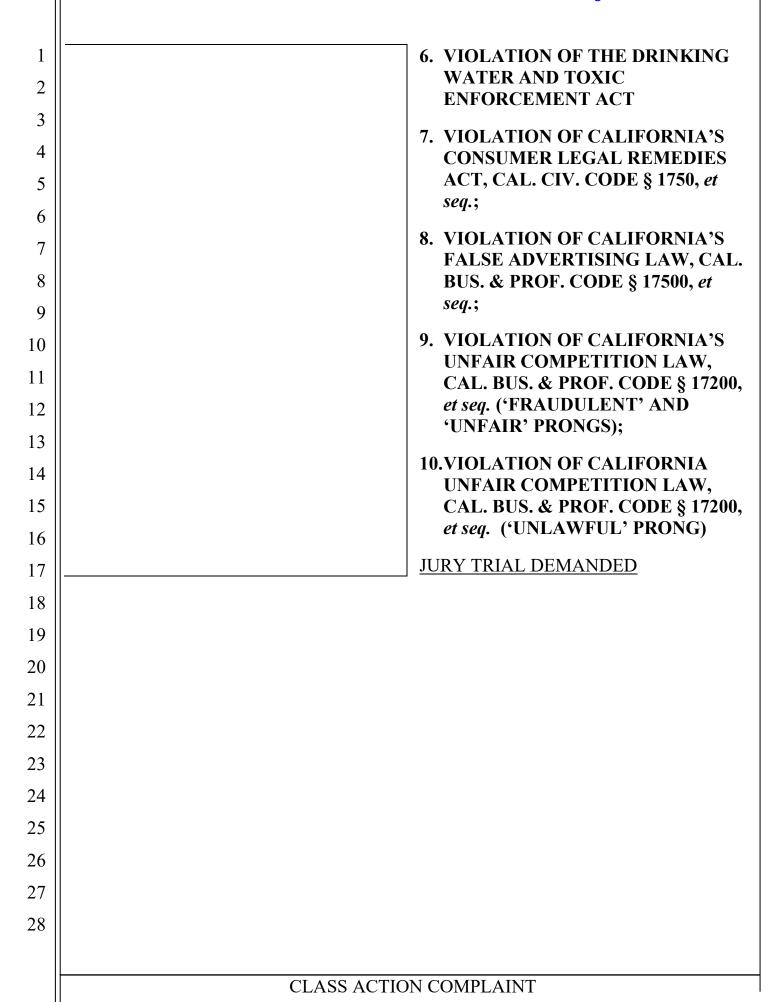
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115 116 117 118 119 220 221 222	EASTERN DISTR LA NITA M. DOMINIQUE-TATE, on behalf of herself and all others similarly situated, Plaintiff, v. TARGET CORPORATION,	Case No.: CLASS ACTION COMPLAINT 1. BREACH OF EXPRESS WARRANTY;				
115 116 117 118 119 220 221 222 223	LA NITA M. DOMINIQUE-TATE, on behalf of herself and all others similarly situated, Plaintiff, v.	Case No.: CLASS ACTION COMPLAINT 1. BREACH OF EXPRESS WARRANTY; 2. BREACH OF IMPLIED				
115 116 117 118 119 220 221 222	EASTERN DISTR LA NITA M. DOMINIQUE-TATE, on behalf of herself and all others similarly situated, Plaintiff, v. TARGET CORPORATION,	Case No.: CLASS ACTION COMPLAINT 1. BREACH OF EXPRESS WARRANTY; 2. BREACH OF IMPLIED WARRANTY;				
115 116 117 118 119 220 221 222 223 224	EASTERN DISTR LA NITA M. DOMINIQUE-TATE, on behalf of herself and all others similarly situated, Plaintiff, v. TARGET CORPORATION,	Case No.: CLASS ACTION COMPLAINT 1. BREACH OF EXPRESS WARRANTY; 2. BREACH OF IMPLIED WARRANTY; 3. VIOLATION OF THE MAGNUSON-MOSS WARRANTY				
15 16 17 18 19 20 21 22 23 24 25	EASTERN DISTR LA NITA M. DOMINIQUE-TATE, on behalf of herself and all others similarly situated, Plaintiff, v. TARGET CORPORATION,	Case No.: CLASS ACTION COMPLAINT 1. BREACH OF EXPRESS WARRANTY; 2. BREACH OF IMPLIED WARRANTY; 3. VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT;				



Plaintiff La Nita M. Dominique-Tate ("Plaintiff"), by her undersigned counsel, on behalf of herself and all persons similarly situated, brings this Complaint against Defendant Target Corporation ("Defendant" or "Target") and alleges as follows:

NATURE OF THE ACTION

- 1. This case centers around Defendant's alcohol-based Born Basic Anti-bac Hand Sanitizer gel (the "Product"), which independent testing has recently revealed suffers from benzene contamination. Benzene, a harmful carcinogen, does not appear on the Product label, on the ingredients list, in Defendant's advertisements, or otherwise.
- 2. Defendant is aware of benzene's carcinogenicity, which is well-documented by various agencies and health organizations, including the Centers for Disease Control and Prevention ("CDC"), the Department of Health and Human Services ("DHHS"), the World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC"), the Food and Drug Administration ("FDA"), the American Cancer Society, and California's Office of Environmental Health Hazard Assessment ("OEHHA").
- 3. Defendant is further aware that in March 2021, Valisure, an analytical pharmacy, patient advocacy and consumer protection organization, "detected high levels of benzene and other contaminants in specific batches of hand sanitizer products containing active pharmaceutical ingredients of ethanol and isopropanol," and that the Product was found to contain 3.5 parts per million of benzene with a coefficient of variation of 5 percent.¹
- 4. Despite Defendant's knowledge of the Product's potential carcinogenicity, Defendant sold and continues to sell the Product at its retail locations and on its website without providing consumers with any additional information about its potential health risks.

¹ Valisure, Valisure Citizen Petition on Hand Sanitizer Products Containing Benzene Contamination and Other Significant Issues, at 15 (Mar. 24, 2021), *available at* https://www.valisure.com/wp-content/uploads/Valisure-FDA-Citizen-Petition-on-Hand-Sanitizer-v4.14.pdf (the "Valisure Petition").

In fact, Defendant represents the Product is "[s]afe & effective for the whole family."² Defendant could and should have disclosed the Product's potential carcinogenicity on its website, store shelves and/or at the point of sale.

- 5. Moreover, the presence of benzene in the Product renders it adulterated, misbranded, and an unapproved new drug. As a result, the Product is illegal to sell under federal and state law and is therefore worthless.
- 6. Accordingly, Plaintiff brings this action on behalf of herself and the Classes alleging: (i) breach of express warranty, (ii) breach of implied warranty, (iii) violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, et seq., (iv) unjust enrichment, (v) fraud, (vi) violation of the Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.5 et seq. ("Proposition 65"), (vii) violation of California's Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750, et seq. ("CLRA"), (viii) violation of California's False Advertising Law, Cal. Bus. & Prof. Code § 17500, et seq. ("FAL"), (ix) violation of the 'fraudulent' and 'unfair' prongs of California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, et seq. ("UCL"), and (x) violation of the 'unlawful' prong of the UCL.

JURISDICTION AND VENUE

- 7. Jurisdiction is proper in this Court pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d) ("CAFA"). Defendant is either incorporated and/or has its principal place of business outside the state in which Plaintiff and members of the proposed Classes reside. Furthermore, there are more than 100 Class Members and the amount-in-controversy exceeds \$5,000,000 exclusive of interest and costs.
- 8. This Court has personal jurisdiction over Defendant because Defendant is a foreign corporation authorized to do business in California and has sufficient minimum

² Target, webpage for Born Basic Anti-Bac Hand Sanitizer - 33 fl oz, *available at* https://www.target.com/p/born-basic-anti-bac-hand-sanitizer-33-fl-oz/-/A-79786606#lnk=sametab (last visited Feb. 22, 2022). A copy of this webpage is attached hereto as **Exhibit A**.

contacts with California or otherwise intentionally avails itself of the laws and markets of California, through the sale and distribution of the Product in California, to render the exercise of jurisdiction by the California courts permissible.

9. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c) because Defendant's improper conduct alleged in this complaint occurred in, was directed from, and/or emanated from this judicial district, because Defendant has caused harm to Class Members residing in this district, and/or because Defendant is subject to personal jurisdiction in this district.

THE PARTIES

- 10. Plaintiff La Nita M. Dominique-Tate is a resident and citizen of California. In early 2021, Plaintiff purchased the Product from a Target location in Elk Grove, California.
- 11. Defendant Target Corporation is a Minnesota corporation that maintains its principle place of business at 1000 Nicollet Mall in Minneapolis, Minnesota.
- 12. Target conducts substantial business in the Eastern District of California. There are 1,897 Target stores in the United States and 307 in California alone, representing Target's largest United States presence.
- 13. At all relevant times, Target engaged in the marketing, advertising, and sale of the Product.
- 14. The Product is manufactured by nonparty Real Clean Distribuciones, S.A. de C.V. The Product is sold through the manufacturer's distributor, Scent Theory Products, LLC, which re-sells the Product to Target. Target in turn sells the Product directly to consumers.
- 15. Target advertises and sells the Product throughout California and the United States, including in Sacramento County, California.

FACTUAL ALLEGATIONS

I. BACKGROUND ON HAND SANITIZERS AND THE PRODUCT

16. Hand sanitizers are products that are applied and rubbed on hands to kill various types of bacteria and viruses.

- 17. To date, most effective hand sanitizer products are alcohol-based formulations containing 62%-95% of alcohol as they are capable of denaturing the proteins of microbes and inactivating viruses.³
- 18. Alcohol-based hand sanitizers ("ABHS") have emerged as an important tool in the fight against SARS-CoV-2, the virus that causes coronavirus disease 2019 ("COVID-19").
- 19. In response to the growing spread of COVID-19, the CDC promoted and encouraged the use of ABHS as an alternative to handwashing.⁴
- 20. ABHS are available in different dosage forms, namely gel, liquid, and foam. These products are designed to dry rapidly after application, thereby eliminating the need for soap, water and drying aids such as towel.
- 21. Ethanol and isopropanol (2-propanol) are the commonly used alcohols in ABHS. They are typically formulated as aqueous mixtures with several other ingredients such as emollients, moisturizers and fragrances. Amongst the usable alcohols, ethanol emerges as the most common choice since it is easily produced through fermentation and distillation.⁵
- 22. The Product sold by Target is an ethanol-based ABHS (62% ethanol) that comes in a gel formula, which also includes Vitamin E and Aloe Vera for purported moisturizing effects.⁶

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³ Jing JLJ, *et al.*, Hand sanitizers: a review on formulation aspects, adverse effects, and regulations, Int J Environ Res Public Health, 17, 3326 (2020), *available at* https://www.mdpi.com/1660-4601/17/9/3326/htm.

⁴ COVID-19 Protect Yourself, Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html (updated Jan. 20, 2022).

⁵ Nyamwweya, N.N.; Abuga, K.O. Alcohol-Based Hand Sanitizers – A Multidimensional Perspective, Pharmacy (2021), *available at* https://www.mdpi.com/2226-4787/9/1/64/htm.

⁶ Target, webpage for Born Basic Anti-Bac Hand Sanitizer - 33 fl oz, *available at* https://www.target.com/p/born-basic-anti-bac-hand-sanitizer-33-fl-oz/-/A-79786606#lnk=sametab.

23. Target touts the product as killing 99.99% of germs and being "[s]afe for the whole family."⁷

II. BENZENE IN DEFENDANT'S PRODUCT

- The carcinogenic properties of benzene are well documented, as noted by the 24. CDC.8
- 25. The DHHS has determined that benzene causes cancer in humans. Long-term exposure to high levels of benzene in the air can cause leukemia, cancer of the blood-forming organs.
- 26. The WHO's IARC has classified benzene as a Group 1 compound thereby defining it as "carcinogenic to humans."9
- The FDA has listed benzene as a "Class 1 solvent" that "should not be employed 27. in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity."10
- The American Cancer Society has recognized benzene is "known to cause 28. cancer, based on evidence from studies in both people and lab animals."¹¹
- The OEHHA has also listed benzene as a chemical known to cause cancer, 29. pursuant to Proposition 65.12
- Its carcinogenic properties aside, another major effect of benzene from long-30. term exposure is on the blood. (Long-term exposure means exposure of a year or more.) Benzene causes harmful effects on the bone marrow and can cause a decrease in red blood

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⁷ *Id*.

⁸ See CDC, Facts About Benzene (2018), available at

https://emergency.cdc.gov/agent/benzene/basics/facts.asp.

⁹ International Agency for Research on Cancer and World Health Organization, *IARC Monographs on the* Identification of Carcinogenic Hazards to Humans, available at https://monographs.iarc.who.int/list-ofclassifications.

¹⁰Department of Health and Human Services, "International Conference on Harmonisation; Guidance on Impurities: Residual Solvents," 62 F.R. 67377 (Dec. 24, 1997).

¹¹ American Cancer Society, "Benzene and Cancer Risk," available at

https://www.cancer.org/cancer/cancer-causes/benzene.html.

¹² OEHHA, "The Proposition 65 List," available at https://oehha.ca.gov/proposition-65/proposition-65-list.

- 31. The National Institute for Occupational Safety and Health ("NIOSH") recommends protective equipment be worn by workers expecting to be exposed to benzene at concentrations of 0.1 ppm and defines "inhalation, skin absorption, ingestion, skin and/or eye contact" as exposure routes.¹³
- 32. Due to its industrial applications, benzene is regularly found in products such as gasoline, plastics, detergents, pesticides, drugs, synthetic fibers, and cigarette smoke.
- 33. Because exposure to benzene is so prevalent in industrial products, limiting or eliminating its use in products where it is not necessary (such as Defendant's Product) is even more important.
- 34. In or around March 2021, Valisure released testing results of a number of hand sanitizer products.¹⁴
- 35. Valisure analyzed 260 unique batches from 168 brands and found that 44 batches (17%) contained benzene at 0.1 ppm or above and 21 batches (8%) contained benzene at 2 ppm or above.¹⁵
- 36. The Product was found to contain 3.5 parts per million of benzene with a coefficient of variation of 5 percent.¹⁶
- 37. Because the majority of the hand sanitizer products tested did *not* contain detectable levels of benzene, its use was not unavoidable to manufacture an effective hand sanitizer product.
- 38. Upon information and belief, the presence of benzene in the hand sanitizer products was likely due to one of the following: (a) it was added intentionally to the hand sanitizer formulation, one of its ingredients, or its packaging; (b) contamination occurring

¹³ CDC, *The National Institute for Occupational Safety and Health (NIOSH), Benzene* (October 30, 2019), https://www.cdc.gov/niosh/npg/npgd0049.html.

See Valisure Petition.Id. at 12.

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during the manufacturing, processing, packing, or holding processes; or (c) leftover impurities in case benzene was utilized in some other way, such as a solvent in which other materials were dissolved to form a solution.

- Under any scenario, however, the Product would still violate federal and state 39. law, including the regulations pertaining to hand sanitizers and over-the-counter drug products. Because the source of the benzene is unknown to Plaintiff at this time (and absent discovery), these factual theories (and corresponding regulatory violations) are pled in the alternative.
- 40. The benzene contamination of the Product was not divulged to the consumer on the product label, in the ingredients list, on Target's website, Target's store shelves and/or at the point of sale.
- 41. Target has not recalled the Product and continues to fail to disclose any reference to benzene, instead representing that it is "[s]afe for the whole family."

III. THE PRODUCT VIOLATES THE FDCA AND ITS IMPLEMENTING REGULATIONS, AND CONTRAVENES AGENCY GUIDANCE.

- Plaintiff brings claims under various state consumer and warranty theories and 42. is not seeking to enforce any federal statute or regulation. However, much of the conduct giving rise to Plaintiff's claims was likewise in violation of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301, et seq. ("FDCA") and its implementing regulations.
- 43. Most hand sanitizers, including the Product, are considered drugs that are regulated by the U.S. Food and Drug Administration ("FDA"). Accordingly, such products are subject to the FDCA and its implementing regulations, as well as analogous state statutes and regulations. These include, inter alia, the FDCA's provisions regarding misbranded drugs, adulterated drugs, and nonprescription over-the-counter ("OTC") drugs that may be marketed without an approved drug application. 21 U.S.C. §§ 351, 352, 355h.
- 44. Defendant's sale of its hand sanitizer products is also subject to California's Sherman Food, Drug & Cosmetic Law, California Health & Safety Code § 109875, et seq.

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("Sherman Law"), which adopts, incorporates, and is identical in the respects relevant here to the federal FDCA.

- 45. Under the FDCA and its implementing regulations, Defendant's Product constitutes a misbranded drug, adulterated drug, and/or unapproved new drug that does not meet the general requirements for nonprescription drugs to be marketed without an approved application.
- The introduction of any misbranded or adulterated drug into interstate commerce 46. is prohibited under federal law. 21 U.S.C. § 331. The same is true under the Sherman Law. Cal. Health & Safety Code § 111440 (sale of misbranded drug unlawful); Cal. Health & Safety Code § 111295 (sale of adulterated drug unlawful).
- Further, the introduction or delivery for introduction into interstate commerce of 47. a purported nonprescription OTC drug that fails to meet the OTC drug requirements is prohibited under federal law. 21 U.S.C § 355(a) and 331(d). The same is true under the Sherman Law. Cal. Health & Safety Code § 111550.
 - Defendant's Product is 'Misbranded' Under 21 U.S.C. § 352 and the (i) Sherman Law.
- Defendant's Product is 'misbranded' under 21 U.S.C. § 352(a), which provides 48. that a drug shall be deemed to be misbranded under the FDCA if, inter alia, if "its labeling is false or misleading in any particular."
- 49. Further, "[i]f an article is alleged to be misbranded because the labeling...is misleading, then in determining whether the labeling...is misleading there shall be taken into account (among other things) not only representations made or suggested by statement [or] word,...but also the extent to which the labeling...fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article...under such conditions of use as are customary or usual." 21 U.S.C. § 321(n).
- 50. The Product labeling (in the ingredients list or otherwise) fails to reveal that the Product contains or may contain benzene. This absence of this disclosure conveys that it is

not possible that benzene may be in the product bottle, which independent third-party testing has proved demonstrably false.

- 51. The omission that the Product contains or may contain a dangerous carcinogen is a material fact for any consumer item.
- 52. The Product purchased by Plaintiff was even marketed as "[s]afe for the whole family."
- 53. Exposure or potential exposure to carcinogens is even more material given that other products which offer the same protection are carcinogen-free.
- 54. 21 U.S.C. § 352(e)(1)(A)(iii) provides that a drug is also misbranded under the FDCA "[i]f it is a drug, unless its label bears[, *inter alia*,] the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package." The regulations incorporate the same, mandating disclosure of "[t]he ingredient information required by [21 USC § 352(e)]" of the FDCA. 21 C.F.R. § 201.10(a).¹⁷
- 55. The regulations similarly provide, as part of the label's content requirements, that the label discloses the "inactive ingredients' followed by a listing of the established name of each inactive ingredient." 21 C.F.R. § 201.66(c)(8).
- 56. While 'component' as it is used in Part 201 is not defined, Part 201 specifies that with respect to a finished product's label ingredient list, "[t]he term ingredient applies to *any substance in the drug*[.]" 21 C.F.R. § 201.10(b) (emphasis added). Thus, OTC drugs as they are delivered to consumers may only contain 'active ingredients' or 'inactive ingredients.'
- 57. Further, a substance that is present in some, but not all, bottles of a drug product should still be listed as an 'inactive ingredient' if a manufacturer were to, as here, use a uniform ingredients list.
- 58. In its OTC Labeling Guidance, when discussing 21 C.F.R. § 201.66(c)(8)'s 'inactive ingredient' requirement, FDA explains:

¹⁷ The FDCA requires a label to list, *inter alia*, "the established name and quantity of…each active ingredient" as well as "the established name of each inactive ingredient[.]" 21 U.S.C. § 352(e)(ii), (iii).

E. Inactive ingredients: "contains one or more of these ingredients" labeling.

There may be circumstances when manufacturers, packers, and distributors who market OTC drug products use multiple suppliers for some drug products to maintain an uninterrupted supply of the drug product to their customers. In such cases, the specific inactive ingredients in the drug products may vary slightly from supplier to supplier: some inactive ingredients may be present in drug products coming from all suppliers while other inactive ingredients may not be present. To have one label for all drug products, we recommend that the ingredients that may (or may not) be contained in each individual drug product be listed on the labeling in the following manner.

• We believe that this type of inactive ingredient labeling can be accomplished best by placing those ingredients that may (or may not) be contained in an OTC drug product in the inactive ingredient listing, as set forth in 201.66(c)(8), with an asterisk placed next to those ingredients (e.g., acacia*, dextrose*, sucrose, xanthum gum*). The asterisk would then be reprinted at the bottom or end of the inactive ingredient section in the Drug Facts box with the notation "* contains one or more of these ingredients" (if more than one ingredient may (or may not) be in the drug product), or "* may contain this ingredient" (if only one ingredient may (or may not) be in the drug product), whichever is appropriate.

. . .

Manufacturers, packers, and distributors are also reminded to follow all applicable current good manufacturing practice regulations in 21 CFR part 211 for finished pharmaceuticals so that manufacturers maintain appropriate records showing which lot numbers of the drug product contain which inactive ingredients.

FDA, Guidance for Industry: Labeling OTC Human Drug Products (May 2009) at 9, 12-13, available at https://www.fda.gov/media/76481/download.

- 59. Thus, for the Product to comply with FDA's guidance, it would have at least included benzene in the inactive ingredients list with a 'may contain this ingredient' asterisk.
 - 60. The Product is 'misbranded' under 21 U.S.C. § 352(e).
- 61. Benzene is a substance found in the Product by independent, third-party testing. Upon information and reasonable belief, benzene is not an 'active ingredient' in the Product, but rather, an inactive ingredient. The presence of benzene should have been included on the Product label in the 'inactive ingredients' panel, with or without a 'may contain this ingredient' as appropriate.
- 62. Alternatively, even if benzene were not required to be listed as an inactive ingredient, 21 U.S.C. § 352(j) provides that a drug is also misbranded under the FDCA if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."
- 63. Here, the Defendant has violated 21 U.S.C. § 352(j), rendering the Product 'misbranded.'
- 64. According to the NIOSH, humans can become exposed to benzene through "inhalation, **skin absorption**, ingestion, **skin** and/or eye contact." (emphasis added). Skin absorption is particularly concerning as there have been multiple FDA studies showing that structurally similar chemicals in sunscreen products are found in the blood at high levels after application to exposed skin.¹⁸
- 65. Given that the Product is to be applied on exposed skin, and given that carcinogen-free hand sanitizers exist offering the same benefit, utilizing a hand sanitizer containing benzene creates a completely avoidable and unreasonable risk, and is dangerous to one's health.

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66. This is consistent with FDA's approach to the use of benzene in drug manufacturing. Recognizing benzene's industrial use as a solvent, FDA has advised drug manufacturers to avoid using benzene, which it classifies as a "known human carcinogen" and "Class 1 solvent...to be avoided[.]" In its non-binding guidance as to residual solvents (solvents than remain as impurities in finished drug products), FDA explains:

IV. LIMITS OF RESIDUAL SOLVENTS

A. Solvents to be Avoided

Solvents in Class 1 (Table 1; see companion document) should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicity or their deleterious environmental effect. However, if their use is unavoidable in order to produce a drug product with a significant therapeutic advance, then their levels should be restricted as shown in Table 1, unless otherwise justified.

FDA, Guidance for Industry: Q3C Impurities: Residual Solvents (Dec. 1997), available at https://www.fda.gov/media/71736/download, at 6 (emphasis in original).

- 67. Insofar as the benzene in Defendant's Product was intentionally utilized or was a residual solvent impurity, since its use was not unavoidable, its presence at any level presents an unacceptable toxicity, rendering the product dangerous.
- In early March 2020, however, the FDA issued a Temporary Policy for 68. Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), Guidance for Industry. This policy was issued "to communicate its policy for the temporary preparation of certain alcohol-based hand sanitizer products by firms

that register their establishment with FDA as an over-the-counter (OTC) drug manufacturers"¹⁹ This policy has been updated several times since it was first implemented.

- 69. Among the interim limits on ethanol-related impurities established in the FDA policy were limits on benzene, for which the FDA established an interim limit of 2 parts per million ("PPM").
 - 70. Nevertheless, the benzene in the Product exceeds this threshold.
- 71. Accordingly, the Product is 'misbranded' under the FDCA. It is similarly misbranded under the Sherman Law. *See* Cal. Health & Safety Code § 111330 ("Any drug or device is misbranded if its labeling is false or misleading in any particular."); Cal. Health & Safety Code § 111400 ("Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.").
 - (ii) The Product is 'Adulterated' Under 21 U.S.C. § 351 and the Sherman Law.
- 72. In addition to (or in the alternative to) being 'misbranded' under 21 U.S.C. § 352, the Product is 'adulterated' under 21 U.S.C. § 351 and related regulations.
- 73. 21 U.S.C. § 351(a)(1) provides that a drug shall deemed to be adulterated under the FDCA if, inter alia, "it consists in whole or in part of any filthy, putrid, or decomposed substance[.]"
- 74. The Product consist in part of benzene, an inherently volatile and unstable compound subject to rapid decomposition.
- 75. The inherent nature of benzene aside, insofar as the benzene exists as an impurity or contaminant (rather than an intentional ingredient), its presence in the Product exists as a filthy, putrid, and/or decomposed substance.
- 76. 21 U.S.C. § 351(a)(2)(A) provides that a drug is also adulterated under the FDCA "if it has been prepared, packed, or held under insanitary conditions...whereby it may

¹⁹ FDA, Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (Mar. 22, 2020), *available at* https://www.regulations.gov/document/FDA-2020-D-1106-0020.

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have been rendered injurious to health[.]" Similarly, a drug is also adulterated "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health[.]" 21 U.S.C. § 351(a)(3).

- If it is the case that the benzene in the Product was not added intentionally to the 77. hand sanitizer formulation, it follows that the benzene exists due to either contamination or the failure to remove impurities.
- With respect to potential contamination, the undisputed discovery of benzene in 78. the Product—if not intentional—evidences that the Product was either manufactured, packaged, or stored under conditions where it, at the very least, may have been rendered injurious to health. This renders the Product adulterated, regardless of whether those conditions resulted in benzene contamination in every single product bottle.
- 79. Alternatively, if the presence of benzene is that of an impurity (left over after its use as a solvent during the manufacturing process), the mere decision to utilize benzene—as opposed to other equally effective, less harmful (and non-carcinogenic) chemicals—amounts to preparing the Product in a way whereby it may be rendered injurious to health.
- In the further alternative, even if the decision of the manufacturer to utilize 80. benzene as a solvent does not amount to preparing the hand sanitizer in a way potentially rendering in injurious to health, the failure to utilize adequate procedures to remove impurities during the manufacturing process amounts to precisely that.
- 21 U.S.C. § 351(a)(2)(B) provides that a drug is also adulterated under the FDCA if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug...has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess[.]"
- The general regulations governing OTC drugs clarify that OTC drugs must be 82. "manufactured in compliance with current good manufacturing practices, as established by [21 C.F.R.] parts 210 and 211." 21 C.F.R. § 330.1(a); see also 21 C.F.R. § 330.1(f) ("[t]he

- product container and container components meet the requirements of [21 C.F.R.] § 211.94"). "The failure to comply with any regulation set forth in [Parts 210 and 211] in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under [21 U.S.C. § 351(a)(2)(B)]." 21 C.F.R. § 210.1(b).
- 83. Insofar as benzene—a harmful carcinogen—made its way into the Product by accident, it follows that it was due to poor manufacturing processes by either the manufacturer or its agents.
- 84. Accordingly, the Product is 'adulterated' under the FDCA. It is similarly adulterated under the Sherman Law. Cal. Health & Safety Code § 111250.
 - (iii) The Product Does Not Meet the General Requirements for Nonprescription Drugs to be Marketed Without an Approved Application under 21 U.S.C. § 355 and the Sherman Law.
- 85. In addition to (or in the alternative) to being 'misbranded' and/or 'adulterated' under 21 U.S.C. §§ 351-352, Defendant's Product is an unapproved new drug marketed in violation of 21 U.S.C. §§ 331 and 355.
- 86. 21 U.S.C. § 355h sets forth the requirements for marketing nonprescription OTC drugs without an approved new drug application, and OTC drugs failing to meet those requirements are rendered unapproved new drugs marketed in violation of 21 U.S.C. §§ 355(a) and 331(d).
- 87. In other words, to sell new OTC drugs without FDA approval, certain conditions must be met. If the seller is unable to meet those conditions, then the product must be FDA-approved. If the product that does not meet these conditions is brought to market, it is rendered an illegal unapproved new drug.
- 88. Among those requirements are that the OTC drug is "in conformity with the requirements for nonprescription use of [any applicable] final monograph [and] the general requirements for nonprescription drugs" provided at 21 C.F.R. § 330.1. 21 C.F.R. § 355h(a)(1)(A)(i).

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- 89. As explained above, one or more of the portions of 21 C.F.R. § 330.1 dealing with misbranding and adulteration were violated by Defendant. See *supra* (discussing 21 C.F.R. § 330.1(c)(1).
- Further, 21 C.F.R. § 330.1 provides another requirement for OTC drugs 90. implicated here, that "[t]he product contains only suitable inactive ingredients which are safe in the amounts administered[.]" 21 C.F.R. § 330.1(e). A suitable inactive ingredient generally provides a benefit in terms of the drug formulation (such as a delayed-release mechanism in a prescription drug).
- As discussed herein, the benzene was an inactive ingredient in Defendant's 91. Product, warranting its inclusion on the ingredients panel (with a 'may contain this ingredient' qualifier at best).
- 92. Benzene is not a 'suitable' inactive ingredient. Upon information and belief, the benzene serves no beneficial purpose in the drug.
- Nor is benzene a 'safe' inactive ingredient given its carcinogenic properties and 93. its status as a Class I solvent that should not be used where, as here, a non-carcinogenic substitute was available.
- Therefore, Defendant's Product is an unapproved new drug sold in violation of 94. 21 U.S.C § 355(a) and 331(d). It is similarly an unapproved new drug sold in violation of the Sherman Law. Cal. Health & Safety Code § 111550.
- 95. Plaintiff references federal law in this Complaint not in an attempt to enforce it, but to demonstrate that Plaintiff's state-law claims do not impose any additional obligations on Defendant, beyond what was already required under federal law.

IV. PLAINTIFF'S PURCHASE OF THE PRODUCT

- Plaintiff purchased the Product from a Target location in Elk Grove, California 96. in early 2021.
- 97. Plaintiff purchased the Product for the purpose of protecting against bacteria and viruses, including COVID-19. She purchased the Product with the assumption that it was free of unnecessary carcinogens.

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- 98. When Plaintiff made her purchase, there was no disclosure on the label (in the ingredients list or otherwise), on Target's website, on Target's store shelves and/or at the point of sale, that the Product contained benzene or may have contained benzene.
- In the course of said purchase, Plaintiff was unaware that the Product she was 99. buying either contained or had the risk of containing benzene, or that it was possibly contaminated with benzene. Plaintiff does not want to be exposed to benzene or risk being exposed to benzene. Had she known that any amount of benzene was or risked being contained in the Product she purchased, she would have purchased a different hand sanitizer that did not have the risk of containing benzene.
- 100. Defendant is the responsible for omitting the material information regarding the presence of benzene in the Product on its website, on its store shelves and/or at the point of sale, and is also the responsible for the FDCA violations described herein.
- 101. Plaintiff and the Classes have suffered injury in fact and have lost money as a result of Defendant's unlawful sale of the Product. No reasonable consumer, including Plaintiff, would have purchased the Product had they known it was adulterated, misbranded, contained benzene or may have contained benzene.
- 102. Defendant's egregious conduct in selling a drug that is unlawfully adulterated and/or misbranded aside, Defendant engaged in further fraudulent, unfair, deceptive, misleading, and/or unlawful conduct stemming from its omissions surrounding the presence or potential presence of benzene, or benzene contamination affecting the Product.
- 103. No reasonable consumer, including Plaintiff, would have purchased Defendant's Product had they known the truth of the representations and omissions described herein. Accordingly, Plaintiff and the Classes suffered injury in fact and lost money as a result of Defendant's misleading representations and omissions and did not receive the benefit-of-thebargain.
- 104. Plaintiff and the Classes' injury is underscored by the fact that numerous other products offering the same benefit at comparable prices exist that are not prone to benzene contamination.

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105. Plaintiff and the Classes may be harmed again in the future because they want to purchase the Product in the future; however, Plaintiff would not be able to know or trust that the Product is benzene-free and would be likely to be misled again, absent injunctive relief.

TOLLING OF ANY APPLICABLE STATUTES OF LIMITATION

- 106. The existence of the presence of benzene in the Product was not capable of being ascertained by Plaintiff until March 24, 2021, when the Valisure Report was issued.
- 107. Prior to March 24, 2021, Plaintiff was not on actual or constructive notice and thus could not discover that the Product contained benzene.
- 108. By reason of the foregoing, the claims of Plaintiff are timely under any applicable statutes of limitation pursuant to the discovery rule.

CLASS ACTION ALLEGATIONS

109. In accordance with Fed. R. Civ. P. 23(b)(3) and 23(b)(2), Plaintiff brings this action on behalf of the following class of persons (the "Class"):

> All natural persons residing in the United States who purchased the Product in the United States for personal use and not for re-sale.

110. In accordance with Fed. R. Civ. P. 23(b)(3) and 23(b)(2), Plaintiff further brings this action on behalf of the following class of persons (the "California Sub-Class"):

> All natural persons residing in the State of California who purchased the Product in the State of California for personal use and not for resale.

- 111. Plaintiff reserves the right to modify or amend the definition of the proposed Classes before the Court determines whether certification is proper, as more information is gleaned in discovery.
- 112. Excluded from the Classes are Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals,

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servants, partners, joint ventures, or entities controlled by Defendant, and its heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

- 113. Numerosity. The members of the Class and Sub-Class are so numerous that joinder of all members is impracticable. On information and belief, there are in excess of a hundred thousand members of the Class and Sub-Class. Discovery will reveal, through Defendant's records, the approximate number of Class and Sub-Class members.
- 114. Commonality. Common questions of law and fact apply to the claims of all Class and Sub-Class Members and include (but are not limited to) the following:
 - a. Whether the source of benzene in the Product was by design, an impurity byproduct, or the result of contamination;
 - b. Whether Defendant omitted, in connection with the sale of the Product, whether the Product contained or may have contained benzene;
 - c. Whether Defendant was aware, or should have known, that the Product contained benzene (or, alternatively, a significant risk of benzene contamination) when it marketed, advertised, and sold the Product to Plaintiffs and the other members of the Class and Sub-Class
 - d. Whether the Product was adulterated, misbranded, and/or an unapproved new drug under the FDCA and/or the Sherman Law (for the California Sub-Class);
 - e. Whether Defendant violated the FDCA and/or the Sherman Law (for the California Sub-Class);
 - f. Whether Defendant's violations of the FDCA and/or the Sherman Law (for the California Sub-Class) constitute violations of UCL;
 - g. Whether, independent of whether Defendant's conduct violated the FDCA, Defendant's conduct constitutes an unfair act or practice in violation of the UCL;

- h. Whether, independent of whether Defendant's conduct violated the FDCA,
 Defendant's conduct constitutes a deceptive act or practice in violation of the UCL;
- i. Whether, independent of whether Defendant's conduct violated the FDCA, Defendant's conduct violates the CLRA;
- j. Whether, independent of whether Defendant's conduct violated the FDCA, Defendant's conduct violates the FAL;
- k. Whether Defendant has breached express and/or implied warranties made to Plaintiff and members of the Classes;
- 1. Whether Defendant's conduct violates the Magnuson-Moss Warranty Act;
- m. Whether Defendant's conduct constitutes fraud;
- n. Whether Defendant was unjustly enriched by Plaintiff and the Classes;
- o. Whether Defendant has violated Proposition 65;
- p. Whether Defendant's conduct and/or omissions in the marketing, advertising, labeling, and/or packaging of the Product in the manner discussed herein is likely to deceive reasonable consumers;
- q. Whether Defendant's Product is worthless;
- r. Whether Plaintiff and the Class and Sub-Class Members are entitled to damages, and the proper measure of the loss;
- s. Whether Plaintiff and the Class and Sub-Class Members are entitled to restitution, and the proper measure of the loss;
- t. Whether Plaintiffs and the Class and Sub-Class Members are entitled to attorney's fees and expenses, and in what amount;
- u. Whether Plaintiffs and the Class and Sub-Class Members are entitled to declaratory, injunctive, and/or other equitable relief;
- 115. <u>Typicality</u>. Plaintiff's claims are typical of the claims of all Class and Sub-Class Members. The harm suffered by Plaintiffs and the Classes was and is caused by the same misconduct by Defendant.

- 116. <u>Adequacy</u>. Plaintiffs have retained counsel highly experienced in complex consumer class action litigation and intends to prosecute this action vigorously. Plaintiffs are members of the Class and Sub-Class described herein and do not have interests antagonistic to, or in conflict with, the other members of the Class or Sub-Class.
- 117. Predominance and Superiority. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the monetary damages suffered by individual Class and Sub-Class members are relatively small, the expense and burden of individual litigation make it impossible for individual Class and Sub-Class members to seek redress for the wrongful conduct asserted herein. If class treatment of these claims is not available, Defendant would likely continue its wrongful conduct, will unjustly retain improperly obtained revenues, and/or otherwise escape liability for its wrongdoing. Further, common questions of law and fact predominate.
- 118. Plaintiff knows of no difficulty which will be encountered in the management of this litigation which would preclude its maintenance as a class action.
- 119. The prosecution of separate actions by individual members of the Class and Sub-Class would run the risk of inconsistent or varying adjudications, which might establish incompatible standards of conduct for the Defendant. Prosecution as a class action will eliminate the possibility of repetitious litigation.
- 120. Class Certification Pursuant to Fed. R. Civ. P. 23(b)(2). Class certification is also appropriate under Federal Rule of Civil Procedure 23(b)(2) because Defendant's actions are generally applicable to the Class and Sub-Class as a whole, and Plaintiff seeks equitable remedies with respect to the Class and Sub-Class as a whole. Defendant has acted or refused to act on grounds generally applicable to the Class and Sub-Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Classes as a whole. Moreover, Plaintiff continues to have use for hand sanitizer products. Without an injunction, Plaintiffs would be unable to trust Defendant's representations and would not purchase the Product.

CLAIMS FOR RELIEF

121. Based on the foregoing allegations, Plaintiff's claims for relief include the following:

COUNT I

Breach of Express Warranty

(On Behalf of the Nationwide Class and the California Sub-Class)

- 122. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 123. This cause of action is alleged on behalf of Plaintiff and the Classes against Defendant.
- 124. Plaintiff, and each member of the Classes, formed a contract with Defendant at the time Plaintiff and the members of the Classes purchased the Product. The terms of the contract include the promises and affirmations of fact made by Defendant that the Product is "[s]afe & effective for the whole family." This representation constitutes an express warranty and became part of the basis of the bargain, and are part of the contract between Plaintiff and the members of the Classes and Defendant.
- 125. Defendant's Product did not conform to its express representations and warranties because the Product contains—or risks containing—benzene, a known carcinogen.
- 126. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing express warranties: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. § 72-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat.

1	Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code
2	Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J.
3	Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen
4	Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat
5	tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, §
6	3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-
7	313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. §
8	70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash
9	Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.
10	127. Defendant breached its express warranties with respect to the Product as it

127. Defendant breached its express warranties with respect to the Product as it contains—or risks containing—benzene, a known carcinogen.

- 128. Plaintiff and each member of the Classes would not have purchased the Product had they known it contained or may contain benzene, a known carcinogen.
- 129. As a direct and proximate result of Defendant's breach of warranty, Plaintiff and other Class members have been injured and suffered damages in the amount of the purchase price of the Product, because the Product failed to conform Defendant's representations.
- 130. Prior to the filing of this Complaint, Plaintiff's counsel sent Defendant a notice letter advising them that they breached an express warranty and demanded that they cease and desist from and remedy such breaches.

COUNT II

Breach of Implied Warranty of Merchantability (On Behalf of the Nationwide Class and the California Sub-Class)

- 131. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 132. This cause of action is alleged on behalf of Plaintiff and the Classes against Defendant.

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- 133. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. §
 - 134. Defendant was a merchant within the meaning of the above statutes.
- 135. Defendant's Product constituted a "good" or the equivalent within the meaning of the above statutes.
- 136. Defendant was obligated to provide Plaintiff and other class members a reasonably fit Products for the purpose for which the Product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

16 fully set forth herein. 18

- 137. Defendant breached its implied warranty because the Product was not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.
 - 138. The Product was not altered by Plaintiff or other class members.
- 139. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff and other Class members have been injured and suffered damages, in that the Product they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.
- 140. Prior to the filing of this Complaint, Plaintiff's counsel sent Defendant a notice letter advising them that they breached an implied warranty and demanded that they cease and desist from and remedy such breaches.

COUNT III

Violation of the Magnuson-Moss Warranty Act (On Behalf of the Nationwide Class and the California Sub-Class)

- 141. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if
- 142. This cause of action is alleged on behalf of Plaintiff and the Classes against Defendant.
- 143. The Magnuson-Moss Warranty Act provides a federal remedy for consumers who have been damages by the failure of a supplier or warrantor to comply with any obligation under a written warranty or implied warranty, or other various obligations established under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, et seq.
- 144. The Product is a "consumer product" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(1).
- 145. Plaintiffs and Class members are "consumers" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3).

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- 146. Defendant is a "supplier" and "warrantor" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301(4) & 2301(5).
- 147. Defendant represented in writing that the Product is "[s]afe & effective for the whole family." This statement was made in connection with the sale of the Product, relates to the nature of the Product, and affirms and promises that the Product is as represented and defect free, and as such is a "written warrant[y]" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(6)(A).
- 148. Defendant breached its written warranty by selling consumers Product that contains—or risks containing—benzene, a known carcinogen.
- 149. The Product does not conform to Defendant's written warranty and therefore violates the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, et seq. Consequently, Plaintiff and Class members have suffered injury and are entitled to damages in an amount to be proven at trial.

COUNT IV

Unjust Enrichment

(On Behalf of the Nationwide Class and the California Sub-Class)

- 150. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 151. This cause of action is alleged on behalf of Plaintiff and the Classes against Defendant.
- 152. Regardless of whether Defendant disclosed benzene or not, Defendant should have never sold that Product (and was actually legally precluded therefrom). The drug comprising the Product itself, regardless of any disclosures made or not made, was illegal, as the drug: (a) contained unsuitable inactive ingredients, (b) contained unsafe inactive ingredients, and/or (c) was contaminated with benzene.

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1	53.	As a result of Defendant's selling its Product, Defendant r	receives a	benefit
which v	was c	conferred upon it by Plaintiff and the Classes (and/or at their e	expense), a	and it is
unjust f	for D	Defendant to retain that benefit.		

- 154. Alternatively, despite the serious risks of harm inherent in potentially exposing consumers to benzene, Defendant has not disclosed these risks, and in fact has actively obfuscated the dangers of the Product by promising consumers the Product is safe. Plaintiff and Class members would not have bought the Product if they had known the Product contained benzene (or, alternatively, a significant risk of benzene existing due to impurities or contamination).
- 155. As a result of Defendant's deceptive marketing and advertising of the Product, Defendant receives a benefit which was conferred upon it by Plaintiff and the Classes (and/or at their expense), and it is unjust for Defendant to retain that benefit.
- 156. Under the circumstances, it is against equity and good conscience to permit Defendant to retain the ill-gotten benefits that it received from Plaintiff and Class members.
- 157. As a direct and proximate result of Defendant's actions, Defendant has been unjustly enriched. Plaintiff and Class members have a right to restitution in an amount to be proven at trial.

COUNT V

Fraud

(On Behalf of the Nationwide Class and the California Sub-Class)

- 158. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 159. This cause of action is alleged on behalf of Plaintiff and the Classes against Defendant.
- 160. As discussed above, Defendant provided Plaintiff and members of the Classes with materially false or misleading information about the Product. Specifically, Defendant has marketed the Product as safe for human use. As indicated above, however, these

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representations are false and misleading as the Product contained elevated levels of benzene, a known carcinogen.

- 161. Defendant also materially omitted key facts regarding the true nature of the Product, specifically that the Product contained dangerous levels of benzene, was adulterated, and was unsafe for use as a hand sanitizer—facts going directly to the safety of the use of the Product. Had Plaintiffs and members of the Classes been apprised of these presumptively material facts, they would have been aware of them and would not have purchased the Product.
- 162. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and members of the Classes reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and members of the Classes to purchase the Product.
- 163. Defendant knew the Product was contained—or may contain—benzene, a known carcinogen, but continued to sell it nonetheless.
- 164. The fraudulent actions of Defendant caused damage to Plaintiff and members of the Classes, who are entitled to damages and other legal and equitable relief as a result.
- 165. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT VI

Violations of Proposition 65

California Health and Safety Code § 25249.5 et seq. (On Behalf of the California Sub-Class)

- 166. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 167. Within the last one (1) year from the service of the Proposition 65 Notice Letter and continuously ongoing at present, Defendant has engaged in acts and omissions in violation of the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") by knowingly and intentionally exposing Plaintiff and members of the California Sub-Class

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26 27 28 to a chemical known to the state to cause cancer or reproductive toxicity (namely, benzene), through the sale of the Product, without first giving clear and reasonable warning to such individual.

- 168. On October 4, 2021, Plaintiff sent the Proposition 65 Notice Letter to Defendant and incorporates the same by reference, as though fully set forth herein.
- 169. An action for injunctive relief under Proposition 65 is specifically authorized by California Health & Safety Code § 25249.7 against Defendant for violating or threatening to violate Section 25249.5.
- 170. In the absence of preliminary and then permanent injunctive relief, Defendant will continue to create a substantial risk of irreparable injury by continuing to cause citizens of the State of California to be involuntarily, unknowingly and unwittingly exposed to the benzene as a result of Defendant's acts and omissions.
- 171. Because of its violation of Proposition 65, Defendant is also liable for civil penalties of \$2,500 per day for each violation in addition to any other penalty established by law.

COUNT VII

Violations of the Consumer Legal Remedies Act California Civil Code § 1750, et seq. (On Behalf of the California Sub-Class)

- 172. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 173. Plaintiff brings this claim under California Civil Code § 1750, et seq., the CLRA, on behalf of herself and the California Sub-Class, who were subject to Defendant's abovedescribed unfair and deceptive conduct.
- 174. Plaintiff and members of the California Sub-Class are consumers as defined by California Civil Code section 1761(d). The Product is a good within the meaning of California Civil Code section 1761(a).

- 175. Plaintiff is concurrently filing the declaration of venue required by California Civil Code § 1780(d) with this complaint.
- 176. Defendant engaged in the sale of the Product, which contains—or may contain—benzene, a known carcinogen.
- 177. In the course of its business, Defendant failed to disclose the presence of benzene in the Product, on its website, store shelves and/or at the point of sale, in violation of the CLRA.
- 178. Defendant violated and continues to violate the CLRA by engaging in the following practices proscribed by California Civil Code section 1770(a) in transactions with Plaintiff and members of the California Sub-Class, which were intended to result in, and did result in, the sale of the Product:
 - a. By failing to disclose the presence of benzene in the Product and by misleading consumers about its safety for personal use, Defendant is representing the Product has "sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have," in violation of Civ. Code § 1770(a)(5);
 - b. By failing to disclose the presence of benzene in the Product and by misleading consumers about its safety for personal use, Defendant is representing the Product is "of a particular standard, quality, or grade . . . if they are of another," in violation of Civ. Code § 1770(a)(7);
 - c. By failing to disclose the presence of benzene in the Product and by misleading consumers about its safety for personal use, Defendant is "[a]dvertising goods or services with intent not to sell them as advertised," in violation of Civ. Code § 1770(a)(9); and,
 - d. By failing to disclose the presence of benzene in the Product and by misleading consumers about its safety for personal use, Defendant is representing that the Product has "been supplied in accordance with a previous representation when it has not," in violation of Cal. Civ. Code § 1770(a)(16).

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- 179. Defendant's misrepresentations and omissions were material in that they would be a substantial factor in deciding whether to buy the Product and were likely to deceive reasonable consumers.
- 180. Defendant concealed and continues to conceal material facts concerning the presence or potential presence of benzene in the Product. Plaintiff did not know the Product posed the risk of cancer at the time she purchased the product and, had she been aware of these material facts, Plaintiff would not have purchased the Product.
- 181. Defendant's actions as described herein were done with conscious disregard of Plaintiff's rights, and Defendant was wanton and malicious in its concealment of the same.
- 182. Defendant's wrongful business practices constituted, and constitute, a continuing course of conduct in violation of the CLRA because Defendant continues to sell the Product while failing to disclose the presence of potential presence of benzene, and has thus injured and continues to injure Plaintiff and the California Sub-Class.
- 183. Plaintiff and other members of the California Sub-Class have suffered injury in fact and have lost money as a result of Defendant's deceptive conduct. Plaintiff would not have purchased the Product had she known it contained—or may contain—benzene at the time she purchased it.
- 184. Pursuant to California Civil Code § 1780(a), Plaintiff and the California Sub-Class seek restitution and injunctive relief compelling Defendant to (1) recall the Products currently in distribution with their material misrepresentations and omissions, (2) permanently refrain from selling the Product in the future with these material misrepresentations and omissions, and (3) disclosing on its website, store shelves and/or at the point of sale, that the Product contains—or may contain—benzene. Plaintiff and members of the California Sub-Class shall be irreparably harmed if such an order is not granted.
- 185. On February 22, 2022, Plaintiff sent Defendant notice advising Defendant it violated, and continues to violate, Section 1770 of the CLRA (the "Notice"). The Notice complies in all respects with Section 1782 of the CLRA. Plaintiff sent the Notice by Certified U.S. Mail, return-receipt requested to Defendant at Defendant's principal place of business.

Plaintiff's Notice advised Defendant it must correct, repair, replace or otherwise rectify its conduct and the product alleged to be in violation of Section 1770, including that Defendant refrain from the sale of the Product in the future with these material misrepresentations and omissions, and provide corrective advertising and provide restitution to its customers who paid money to Defendant for said products. However, Plaintiff advised Defendant that if it fails to respond to Plaintiff's demand within thirty (30) days of receipt of the Notice, Plaintiff will take appropriate action, which includes amending this complaint to seek actual and punitive damages pursuant to Sections 1782(a) and (d) of the CLRA.

COUNT VIII

Violations of the False Advertising Law California Bus. and Prof. Code § 17500, et seq.

(On Behalf of the California Sub-Class)

- 186. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 187. Plaintiff brings this claim under the False Advertising Law, Cal. Bus. & Prof. Code § 17500, *et seq.* ("FAL"), on behalf of herself and the California Sub-Class, who were subject to Defendant's above-described unfair and fraudulent conduct.
- 188. As alleged hereinabove, Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and has lost money or property as a result of Defendant's actions as set forth herein. Specifically, prior to filing this action, Plaintiff purchased the Product for her own personal use. In so doing, she relied upon the representations and omissions referenced above and believed the Product was safe for personal use, and was not aware that it contains—or may contain—benzene.
- 189. The FAL provides that it is unlawful for any person or corporation, or any employee thereof "with intent directly or indirectly to dispose of real or personal property...or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any

newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property...or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading" Cal. Bus. & Prof. Code § 17500.

- 190. In advertising the Products, Defendant made false and misleading statements in order to induce consumers into purchasing the Product on the belief the Product was safe for personal use. For example, Defendant represented on its website the Product is "[s]afe & effective for the whole family."
- 191. Defendant uses advertising on its website, among other things, to promote the Product.
- 192. Defendant's advertising is deceptive, or misleading within the meaning of the FAL because, contrary to its affirmative representations, the Product is not safe for personal use, as it contains—or may contain—benzene.
- 193. In disseminating the statements alleged herein, Defendant knew that the statements were untrue or misleading.
- 194. Through its deceptive and unlawful marketing practices, Defendant has improperly and illegally obtained money from Plaintiff and the California Sub-Class.
- 195. Pursuant to the FAL, specifically Cal. Bus. & Prof. Code § 17535, Plaintiff and the California Sub-Class seek restitution and an order of this Court enjoining Defendant from engaging in the false and/or misleading advertising alleged herein in connection with the sale of the Product.
- 196. Specifically, Plaintiff and the California Sub-Class seek an order of this Court enjoining Defendant from engaging in the false and/or misleading advertising alleged herein in connection with the sale of Roundup. Specifically, Plaintiff seeks injunctive relief compelling Defendant to (1) recall the Products currently in distribution with their material misrepresentations, (2) permanently refrain from selling the Product in the future with these

material misrepresentations, and (3) disclosing on its website, store shelves and/or at the point of sale, that the Product contains—or may contain—benzene.

COUNT IX

Violations of the Unfair Competition Law – Unfair and Fraudulent Prongs California Bus. and Prof. Code § 17200, et seq.

(On Behalf of the California Sub-Class)

- 197. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 198. Plaintiff brings this claim under the 'unfair' and 'fraudulent' prongs of the UCL, on behalf of herself and the California Sub-Class, who were subject to Defendant's above-described unfair and fraudulent conduct.
- 199. As alleged hereinabove, Plaintiff has standing to pursue this claim as Plaintiff has suffered injury in fact and has lost money or property as a result of Defendant's actions as set forth herein. Specifically, prior to filing this action, Plaintiff purchased the Product for her own personal use. In so doing, she relied upon the representations and omissions referenced above and believed the Product was safe for personal use, and was not aware that it contains—or may contain—benzene.
- 200. Defendant's conduct in selling the Product is likely to deceive reasonable consumers. Indeed, reasonable consumers would not pay money for a product that poses, or may pose, a cancer risk.
 - 201. Defendant is aware that its conduct is likely to deceive reasonable consumers.
- 202. As alleged in detail above, Plaintiff would not have purchased the Product from Defendant had she known it contains—or may contain—benzene at the time she purchased it.
- 203. The misrepresentations, conduct and inadequate disclosures by Defendant are material and constitute an unfair and fraudulent business practice within the meaning of the UCL.

204. Defendant's business practices, as alleged herein, are unfair because: (1) the injury to the consumer is substantial; (2) the injury is not outweighed by any countervailing benefits to consumers or competition; and (3) consumers could not reasonably have avoided the injury because Defendant misled the consuming public through its misrepresentations and omissions as set forth herein.

- 205. Defendant's business practices are also unfair because their conduct in selling the Product offends established public policy and is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers. Such public policy is tethered to a specific constitutional and statutory provisions, including California's consumer protection statutes.
- 206. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described above.
- 207. Defendant's business practices as alleged herein are fraudulent because they are likely to deceive customers into believing that the Product is actually safe for personal use. Defendant knows its representations and omissions will deceive consumers into purchasing a product that may indeed be harmful.
- 208. Plaintiff was misled into purchasing the Product by Defendant's deceptive and fraudulent conduct as alleged above.
- 209. Plaintiffs was misled and, because the omissions were uniform and material, presumably believed the Product was safe for personal use.
- 210. Defendant's wrongful business practices constituted, and constitute, a continuing course of conduct of unfair competition since Defendant is selling the Product in a manner likely to deceive the public.
- 211. Pursuant to section 17203 of the UCL, Plaintiff and the California Sub-Class seek restitution and an order of this Court enjoining Defendant from engaging in the unfair and fraudulent business practices alleged herein in connection with the sale of the Product.
- 212. Specifically, Plaintiff and the California Sub-Class seek an order of this Court enjoining Defendant from engaging in the unfair and fraudulent business practices alleged

herein in connection with the sale of Roundup. Specifically, Plaintiff seeks injunctive relief compelling Defendant to (1) recall the Products currently in distribution with their material misrepresentations and omissions, (2) permanently refrain from selling the Product in the future with these material misrepresentations and omissions, and (3) disclosing on its website, store shelves and/or at the point of sale, that the Product contains—or may contain—benzene.

COUNT X

Violations of the Unfair Competition Law – Unlawful Prong California Bus. and Prof. Code § 17200, et seq.

(On Behalf of the California Sub-Class)

- 213. Plaintiff re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 214. Plaintiff brings this claim under the 'unlawful' prong of the UCL, on behalf of herself and the California Sub-Class, who were subject to Defendant's above-described unfair and fraudulent conduct.
- 215. Defendant's sale of the Product constitutes violations of the FDCA and the Sherman Law. Specifically, Defendant violated 21 U.S.C. § 331, 21 U.S.C. § 355(a), Cal. Health & Safety Code § 111440, Cal. Health & Safety Code § 111295, and Cal. Health & Safety Code § 111550 because it sold a product that was adulterated and/or misbranded, and/or contained unsafe and/or unsuitable inactive ingredients such that it is rendered an unapproved new drug. Defendant also violated Proposition 65, the CLRA, and the FAL, as set forth above.
- 216. Defendants' violations of the FDCA, the Sherman Law, the CLRA, the FAL, and Proposition 65 constitute predicate acts which violate the UCL's 'unlawful' prong.
- 217. Plaintiff was misled because Defendants' misrepresentations and omissions, described above, were uniform and material. Plaintiff reasonably relied on those misrepresentations and material omissions, believing based thereon that the Product was safe for personal use. Plaintiff was not aware the Product contains—or may contain—benzene.

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- 218. Pursuant to section 17203 of the UCL, Plaintiff and the California Sub-Class seek restitution and an order of this Court enjoining Defendant from engaging in the unlawful business practices alleged herein in connection with the sale of the Product.
- 219. Specifically, Plaintiff and the California Sub-Class seek an order of this Court enjoining Defendant from engaging in the unfair and fraudulent business practices alleged herein in connection with the sale of Roundup. Specifically, Plaintiff seeks injunctive relief compelling Defendant to (1) recall the Products currently in distribution with their material misrepresentations and omissions, (2) permanently refrain from selling the Product in the future with these material misrepresentations and omissions, and (3) disclosing on its website, store shelves and/or at the point of sale, that the Product contains—or may contain—benzene.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment in her favor and against Defendant, as follows:

- An order certifying that the action may be maintained as a Class Action and that Α. Plaintiff be appointed the Class Representative and their undersigned counsel as Class Counsel;
- An order enjoining Defendant from pursuing the policies, acts, and practices В. complained of herein;
- C. Damages;
- Restitution; D.
- Civil penalties of \$2,500 per day for each violation pursuant to California Health Ε. and Safety Code section 25249.7
- F. Pre-judgment interest from the date of filing this suit;
- Declaratory relief; G.
- Η. Reasonable attorneys' fees;
- I. Costs of this suit; and,
- Such other and further relief as the Court may deem necessary or appropriate. J.

1 **DEMAND FOR JURY TRIAL** Plaintiffs demand a trial by jury of all issues in this action so triable. 2 3 4 Dated: March 14, 2022 5 MILSTEIN JACKSON 6 FAIRCHILD & WADE, LLP 7 Gillian L. Wade, State Bar No. 229124 gwade@mjfwlaw.com 8 Sara D. Avila, State Bar No. 263213 savila@mjfwlaw.com 9 Marc A. Castaneda, State Bar No. 299001 10 mcastaneda@mjfwlaw.com 10990 Wilshire Boulevard, 8th Floor 11 Los Angeles, California 90024 12 Phone: (310) 396-9600 13 **HONIK LLC** 14 Ruben Honik (pro hac vice to be 15 filed) ruben@honiklaw.com 16 David Stanoch (pro hac vice to be 17 filed) david@honiklaw.com 18 1515 Market Street, Suite 1100 Philadelphia, Pa. 19102 19 Phone: (267) 435-1300 20 Counsel for Plaintiff and the 21 **Proposed Classes** 22 23 24 25 26 27 28