

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

JASMINE LERNER, on behalf of herself  
and all others similarly situated,

Plaintiff,

v.

CVS HEALTH CORPORATION,

Defendant.

Civil Action No.

**CLASS ACTION COMPLAINT AND  
DEMAND FOR JURY TRIAL**

Plaintiff Jasmine Lerner (“Plaintiff”) brings this action on behalf of herself and all others similarly situated against Defendant CVS Health Corporation (“CVS” or “Defendant”) for the manufacture, marketing, and sale of CVS After-sun Aloe Vera Soothing Spray and After-Sun Aloe Vera Moisturizing Gel (the “Products”) that are contaminated with the carcinogenic impurity benzene. Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to Plaintiff herself, which are based on personal knowledge.

**FACTS COMMON TO ALL CLAIMS**

1. This is a class action lawsuit against Defendant for the manufacture and sale of the Products, which were defective because they contain benzene, a carcinogenic chemical impurity that has been linked to leukemia and other cancers. The Products are not designed to contain benzene (nor is the presence of benzene disclosed in any way on the Products’ labels), and in fact no amount of benzene is acceptable in the Products. However, Defendant’s Products not only contained benzene, but many contained benzene at levels far exceeding acceptable limits set by the United States Food & Drug Administration (“FDA”), including even emergency

interim limits. The presence of benzene in the Products renders them unsafe and worthless, and unsuitable for their principal and intended purpose.

2. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals. The Department of Health and Human Services has determined that benzene causes cancer in humans. Likewise, the FDA lists benzene as a “Class 1 solvent” that “should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity.” The World Health Organization (“WHO”) and the International Agency for Research on Cancer (“IARC”) have classified benzene as a Group 1 compound, defining it as “carcinogenic to humans.”<sup>1</sup> In 2011, the United States Environmental Protection Agency introduced regulations that lowered limits on benzene in gasoline due to its carcinogenic nature.<sup>2</sup> California’s Proposition 65 Fact Sheet for benzene states, “[b]enzene is on the Proposition 65 list because it can cause cancer and birth defects or other reproductive harm. Exposure to benzene can cause leukemia. Exposure to benzene during pregnancy may affect development of the child. It may also harm the male reproductive system.”<sup>3</sup>

3. According to the American Cancer Society:

IARC classifies benzene as “carcinogenic to humans,” based on sufficient evidence that benzene causes acute myeloid leukemia (AML). IARC also notes that benzene exposure has been linked with acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma.<sup>4</sup>

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<sup>1</sup> <https://monographs.iarc.who.int/list-of-classifications>

<sup>2</sup> <https://www.epa.gov/gasoline-standards/gasoline-mobile-source-air-toxics>

<sup>3</sup> <https://www.p65warnings.ca.gov/fact-sheets/benzene>

<sup>4</sup> American Cancer Society. Benzene and Cancer Risk (January 5, 2016) (<https://www.cancer.org/cancer/cancer-causes/benzene.html>)

4. According to the National Institute for Occupational Safety and Health, humans can become exposed to benzene through “inhalation, skin absorption, ingestion, skin and/or eye contact.”<sup>5</sup>

5. While investigating the carcinogenic potential of active ingredients in sun care products, Valisure, an online pharmacy registered with the FDA, recently detected high levels of benzene, a known human carcinogen, in the Products.

6. Valisure tested Defendant’s Products listed below using a sophisticated gas chromatography flame ionization test modified to follow FDA guidance for impurities detection. Valisure’s testing revealed quantities of benzene in the Products in excess of the “FDA concentration limit of 2 parts per million (ppm).”<sup>6</sup>

7. Defendant’s Products contained among the highest concentrations of benzene of all of the products tested by Valisure. For example, Defendant’s After-Sun Aloe Vera Soothing Spray, Lot No. 8140449A, contained between 4.55 and 4.71 ppm of benzene, over double the interim limit of 2 ppm set by the FDA.<sup>7</sup> Another tested lot, 4111849A, contained between 3.58 and 3.93 ppm of benzene, also well above FDA interim limits.<sup>8</sup> The gel Product and an additional tested lot of the spray Product also tested positive for benzene.<sup>9</sup>

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<sup>5</sup> National Institute for Occupational Safety and Health (NIOSH), Benzene, <https://www.cdc.gov/niosh/npg/npgd0049.html>.

<sup>6</sup> Valisure, Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care products, May 24, 2021 (“Valisure Petition”), <https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/>, at 1.

<sup>7</sup> *Id.*, at 12.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 13.

8. Following the Valisure petition, on or around July 15, 2021, Defendant announced it was halting the sale of the Products “found to contain the carcinogen benzene.”<sup>10</sup>

9. Benzene is not listed as an ingredient on the Products’ labels. Defendant does not disclose the actual or potential presence of benzene in its Products at all on the Product’s labeling, or in any advertising or website promoting the Product.

10. The Products are regulated by the FDA as cosmetics pursuant to the federal Food, Drug and Cosmetics Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, as well as analogous state statutes and regulations. The FDCA “prohibits the distribution of cosmetics which are adulterated or misbranded. A cosmetic is considered adulterated **if it contains a substance which may make the product harmful to consumers under customary conditions of use.**”<sup>11</sup> 21 U.S.C. § 361.

11. Further, as cosmetics regulated by the FDA, the Products must “bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.” 21 C.F.R. § 740.1(a).

12. Defendant disregarded the laws and regulations outlined above. As a manufacturer, distributor, and seller of a cosmetics product, Defendant had and has a duty to ensure that its Products did not contain excessive (or any) levels of benzene, including through regular testing. But based on Valisure’s testing results set forth above, Defendant made no reasonable effort to test its Products for benzene or other impurities. Nor did it disclose to Plaintiff or any other consumers in any product advertising, labeling, packaging, or marketing

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<sup>10</sup> <https://www.bloomberg.com/news/articles/2021-07-15/cvs-halts-sales-of-two-of-its-store-brand-sun-care-products#:~:text=CVS%20Health%20Corp.%20has%20halted,also%20contaminated%20with%20the%20chemical.> (last visited 1/26/22).

<sup>11</sup> <https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/summary-cosmetics-labeling-requirements#Adulterated> (emphasis added).

that its Products contained benzene, let alone at levels in certain Products that are many multiples of the emergency, interim limit set by the FDA. To the contrary, Defendant represented and warranted, expressly and impliedly, that the Products were of merchantable quality, complied with federal and state law, and did not contain carcinogens, reproductive toxins, or other impurities such as benzene.

13. If Defendant had fulfilled its quality assurance obligations, Defendant would have identified the presence of the benzene contaminant almost immediately.

14. Further, had Defendant adequately tested its Products for benzene and other carcinogens, reproductive toxins, and impurities, it would have discovered that its Products contained benzene at levels above the FDA's limit (to the extent even applicable), making those products ineligible for distribution, marketing, and sale.

15. Instead, Defendant introduced contaminated, adulterated, and/or misbranded Products containing dangerous amounts of benzene into the U.S. market.

16. Defendant also knew or should have known about the carcinogenic potential of benzene because it is classified as a Group 1 compound by the WHO and the IARC, meaning that it is "carcinogenic to humans."

17. The presence of benzene renders the Products both adulterated and misbranded under the FDCA because benzene is a substance that makes the Products harmful to consumers under customary conditions of use.

18. Further, the Products are misbranded because their labeling is "false" and "misleading" because it does not disclose the presence of benzene, even though a warning statement concerning benzene is necessary or appropriate to prevent a health hazard. 21 C.F.R. § 740.1(a).

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