market” for an over-the-counter acne treatment product that is adulterated with a known human
7 carcinogen and illegal to sell. As a result, the BPO Products are rendered valueless.
8

9 125. Wherefore, Plaintiffs pray for judgement against Defendants, as set forth
10 hereafter. Defendants’ conduct with respect to the labeling, advertising, marketing, and sale of
11 the BPO Products is unfair because Defendant’s conduct was immoral, unethical, unscrupulous,
12 or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh
13 the gravity of the harm to its victims.
14

15 **COUNT II – Violations of California’s False Advertising Law, California Business**
16 **& Professions Code §§17500, *Et. Seq.***
17 **(On Behalf of Plaintiff Nguyen and the California Class)**

18 126. Plaintiffs incorporate by reference and re-allege each and every allegation
19 contained above, as though fully set forth herein.

20 127. Plaintiffs bring this Count II on behalf of the California Class against Defendants.

21 128. California’s False Advertising Law prohibits any statement in connection with the
22 sale of goods “which is untrue or misleading.” Cal. Bus. & Prof. Code §17500.
23

24 _____
25 ⁷⁴ “Actions for relief pursuant to this chapter shall be prosecuted . . . by a person who has
26 suffered injury in fact and lost money or property as a result of the unfair competition.” Cal. Bus.
27 & Prof. Code § 17204. “The court may make such orders or judgments . . . as may be necessary
28 to restore to any person in interest any money or property, real or personal, which may have been
acquired by means of such unfair competition.” Cal. Bus. & Prof. Code § 17203.

1 129. As set forth herein, Defendants' labeling represents that their BPO Products are
2 safe and effective to use as directed. Similarly, Defendants claim that their BPO Products'
3 ingredients are safe and effective.

4 130. Such claims are false and likely to deceive the public because Defendants' BPO
5 Products contain benzene and/or degrade to form benzene.
6

7 131. Defendants knew, or reasonably should have known, that these claims were
8 untrue or misleading.

9 132. Wherefore, Plaintiffs and members of the Class are entitled to injunctive and
10 equitable relief, and restitution in the amount they spent on the BPO Products.

11 **COUNT III – Violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat.**
12 **§ 407.010, *et seq.***
13 **(On Behalf of Plaintiff Scroggs and the Missouri Class)**

14 133. Plaintiffs incorporate by reference and re-allege each and every allegation
15 contained above, as though fully set forth herein.

16 134. Plaintiffs bring this Count III on behalf of the Missouri Class against Defendants.

17 135. The acts and practices engaged in by Defendants, and described herein, constitute
18 unlawful, unfair and/or fraudulent business practices in violation of the Missouri Merchandising
19 Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*

20 136. Defendants engaged in unlawful practices including deception, false promises,
21 misrepresentation, and/or the concealment, suppression, or omission of material facts in
22 connection with the sale, distribution or advertisement of the BPO Products, in violation of Mo.
23 Rev. Stat. § 407.020.
24

25 137. Plaintiffs and the Class members purchased the BPO Products, Products that were
26 falsely represented, as stated above, in violation of the Missouri Merchandising Practices Act,
27 and as a result, Plaintiffs and the Class members suffered economic damages in that the BPO
28

1 Products were worth less than the product they thought they had purchased had Defendants'
2 representations been true.

3 **COUNT IV – Fraud/Misrepresentation**
4 **(On Behalf of all Plaintiffs against Defendants)**

5 138. Plaintiffs incorporate by reference and re-allege each and every allegation
6 contained above, as though fully set forth herein.

7 139. Plaintiffs bring this Count IV on behalf of the California and Missouri Classes
8 against Defendants.

9 140. Defendants intentionally and knowingly falsely concealed, suppressed and/or
10 omitted material facts including as to the standard, quality or grade of the BPO Products.
11

12 141. Due to Defendants' fraudulent conduct, Plaintiffs and the other Class members
13 have suffered actual damages.

14 142. Defendants knew or should have known that the BPO Products contain benzene
15 or degrade into benzene when used as directed.

16 143. Defendants knew or should have known that their concealment and suppression of
17 material facts was false and misleading and knew the effect of concealing those material facts.
18

19 144. Defendants acted with malice, oppression, and fraud.

20 145. Defendants knew or should have known of the dangers associated with benzene in
21 its BPO Products based on regulatory studies and regulatory guidance.

22 146. Defendants were obligated to inform Plaintiffs and the other Class members of the
23 dangers associated with benzene in the BPO Products due to their exclusive and superior
24 knowledge of the Products.

25 147. Plaintiffs and other Class members also expressly reposed a trust and confidence
26 in Defendants because of their dealings as a healthcare entity and with Plaintiffs and other Class
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1 members as their customers.

2 148. Plaintiffs and the other Class members would not have purchased the BPO
3 Products but for Defendants' omissions and concealment of material facts regarding the nature
4 and quality of the Products, or would have paid less for the Products.

5 149. Plaintiffs and Class members were justified in relying on Defendants'
6 misrepresentations and/or omissions.

7 150. As alleged herein, Plaintiffs and the Class members have suffered injury in fact
8 and lost money as a result of Defendants' conduct because they purchased BPO Products from
9 Defendants in reliance on Defendants' misrepresentation and/or omissions that the BPO Products
10 were safe to use as directed.

11 151. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the
12 Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on
13 the BPO Products.

14
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16 **COUNT V – Negligent Misrepresentation**
17 **(On Behalf of all Plaintiffs against Defendants)**

18 152. Plaintiffs incorporate by reference and re-alleges each and every allegation
19 contained above, as though fully set forth herein.

20 153. Plaintiffs bring this Count V on behalf of the California and Missouri Classes
21 against Defendants.

22 154. Defendants owed a duty of reasonable care to Plaintiffs and the Class members in
23 the labeling, manufacturing, sale, and distribution of its BPO Products.

24 155. Defendants also had a duty to exercise reasonable care in properly and accurately
25 representing the safety of its BPO Products to consumers, including Plaintiffs and the Class
26 members.
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1 156. Defendants failed to exercise ordinary care when making the misrepresentations
2 and/or omissions in their marketing and labeling, claiming that their BPO Products were safe.

3 157. Defendants negligently and falsely misrepresented facts regarding the safety of
4 their BPO products to Plaintiffs and the Class members.

5 158. Defendants knew or should have known that the misrepresentations regarding the
6 safety of their BPO Products was misleading. Defendants knew or should have known that these
7 misrepresentations would induce Plaintiffs and the Class members to purchase the BPO Products
8 in reliance of Defendants' claims.

9 159. As a direct and proximate cause of Defendants' negligent misrepresentations,
10 Plaintiffs and the Class members have suffered harm.

11 160. Defendants' misrepresentations were material and substantial factors in Plaintiffs
12 and Class members purchasing and paying for the BPO Products.

13 161. Defendants intended, or had reckless disregard, to induce Plaintiffs and Class
14 members to purchase its BPO Products based on its misrepresentations of safety. Plaintiffs and
15 Class members reasonably relied on the misrepresentations made by Defendants.

16 162. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the
17 Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on
18 the BPO Products.

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22 **COUNT VI – Unjust Enrichment**
(On Behalf of all Plaintiffs against Defendants)

23 163. Plaintiffs incorporate by reference and re-allege each and every allegation
24 contained above, as though fully set forth herein.

25 164. Plaintiffs bring this Count VI on behalf of the California and Missouri Classes
26 against Defendants.
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1 165. Defendants profited exponentially from their marketing and sale of their benzene-
2 contaminated BPO Products. Plaintiffs and Class members were deprived of the money paid for
3 these defective and unsafe products.

4 166. Defendants were unjustly enriched by unlawfully receiving money from Plaintiffs
5 for defective and unsafe products. It would be inequitable and unconscionable for Defendants to
6 retain the compensation obtained based on its wrongful conduct.
7

8 167. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the
9 Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on
10 the BPO Products as well as an order from this Court requiring the disgorgement of all profits,
11 benefits, and additional compensation obtained by Defendants by way of their wrongful conduct.
12

13 **PRAYER FOR RELIEF**

14 WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray
15 for judgment against the Defendants as to each and every count, including:

- 16 A. An order declaring this action to be a proper class action, appointing Plaintiffs and
17 their counsel to represent the Class, and requiring Defendants to bear the costs of
18 class notice;
- 19 B. An order enjoining Defendants from selling the BPO Products;
- 20 C. An order enjoining Defendants from suggesting or implying that the BPO
21 Products are safe for human application;
- 22 D. An order requiring Defendants to engage in a corrective advertising campaign and
23 engage in any further necessary affirmative injunctive relief, such as recalling
24 existing BPO Products;
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- 1 E. An order awarding declaratory relief, and any further retrospective or prospective
2 injunctive relief permitted by law or equity, including enjoining Defendants from
3 continuing the unlawful practices alleged herein, and injunctive relief to remedy
4 Defendants' past conduct;
- 5 F. An order requiring Defendants to pay restitution/damages to restore all funds
6 acquired by means of any act or practice declared by this Court to be an unlawful,
7 unfair, or fraudulent business act or practice, untrue or misleading advertising in
8 violation of the above-cited authority, plus pre- and post-judgment interest
9 thereon;
- 10 G. An order requiring Defendants to disgorge any ill-gotten benefits received from
11 Plaintiffs and members of the Class as a result of any wrongful or unlawful act or
12 practice;
- 13 H. An order requiring Defendants to pay all actual and statutory damages permitted
14 under the counts alleged herein;
- 15 I. An order awarding attorneys' fees and costs to Plaintiffs and the Class; and
16
- 17 J. An order providing for all other such equitable relief as may be just and proper.
18

19 **DEMAND FOR JURY TRIAL**

20 Plaintiffs demand a trial by jury on all issues so triable.
21

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27 ///

1 DATED: April 4, 2024

Respectfully,

2 /s/Mary Liu

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ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Perrigo Benzoyl Peroxide Acne Treatments Contain Carcinogen Benzene, Class Action Alleges](#)
