UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

AGATHA LEWANDOWSKA GIANNESE; and ANDREA FAHEY, individually and on behalf of all others similarly situated, Plaintiffs, v. EDGEWELL PERSONAL CARE BRANDS, LLC, Defendant.	Case No. _____ **CLASS ACTION COMPLAINT** (JURY TRIAL DEMANDED)

Agatha Lewandowska Giannese ("Plaintiff Lewandowska Giannese") and Andrea Fahey ("Plaintiff Fahey") (collectively, "Plaintiffs"), individually and on behalf of all others similarly situated, make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to allegations pertaining specifically to themselves or their counsel, which are based on personal knowledge.

NATURE OF THE CASE

1. Plaintiffs bring this action against Defendant Edgewell Personal Care Brands LLC to redress and put a stop to the false, deceptive, and unlawful manner in which Defendant has labeled, distributed, advertised, promoted, and marketed its sunscreen product "Hawaiian Tropic Everyday Active SPF 50 Sport Sunscreen Lotion" (the "Product"). On the Product's labeling, and in advertising and promotional materials for the Product, Defendant represents that the Product provides a sun protection factor ("SPF") that is far higher than the SPF that the Product actually provides, thereby deceiving consumers into believing that the Product offers better protection against sunburns and other dangerous effects of

exposure to ultraviolet radiation (such as skin cancer and premature aging) than it actually provides, and that the Product is thus worth purchasing at a price higher than what is charged for other lower-SPF sunscreens.

2. Plaintiffs and members of the putative Classes (defined below) purchased the Product based on Defendant's representations that the Product provides SPF 50 protection. Unbeknownst to them, however, the Product actually provides only SPF 20 protection—less than half of the protection Defendant represents—as independent laboratory testing commissioned by Plaintiffs' counsel has revealed. At SPF 20, the Product provides far less protection from the sun's harmful rays—and is of significantly lower quality and worth far less money—than a sunscreen that actually provides SPF 50 protection.

3. Defendant has labeled, distributed, advertised, promoted, and marketed the Product as providing greater protection against the sun's harmful rays than it actually provides in order to capitalize on consumer demand for high-SPF sunscreens, such as SPF 50 sunscreens. By promising SPF 50 protection, the Product sells at premium prices and, in turn, generates more revenue and profit for Defendant than its lower-SPF sunscreen counterparts.

4. By falsely representing the SPF protection provided by the Product, Defendant has knowingly misled and continues to knowingly mislead consumers into believing that they are purchasing a sunscreen with better quality, filtration, absorption, and reflection capabilities against ultraviolet radiation than the lower-SPF product that they actually receive, thereby deceiving them into paying a premium price for a non-premium product.

5. Defendant's practices of falsely, deceptively, and misleadingly representing that the Product provides SPF protection of 50 (including on the Product's labeling and in advertising and promotional materials) induced Plaintiffs and numerous other consumers into either purchasing a product they otherwise

would not have purchased at all, or paying significantly more for a product than they would have paid had it been labeled, distributed, advertised and promoted with accurate SPF representations.

6. Accordingly, Plaintiffs bring this class action complaint against Defendant to redress and put a stop to its practices of falsely, deceptively, and unlawfully misrepresenting the SPF protection provided by the Product—conduct that has caused and continues to cause significant harm to consumers nationwide, including in Florida and Illinois. Plaintiffs seek actual damages, restitution, injunctive relief, and other legal and equitable remedies on behalf of themselves and others similarly situated.

JURISDICTION AND VENUE

7. The Court has subject-matter jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(d) because (i) there are 100 or more members of each of the putative Classes, (ii) the aggregate amount in controversy as to each of the putative Classes exceeds $5,000,000, exclusive of interest and costs, and (iii) at least one member of each of the Classes is a citizen of a state different from Defendant.

8. Personal jurisdiction and venue are proper because Defendant maintains its headquarters and principal place of business in Shelton, Connecticut, within this judicial District.

PARTIES

9. Plaintiff Lewandowska Giannese is, and at all times relevant hereto was, a citizen and resident of Cook County, Illinois. On or about July 28, 2023, from her home in Illinois, Plaintiff Lewandowska Giannese purchased the Product (Hawaiian Tropic Everyday Active SPF 50 Sport Sunscreen Lotion), bearing universal product code ("UPC") 075486091170 and expiration date 03/2026 and containing four active ingredients (Avobenzone 2.7%, Homosolate 9.0%, Octisalate

4.0%, and Octocrylene 5.0%), for $10.97 plus tax from Amazon's online website, www.amazon.com.

10. Plaintiff Fahey is, and at all times relevant hereto was, a citizen and resident of Indian River County, Florida. On or about May 2, 2025, Plaintiff Fahey purchased the Product (Hawaiian Tropic Everyday Active SPF 50 Sport Sunscreen Lotion), bearing UPC 075486091170 and expiration date 10/2027 and containing four active ingredients (Avobenzone 2.7%, Homosolate 9.0%, Octisalate 4.0%, and Octocrylene 5.0%), in a purchase totaling $51.57 plus tax at a Publix grocery store in Florida.

11. Defendant Edgewell Personal Care Brands LLC is a Delaware limited liability company that maintains its corporate headquarters and principal place of business in Shelton, Connecticut. Defendant produces, manufactures and labels the Product, and distributes, advertises, promotes, and markets the Product throughout the United States, including in Florida and Illinois. Defendant's products, including the Product at issue in this case, are sold through various online e-commerce platforms and at physical retail locations nationwide, including throughout Florida and Illinois.

FACTUAL ALLEGATIONS

I. Consumers Perceive High-SPF Sunscreens as Providing Greater Protection from the Sun and Justifying Higher Purchase Prices than Their Lower-SPF Sunscreen Counterparts

12. Sunscreens, topically applied products that protect against sunburns and other effects of exposure to ultraviolet radiation (such as skin cancer and premature aging), are sold by numerous companies in varying SPF values, which these companies prominently represent on the products' labels and in advertisements and other promotional materials for the products.

13. SPF is a standardized rating system that measures the fraction of sunburn-producing ultraviolet rays capable of reaching the skin. The SPF value of a sunscreen product informs consumers of the level of sunburn protection provided by the sunscreen by indicating the approximate measure of time that a person who has applied the sunscreen can stay in the sun without getting burned. As an example, a product represented as providing SPF 50 protection should permit a person to stay in the sun 50 times longer without burning than if that person were wearing no protection at all. Thus, a product with a higher SPF is better able to prevent sunburn by more effectively filtering, absorbing, reflecting, and/or scattering more ultraviolet radiation than products of a lower SPF.

14. Academics,[1] legislators,[2] and medical organizations[3] alike have emphasized the importance of sunscreen in protecting against the damaging effects of ultraviolet radiation and the importance of appropriately disclosing the SPF capabilities of sunscreen products.

15. Consumers are familiar with SPF because SPF values have appeared on sunscreens for decades. Reasonable consumers have learned to correctly understand

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[1] *See* Charles P. Tribby et al., *Perceived Usefulness and Recall of Sunscreen Label Information by Consumers*, 157 JAMA DERMATOLOGY 573 (2021).

[2] *See* Press Release, *Senator Chuck Schumer: New Report Shows Nearly Half of All Sunscreens Make False Claims About SPF Protection* (July 20, 2016), https://www.schumer.senate.gov/newsroom/press-releases/schumer-new-report-shows-nearly-half-of-all-sunscreens-make-false-claims-about-spf-protection-senator-pushes-fda-to-test-sunscreens-confirm-true-spf-numbers-and-crackdown-on-labels-that-promise-protection-but-instead-leave-consumers-burned.

[3] S. Kim et al., *Prevalence and Correlates of Sun Protections with Sunburn and Vitamin D Deficiency in Sun-Sensitive Individuals*, 34 J. EUR. ACAD. DERMATOL. VENEREOL. 2664 (2020); AM. ACAD. DERMATOLOGY ASS'N, *How to Select Sunscreen*, https://www.aad.org/public/everyday-care/sun-protection/shade-clothing-sunscreen/how-to-select-sunscreen (last visited Oct. 6, 2025).

that higher-SPF sunscreens provide greater protection against the sun's harmful rays than lower-SPF sunscreens. Accordingly, reasonable consumers expect that if they purchase and use a sunscreen labeled SPF 50, for instance, that they will be far better protected against sunburn and cancer-causing ultraviolet rays than if they had purchased and used a sunscreen labeled as, for instance, SPF 30.

16. Consumers thus rely on representations of the SPF values of sunscreens as they compare, assess, and make decisions on which sunscreen products to purchase.

II. Defendant's Product

17. The Product in question here, "Hawaiian Tropic Everyday Active SPF 50 Sport Sunscreen Lotion," is produced, manufactured, labeled, distributed, advertised, promoted, and marketed by Defendant.

18. Defendant has entered licensing agreements for the Product to be sold at numerous e-commerce platforms and physical retail stores across the United States, including but not limited to on the websites of and at retail stores operated by CVS, Amazon, Ulta Beauty, and Target, among many others.

19. Regardless where the Product is sold, the Product comes in the same bottle and contains the same uniform labeling, which expressly states (in large letters on the front of the bottle) that the Product provides SPF "50" protection, as shown below:

20. Some online locations where the Product is sold, including Amazon, track the number of sales made for the Product. As shown below, the Product has been purchased over 2,000 times in the last month alone from Amazon:[4]

[4] The Product is offered for purchase at the following Amazon webpage: https://www.amazon.com/dp/B01MY051NZ.

III. Defendant Falsely, Deceptively, and Misleadingly Represents that the Product Provides SPF 50 Protection

21. Defendant's claim that the Product provides SPF 50 protection is false, deceptive, and misleading.

22. This is because the SPF protection provided by the Product is not even close to 50. In reality, the SPF protection provided by the Product is 20.

23. On or about February 21, 2025, Plaintiffs' counsel purchased the Product, bearing UPC 075486091170 and expiration date 08/2027 and containing four active ingredients (Avobenzone 2.7%, Homosolate 9.0%, Octisalate 4.0%, and Octocrylene 5.0%), for $14.99 plus tax at a CVS retail store in Miami, Florida.

24. Plaintiffs' counsel then submitted the purchased Product to a reputable and qualified laboratory for testing. The lab tested the Product by performing a clinical evaluation of static sunscreen efficacy with the sun protection factor (SPF) assay and calculation of the label SPF, following the FDA testing methods embodied in FDA Final Rule, Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35620 (June 17, 2011), and FDA,

Final Administrative Order (OTCOOOOO6); Over-the-Counter Monograph MO20: Sunscreen Drug Products for Over-the-Counter Human Use (Sept. 24, 2021). Testing began on May 29, 2025 and concluded on July 16, 2025.

25. The results of the testing commissioned by Plaintiffs' counsel reveal that the Product does not provide SPF 50 protection, but rather provides SPF 20 protection. *See* **Exhibit A** ("Final Report" of the Product (referred to therein as "Product C") by Consumer Product Testing Company, dated July 31, 2025). The lab's test results were derived from the testing methods embodied in the FDA Final Rule and FDA Final Administrative Order referenced above. *See id.*

26. SPF protection of 20, the actual SPF protection provided by the Product as revealed by the testing commissioned by Plaintiffs' counsel, offers significantly less protection than SPF 50, which Defendant has falsely represented the Product to consumers as providing. SPF 20 protection affords users a significantly shorter period of exposure to ultraviolet radiation without damage when compared to the period of exposure to ultraviolet radiation without damage that SPF 50 protection affords.

27. The Product that Plaintiffs purchased, like the Product purchased by each member of the Classes during the time period relevant to this action, came in the same bottle and with same labeling as the Product sent for testing by Plaintiffs' counsel, contained the same percentage of active ingredients as the Product sent for testing by Plaintiffs' counsel, and was produced and manufactured in the same manner pursuant to the same procedures as the Product sent for testing by Plaintiffs' counsel. Moreover, during the time period relevant to this action, there were no reported recalls, production or manufacturing issues, or other events with respect to the Product to suggest that any bottles of the Product sold to consumers might contain sunscreen that was produced or manufactured in a different manner or pursuant to different procedures, or with different percentages of active ingredients,

than any other bottles of the Product. Accordingly, all bottles of the Product that were purchased by consumers during the time period relevant to this action contain sunscreen that was produced and manufactured in the same manner pursuant to the same procedures, that is comprised of the same or materially the same percentages of the active ingredients, and that provides the same or materially the same SPF protection (all significantly less than SPF 50).

28. Defendant, as the producer, manufacturer, distributor, and labeler of the Product, and the employer of a dedicated team of product testing professionals, has been aware or should have been aware, since the Product's inception and throughout the time period relevant to this action, that the true SPF protection provided by the Product is significantly lower than 50.

29. Moreover, based on the Product's chemical formula and active ingredients alone, Defendant either knew or should have known that the true SPF protection provided by the Product is significantly lower than SPF 50.

30. Additionally, Defendant was required to perform and did perform testing on the Product, including concerning the protection against ultraviolet radiation provided by the Product, prior to the Product being labeled, advertised, promoted, marketed, distributed, and offered for sale to consumers.[5] Such testing either made or should have made Defendant aware that the true SPF protection provided by the Product is significantly lower than SPF 50.

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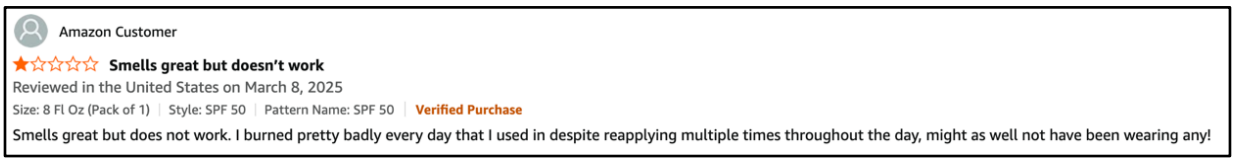
[5] *See, e.g.,* Edgewell, *Edgewell Product Safety Principles*, available at https://cdn.shopify.com/s/files/1/0598/9538/2192/files/Edgewell-Product-Safety-Principles.pdf?v=1657287543 (last visited Sept. 26, 2025) (explaining that Edgewell employs "highly skilled and board-certified toxicologists thoroughly evaluate products before they reach the market to ensure they are safe for consumers to use. Evaluation includes ingredient review, safety testing, and finished product assessment.").

31. Plaintiffs are just two among numerous consumers nationwide who have been deceived by Defendant's false and misleading representations of the SPF protection provided by the Product, as the following examples of publicly available "reviews"[6] of the Product reflect:

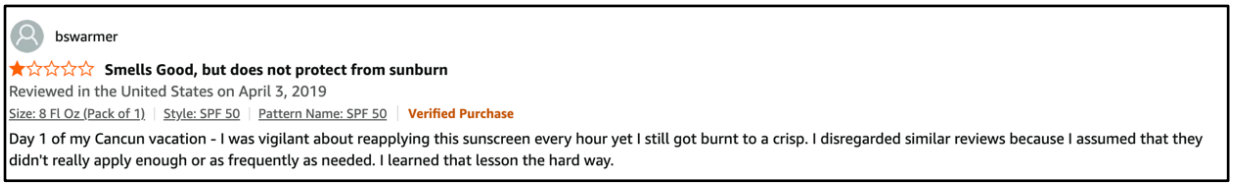

Amazon Customer

★☆☆☆☆ **Smells great but doesn't work**

Reviewed in the United States on March 8, 2025

Size: 8 Fl Oz (Pack of 1) | Style: SPF 50 | Pattern Name: SPF 50 | **Verified Purchase**

Smells great but does not work. I burned pretty badly every day that I used in despite reapplying multiple times throughout the day, might as well not have been wearing any!


bswarmer

★☆☆☆☆ **Smells Good, but does not protect from sunburn**

Reviewed in the United States on April 3, 2019

Size: 8 Fl Oz (Pack of 1) | Style: SPF 50 | Pattern Name: SPF 50 | **Verified Purchase**

Day 1 of my Cancun vacation - I was vigilant about reapplying this sunscreen every hour yet I still got burnt to a crisp. I disregarded similar reviews because I assumed that they didn't really apply enough or as frequently as needed. I learned that lesson the hard way.

32. At all times relevant hereto, Defendant either knew or should have known that its representations that the Product provides SPF protection of 50 were untrue, false and/or misleading, and made these representations knowing that consumers would rely upon the Product's represented SPF value of 50 in deciding to purchase the Product and in using the Product while exposed to the sun's harmful ultraviolet radiation.

33. Defendant's misrepresentations of the SPF protection provided by the Product, on the labeling of the Product and in advertising and promotional materials for the Product, were made for the purpose of inducing—and did in fact induce—consumers (including Plaintiffs and members of the Classes) to purchase the Product at a premium price, based on their reasonable but mistaken beliefs that the Product provides greater protection against the sun's harmful rays than its lower-SPF sunscreen counterparts.

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[6] These reviews are accessible at the following webpage: https://www.amazon.com/product-reviews/B01MY051NZ/.

IV. Plaintiffs' Experiences

A. Plaintiff Lewandowska Giannese

34. Plaintiff Lewandowska Giannese purchased the Product on or about July 28, 2023 in Illinois.

35. SPF was the most important consideration in Plaintiff Lewandowska Giannese's decision to purchase the Product because she values the filtration, absorption, and reflection capabilities against UV rays provided by high SPF sunscreens, such as those of SPF 50 protection.

36. Prior to purchasing the Product, Plaintiff Lewandowska Giannese saw—and in making her decision to purchase, she relied on—Defendant's representations on the label of the Product that the Product provided "SPF 50" protection.

37. Prior to purchasing the Product, Plaintiff Lewandowska Giannese necessarily and justifiably relied upon the written statements on the Product, including those pertaining to its SPF, as accurate. Plaintiff Lewandowska Giannese had no realistic way to review or independently assess Defendant's proprietary knowledge concerning the Product's chemical formula or the Product's true SPF performance prior to purchasing the Product. At the time she purchased the Product, Plaintiff Lewandowska Giannese had no reason to suspect or know that the Product provided significantly less SPF protection than the value of 50 that Defendant had represented on the Product and had advertised, promoted, and marketed the Product as providing.

38. Based on Defendant's representations on the Product's labeling, Plaintiff Lewandowska Giannese reasonably expected the Product she purchased would provide SPF 50 protection in terms of its filtration, absorption, and reflection of ultraviolet radiation.

39. After purchasing the Product, Plaintiff Lewandowska Giannese immediately started using the Product. The Product was not as advertised, and Plaintiff Lewandowska Giannese found the Product to be neither of the quality, absorption, nor filtration she expected (nor that any reasonable consumer would expect) from a sunscreen providing SPF 50 protection. As a result, Plaintiff Lewandowska Giannese later discontinued her use of the Product.

40. As the direct and proximate result of Defendant's false, deceptive, and misleading statements and omissions concerning the Product, as alleged herein, Plaintiff Lewandowska Giannese suffered economic injury by paying a premium for an inferior quality good and by being deprived of the full intended use of the Product and the full benefit of the bargain promised by Defendant.

B. Plaintiff Fahey

41. Plaintiff Fahey purchased the Product on or about May 2, 2025 in Florida.

42. SPF was the most important consideration in Plaintiff Fahey's decision to purchase the Product because she values the filtration, absorption, and reflection capabilities against UV rays provided by high SPF sunscreens, such as those of SPF 50 protection.

43. Prior to purchasing the Product, Plaintiff Fahey saw—and in making her decision to purchase, she relied on—Defendant's representations on the label of the Product that the Product provided "SPF 50" protection.

44. Prior to purchasing the Product, Plaintiff Fahey necessarily and justifiably relied upon the written statements on the Product, including those pertaining to its SPF, as accurate. Plaintiff Fahey had no realistic way to review or independently assess Defendant's proprietary knowledge concerning the Product's chemical formula or the Product's true SPF performance prior to purchasing the Product. At the time she purchased the Product, Plaintiff Fahey had no reason to

suspect or know that the Product provided significantly less SPF protection than the value of 50 that Defendant had represented on the Product and had advertised, promoted, and marketed the Product as providing.

45. Based on Defendant's representations on the Product's labeling, Plaintiff Fahey reasonably expected the Product she purchased would provide SPF 50 protection in terms of its filtration, absorption, and reflection of ultraviolet radiation.

46. After purchasing the Product, Plaintiff Fahey immediately started using the Product. The Product was not as advertised, and Plaintiff Fahey found the Product to be neither of the quality, absorption, nor filtration she expected (nor that any reasonable consumer would expect) from a sunscreen providing SPF 50 protection. As a result, Plaintiff Fahey later discontinued her use of the Product.

47. As the direct and proximate result of Defendant's false, deceptive, and misleading statements and omissions concerning the Product, as alleged herein, Plaintiff Fahey suffered economic injury by paying a premium for an inferior quality good and by being deprived of the full intended use of the Product and the full benefit of the bargain promised by Defendant.

CLASS ALLEGATIONS

48. Pursuant to Federal Rule of Civil Procedure 23, Plaintiffs seek to represent the following "Nationwide Class":

> All persons who, during the applicable limitation period continuing through the date of an order certifying this class, purchased "Hawaiian Tropic Everyday Active SPF 50 Sport Sunscreen Lotion" in the United States.

49. Plaintiff Lewandowska Giannese also seeks to represent the following "Illinois Subclass" pursuant to Federal Rule of Civil Procedure 23:

> All persons who, during the applicable limitation period continuing through the date of an order certifying this class, purchased "Hawaiian Tropic Everyday Active SPF 50 Sport Sunscreen Lotion" in Illinois.

50. Plaintiff Fahey also seeks to represent the following "Florida Subclass" pursuant to Federal Rule of Civil Procedure 23:

> All persons who, during the applicable limitation period continuing through the date of an order certifying this class, purchased "Hawaiian Tropic Everyday Active SPF 50 Sport Sunscreen Lotion" in Florida.

51. The "Nationwide Class," the "Florida Subclass," and "Illinois Subclass" are at times referred to herein collectively as the "Classes".

52. Plaintiffs reserve the right to modify the definitions of the Classes following the commencement of discovery and further investigation.

53. Excluded from the Classes are Defendant, any parent, subsidiary, or affiliate of Defendant, as well as the officers, directors, agents, servants, or employees of the foregoing.

54. This action may properly be brought and maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b). This class action satisfies the numerosity, typicality, adequacy, commonality, predominance, and superiority requirements.

55. The Classes are so numerous that their individual joinder herein is impracticable. The number of persons within the Classes is substantial. Plaintiffs are informed and believe, and thereupon allege, that there are millions of persons who comprise the Nationwide Class, at least several hundred thousand persons who comprise the Florida Subclass, and at least several hundred thousand persons who comprise the Illinois Subclass. The precise number of members of the Classes and their identities are unknown to Plaintiffs at this time but may be determined through discovery. Members of the Classes may be notified of the pendency of this action

by mail and/or publication through the purchase records of Defendant and relevant third parties.

56. Common questions of law and fact exist for all members of the Classes and predominate over questions affecting only individual members. Common legal and factual questions include, but are not limited to:

(a) whether Defendant's representations that the Product provided SPF protection of 50 were false, deceptive, and/or misleading;

(b) whether Defendant knew or should have known that its misrepresentations, as alleged herein, were false or misleading to consumers;

(c) whether reasonable consumers would rely on Defendant's misrepresentations concerning the Product's SPF, as alleged herein, to believe the Product provided the advertised level of protection from the sun's harmful radiation;

(d) whether Defendant received and retained profits attributable to sales of the Product in Connecticut;

(e) whether Defendant's conduct, as alleged herein, violated the statutes and laws at issue; and

(f) The damages to which Plaintiffs and the members of the Classes are entitled to redress Defendant's unlawful conduct, as alleged herein.

57. The named Plaintiffs' claims are typical of the claims of unnamed members of the Classes in that the named Plaintiffs and all members of the Classes suffered similar injuries as a result of the same uniform conduct and practices by Defendant, as alleged herein.

58. Plaintiffs are adequate representatives of the Classes they seek to represent because their interests are aligned, and do not conflict, with the interests of the unnamed members of the Classes, they have retained competent counsel experienced in prosecuting consumer class actions, and they intend to prosecute this

action vigorously. Plaintiffs and their counsel will fairly and adequately protect the interests of the Classes.

59. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because individual litigation of the claims of all members of the Classes is impracticable. The individual interest of each member of the Classes in controlling the prosecution of separate claims is small because the damages at stake for these claims on an individual basis are small. Even if every member of the Classes could afford to pursue individual litigation, the Court system could not. It would be unduly burdensome to the courts in which such individualized litigation would proceed. Individualized litigation would also present the potential for varying, inconsistent or contradictory judgments, and would magnify the delay and expense to all parties and to the court system resulting from multiple trials of the same factual issues. By contrast, the maintenance of this action as a class action, with respect to some or all of the issues presented herein, presents few management difficulties, conserves the resources of the parties and of the court system, and protects the rights of each member of the Classes. Plaintiffs anticipate no difficulty in the management of this action as a class action.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Unjust Enrichment
(By Plaintiffs, Individually and on Behalf of the Nationwide Class, Against Defendant)

60. Plaintiffs repeat and incorporate paragraphs 1-59 above as though fully set forth herein.

61. Plaintiffs bring this claim individually and on behalf of the members of the Nationwide Class against Defendant under Connecticut common law.

62. Plaintiffs and the Nationwide Class Members have conferred substantial benefits on Defendant by purchasing the Product, including the monetary profits that Defendant received attributable to sales of the Product to Plaintiffs and members of the Nationwide Class.

63. Defendant received and retained, at its corporate headquarters in Connecticut, the monetary revenue and profits that it received attributable to sales of the Product to Plaintiffs and members of the Nationwide Class. Defendant appreciates or has knowledge of such benefits.

64. Defendant has knowingly and willingly accepted and enjoyed these benefits in Connecticut.

65. Defendant either knew or should have known that the payments rendered by Plaintiffs and the Nationwide Class members were given and received with the expectation that the Product would be as represented and warranted. For Defendant to receive and retain, in Connecticut, the benefit of Plaintiffs' and Nationwide Class members' payments under these circumstances is inequitable.

66. As a result of Defendant's misrepresentations that the Product provides SPF protection of 50—made on the labeling of the Product and in advertising and promotional materials for the Product, from Defendant's headquarters in Connecticut—Defendant wrongfully received and retained, in Connecticut, monetary revenue and profits attributable to sales of the Product.

67. As described above, had Plaintiffs been aware of the actual SPF protection provided by the Product, they would not have paid as much as they did for the Product or would not have purchased the Product at all.

68. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and the other Nationwide Class members have suffered actual damages, in the form of the monetary revenue and profit received and retained by Defendant in Connecticut attributable to the money that Plaintiffs and members of the Classes

paid to purchase a product labeled as "SPF 50" but which actually provided only SPF 20 protection.

69. Equity demands disgorgement of Defendant's ill-begotten gains. Defendant will be unjustly enriched unless it is ordered to disgorge those profits for the benefit of Plaintiffs and Nationwide Class members.

70. Plaintiffs and the Nationwide Class members are entitled to restitution from Defendant and institution of a constructive trust disgorging all profits, benefits, and other compensation obtained by Defendant through this inequitable conduct.

SECOND CLAIM FOR RELIEF
Unfair and Deceptive Practices in Violation of 815 ILCS 505/1
(By Plaintiff Lewandowska Giannese, Individually and on Behalf of the Illinois Subclass, Against Defendant)

71. Plaintiff Lewandowska Giannese repeats and incorporates paragraphs 1-59 above as though fully set forth herein.

72. Plaintiff Lewandowska Giannese brings this claim individually and on behalf of the members of the Illinois Subclass against Defendant.

73. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.* ("ICFA"), is designed to "protect consumers". . . "against fraud, unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce…." 815 ILCS 505/1. The ICFA declares unlawful "unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omissions of such material fact … in the conduct of any trade or commerce." *See* 815 ILCS 505/2.

74. Plaintiff Lewandowska Giannese and the members of the Illinois Subclass purchased the Product in Illinois and are thus "consumers" within the meaning of 815 ILCS 505/1(e).

75. Defendant is engaged in "trade or commerce" as defined by 815 ILCS 505/1(f).

76. Defendant's acts and practices, as alleged herein, were unfair, unconscionable, and deceptive under ICFA.

77. Defendant's conduct, as alleged herein, was "unfair or deceptive" because, as alleged herein, Defendant produced, manufactured, labeled, distributed, advertised, promoted, and marketed the Product to consumers throughout Illinois as providing materially greater protection against the sun's harmful rays than it actually provides. In so doing, Defendant intentionally mislabeled and misbranded the Product, deceptively and falsely advertised the Product, misrepresented and omitted material facts regarding the Product, and otherwise engaged in activities that were substantially injurious to consumers in Illinois.

78. Defendant intended that consumers, like Plaintiff Lewandowska Giannese and members of the Illinois Subclass, rely upon its false, misleading, and deceptive representations that the Product provides SPF protection of 50, as stated on the labels of the Product and in advertising and promotional materials for the Product.

79. Defendant's misrepresentations that the Product provides SPF protection of 50 deceived and induced reasonable consumers and the public in Illinois, including Plaintiff Lewandowska Giannese and the Illinois Subclass members, into believing the Product has greater filtration, absorption, and reflection capabilities against ultraviolet radiation than other alternative products that provide less than SPF 50 protection, causing them to reasonably and justifiably rely on such misrepresentations in deciding to purchase the Product.

80. Defendant's conduct, as alleged herein, has been and continues to be substantially injurious to consumers in Illinois.

81. No benefit to consumers or competition results from the unfair and deceptive conduct alleged herein. Since consumers reasonably rely on Defendant's representations that the Product provides SPF 50 protection, consumers could not have reasonably avoided such injury.

82. Plaintiff Lewandowska Giannese and the members of the Illinois Subclass purchased the Product without knowledge that Defendant's representations that the Product provides "SPF 50" protection were false.

83. Plaintiff Lewandowska Giannese and the members of the Illinois Subclass either would not have purchased the Product at all or would not have paid nearly as much money for the Product had it been labeled, marketed, and advertised with accurate, truthful representations concerning the SPF protection that it provides.

84. By committing the acts alleged herein, Defendant engaged in unfair or deceptive acts or practices in the conduct of trade or commerce within the meaning of the ICFA.

85. As a direct and proximate result of Defendant's conduct, Plaintiff Lewandowska Giannese and the members of the Illinois Subclass have suffered and continue to suffer damages, including economic damages, in terms of the full amount of money they paid for the Product or, at the very least, the amount of money paid for the Product as represented in excess of what a consumer reasonably would have paid for the Product as delivered.

86. Pursuant to 815 ILCS 505/10a, Plaintiff Lewandowska Giannese and the members of the Illinois Subclass seek a court order enjoining the above-described wrongful acts and practices of Defendant and for restitution and disgorgement, economic damages, punitive damages, and attorneys' fees and costs.

87. In accordance with 815 ILCS 505/10a, Plaintiff Lewandowska Giannese, concurrent with the filing of this complaint, has served notice of this complaint on the Illinois Attorney General.

THIRD CLAIM FOR RELIEF
Breach of Express Warranty in Violation of 810 ILCS 5/2-313
(By Plaintiff Lewandowska Giannese, Individually and on Behalf of the Illinois Subclass, Against Defendant)

88. Plaintiff Lewandowska Giannese repeats and incorporates paragraphs 1-59 above as though fully set forth herein.

89. Plaintiff Lewandowska Giannese brings this claim individually and on behalf of the members of the Illinois Subclass against Defendant under 810 ILCS 5/2-313.

90. Defendant produced, manufactured, labeled, distributed, advertised, promoted, and marketed the Product in its regular course of business.

91. Plaintiff Lewandowska Giannese and the Illinois Subclass members purchased the Product in Illinois.

92. Defendant represented that the Product provides SPF protection of 50 to the consuming public in Illinois on the labeling of the Product and in advertising and promotional materials for the Product.

93. Defendant intended its SPF 50 representations—which figure prominently on the Product's labeling and in advertising and promotional materials for the Product—to be relied upon by consumers in Illinois like Plaintiff Lewandowska Giannese and Illinois Subclass members in purchasing the Product and ultimately using the Product on themselves and their loved ones.

94. Plaintiff Lewandowska Giannese reasonably relied on these representations, which formed the basis of his bargain, in purchasing the Product.

95. Defendant breached the express warranty of the Product it provided to consumers in Illinois because the Product does not provide SPF protection of 50 but rather provides SPF protection far lower than 50.

96. The SPF protection represented on the labels of the Product was false when the sales of the Product to Plaintiff Lewandowska Giannese and Illinois Subclass members took place, and the falsity of these representations was undiscoverable by Plaintiff Lewandowska Giannese and Illinois Subclass members at the time they made their purchases.

97. All conditions precedent to seeking liability under this claim for breach of express warranty have been performed by or on behalf of Plaintiff Lewandowska Giannese and the Illinois Subclass members in terms of paying for the goods at issue.

98. Defendant also had actual or constructive notice of the falsity of the SPF representations on the labeling of the Product based upon the testing Defendant performed on the Product and Defendant's knowledge of the active ingredients and formula of the Product.

99. Defendant's breach of express warranty has caused Plaintiff Lewandowska Giannese and the Illinois Subclass members to suffer injuries, pay for a falsely labeled Product, and enter into transactions that they either would not have entered into at all or would not have entered into for the consideration paid. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff Lewandowska Giannese and the Illinois Subclass members have suffered damages and continue to suffer damages, including economic damages, in terms of the full amount of money they paid for the Product or, at the very least, the amount of money paid for the Product as represented in excess of what a consumer reasonably would have paid for the Product as delivered.

100. As a result of Defendant's breach of an express warranty, Plaintiff Lewandowska Giannese and the Illinois Subclass members are entitled to legal and

equitable relief, including damages, costs, attorneys' fees, rescission, and other relief as deemed appropriate, for an amount to compensate them for not receiving the benefit of their bargain.

FOURTH CLAIM FOR RELIEF
Breach of Implied Warranty in Violation of 810 ILCS 5/2-314 & 5/2-315
(By Plaintiff Lewandowska Giannese, Individually and on Behalf of the Illinois Subclass, Against Defendant)

101. Plaintiff Lewandowska Giannese repeats and incorporates paragraphs 1-59 above as though fully set forth herein.

102. Plaintiff Lewandowska Giannese brings this claim individually and on behalf of the members of the Illinois Subclass against Defendant under 810 ILCS 5/2-314 and 5/2-315.

103. Defendant is a "merchant" with respect to the goods at issue here—the Product, a sunscreen lotion.

104. By placing the Product into the stream of commerce, Defendant made—and breached—at least two implied warranties.

105. First, to be merchantable, a product must conform to any written representations on its labels. Because the true SPF protection provided by the Product does not, in fact, comport with the advertised SPF protection provided by the Product, as alleged herein, Defendant breached an implied warranty of merchantability.

106. Second, to be merchantable, the Product must be fit for its intended purpose as a consumer sunscreen lotion. Because consumer sunscreens containing materially less SPF protection than represented are generally considered dangerous and unsuitable, consumer sunscreen represented as providing SPF 50 protection is not fit for its intended purposes if such sunscreen actually provides far less than SPF 50 protection (such as SPF 20 protection in the case of the Product). Defendant breached an implied warranty of merchantability by producing, manufacturing,

labeling, distributing, advertising, promoting, and marketing a product that it represented as providing SPF 50 protection but, in reality, provides only SPF 20 protection.

107. Defendant's breaches of these implied warranties have caused Plaintiff Lewandowska Giannese and the Illinois Subclass members to suffer injuries, pay for a falsely labeled Product, and enter into transactions that they either would not have entered into at all or would not have entered into for the consideration paid. As a direct and proximate result of Defendant's breach, Plaintiff Lewandowska Giannese and the Illinois Subclass members have suffered damages and continue to suffer damages, including economic damages, in terms of the full amount of money they paid for the Product or, at the very least, the amount of money paid for the Product as represented in excess of what a consumer reasonably would have paid for the Product as delivered.

FIFTH CLAIM FOR RELIEF
Unfair and Deceptive Practices in Violation of Fla. Stat. § 501.201
(By Plaintiff Fahey, Individually and on Behalf of the Florida Subclass, Against Defendant)

108. Plaintiff Fahey repeats and incorporates paragraphs 1-59 above as though fully set forth herein.

109. Plaintiff Fahey brings this claim individually and on behalf of the members of the Florida Subclass against Defendant under Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.* ("FDUTPA").

110. FDUTPA prohibits "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204.

111. FDUTPA is intended "[t]o protect the consumer public and legitimate business enterprises from those who engage in unfair methods of competition, or

unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." *Id.* § 501.202.

112. Defendant's acts and practices, as alleged herein, were unfair, unconscionable, and deceptive under FDUTPA.

113. Defendant's conduct, as alleged herein, was "unfair or deceptive" because, as alleged herein, Defendant produced, manufactured, labeled, distributed, advertised, promoted, and marketed the Product to consumers throughout Florida as providing materially greater protection against the sun's harmful rays than it actually provides. In so doing, Defendant intentionally mislabeled and misbranded the Product, deceptively and falsely advertised the Product, misrepresented and omitted material facts regarding the Product, and otherwise engaged in activities that were substantially injurious to consumers in Florida.

114. Defendant intended that consumers, like Plaintiff Fahey and the Florida Subclass, rely upon its false, misleading, and deceptive representations that the Product provides SPF protection of 50, as stated on the labels of the Product and in advertising and promotional materials for the Product.

115. Defendant's misrepresentations that the Product provides SPF protection of 50 deceived and induced reasonable consumers and the public in Florida, including Plaintiff Fahey and the Florida Subclass members, into believing the Product has greater filtration, absorption, and reflection capabilities against ultraviolet radiation than other alternative products providing lower SPF protection than the Product was represented to provide, causing them to justifiably rely on such misrepresentations in deciding to purchase the Product.

116. Defendant's conduct, as alleged herein, has been and continues to be substantially injurious to consumers in Florida.

117. No benefit to consumers or competition results from the unfair and deceptive conduct alleged herein. Since consumers reasonably rely on Defendant's

representations that the Product provides SPF 50 protection, consumers could not have reasonably avoided such injury.

118. Plaintiff Fahey and Florida Subclass members purchased the Product without knowledge that Defendant's representations that the Product provides "SPF 50" protection were false.

119. Plaintiff Fahey and the Florida Subclass either would not have purchased the Product at all or would not have paid nearly as much money for the Product had it been labeled, marketed, and advertised with accurate, truthful representations concerning the SPF protection that it provides.

120. By committing the acts alleged herein, Defendant engaged in unconscionable, deceptive, or unfair acts or practices, which constitute unfair competition within the meaning of FDUTPA.

121. As a direct and proximate result of Defendant's breach, Plaintiff Fahey and members of the Florida Subclass have suffered damages and continue to suffer damages, including economic damages, in terms of the full amount of money they paid for the Product or, at the very least, the amount of money paid for the Product as represented in excess of what a consumer reasonably would have paid for the Product as delivered.

SIXTH CLAIM FOR RELIEF
Fraud in Violation of Illinois and Florida Common Law
(By Plaintiffs, Individually and on Behalf of the
Florida Subclass and Illinois Subclass, Against Defendant)

122. Plaintiffs repeat and incorporate paragraphs 1-59 above as though fully set forth herein.

123. Plaintiffs bring this claim individually and on behalf of the members of the Florida Subclass and the Illinois Subclass against Defendant under Florida and Illinois common law.

124. As alleged above, Defendant made false and misleading statements, and omitted material facts, in representing to Plaintiffs, the Florida Subclass and the Illinois Subclass, that the SPF protection provided by the Product is 50.

125. The actual SPF protection provided by the Product that Plaintiffs, Florida Subclass members, and Illinois Subclass members purchased was far less than the SPF protection that Defendant represented on the labeling of the Product and in materials used to advertise, promote, and market the Product.

126. Defendant also failed to disclose that the Product did not, in fact, provide SPF protection of 50.

127. Defendant knowingly and intentionally misrepresented the SPF protection provided by the Product for the purpose of increasing its revenues and maximizing its corporate profits.

128. Defendant made these misrepresentations and omissions with knowledge of their falsehood.

129. Defendant's misrepresentations and omissions concerning the SPF protection provided by the Product were intended to induce Plaintiffs, the Florida Subclass members, and Illinois Subclass members to purchase the Product.

130. And as Defendant intended, its misrepresentations and omissions concerning the SPF protection of the Product induced Plaintiffs, the Florida Subclass members, and Illinois Subclass members to purchase the Product. In purchasing the Product, Plaintiffs, the Florida Subclass members, and Illinois Subclass members reasonably and justifiably relied on Defendant's misrepresentations and omissions concerning the SPF protection provided by the Product.

131. Had Plaintiffs, the Florida Subclass members, and Illinois Subclass members known that the Product provided SPF protection materially lower than the SPF protection represented by Defendant on the Product's labeling, and in advertising and promotional materials for the Product, they either would not have

purchased the Product at all or would have paid significantly less for the Product than they did.

132. The fraudulent actions by Defendant, as alleged herein, caused substantial harm to Plaintiffs, the Florida Subclass members, and Illinois Subclass members, entitling them to monetary damages and other available legal and equitable remedies.

SEVENTH CLAIM FOR RELIEF
Negligent Misrepresentation in Violation of Illinois and Florida Common Law
(By Plaintiffs, Individually and on Behalf of the
Florida Subclass and the Illinois Subclass, Against Defendant)

133. Plaintiffs repeat and incorporate paragraphs 1-59 above as though fully set forth herein.

134. Plaintiffs bring this claim individually and on behalf of the members of the Florida Subclass and the Illinois Subclass against Defendant under Florida and Illinois common law.

135. Defendant misrepresented a fact. It advertised that the Product provided SPF protection of 50, when in fact the SPF protection provided by the Product is materially lower.

136. There were no reasonable grounds for Defendant to believe that these misrepresentations were true. As an experienced sunscreen producer and manufacturer responsible for testing the sunscreens that it labels, distributes, advertises, promotes, and markets, Defendant should have known that the Product did not in fact provide an SPF protection of 50.

137. This misrepresentation was material. Consumers purchase sunscreens to protect themselves and their loved ones from the dangerous effects of sun exposure. Accordingly, the degree of sun protection as advertised on the Product was a material—if not the sole—factor in Plaintiffs' decision to purchase the

Product. And this would be true of any reasonable consumer, including members of the Florida Subclass and the Illinois Subclass.

138. Defendant intended that consumers, like Plaintiffs, the Florida Subclass members and Illinois Subclass members, rely on its representations that the Product provides SPF protection of 50, as stated on the labels of the Product and in advertising and promotional materials for the Product. As alleged herein, that representation was designed solely for consumers, like Plaintiffs, the Florida Subclass members, and Illinois Subclass members, who will ultimately purchase and use the Product on themselves and their loved ones.

139. Plaintiffs' reliance on Defendant's representation that the Product provided SPF protection of 50 was justifiable. Plaintiffs had no way of verifying this representation before purchase, and consumers generally rely on the SPF stated on the Product instead of paying the substantial costs to have the Product tested by labs.

140. Plaintiffs were proximately damaged by Defendant's misrepresentations. Had Plaintiffs known that Defendant's representations that the Product provided SPF protection of 50 were false, Plaintiffs would not have paid as much as they did for the Product, or they would not have purchased the Product at all.

141. Further, Defendant was in a "special relationship" with Plaintiffs, the Florida Subclass members, and Illinois Subclass members, and thus owed them a duty of care, because:

a) The SPF misrepresentations Defendant made on the Product's labels and in advertising and promotional materials for the Product were intended solely to affect the purchasing decisions of consumers, like Plaintiffs, the Florida Subclass members and Illinois Subclass members, who will ultimately base their decision on these SPF claims and who ultimately use the Product on themselves or their loved ones;

b) It was foreseeable that, by misrepresenting an SPF value as being higher than it is, and charging a premium for that added protection, Defendant would economically harm consumers by misleading them into paying an unjustified premium for a sunscreen that lacked the advertised protection;

c) This harm was certain;

d) Defendant's decision to label and advertise, market, and promote the Product as providing SPF 50 protection was the close, proximate cause of Plaintiffs', the Florida Subclass members' and Illinois Subclass members' deception and the fact that they were overcharged for the Product;

e) Misrepresenting the SPF of a sunscreen is egregious and immoral for several reasons, the most obvious being that it leaves consumers vulnerable to sunburn and heightens their risk of skin cancer by misleading them into trusting inadequate sun protection from a lower quality sunscreen. Charging a steep premium for a sunscreen that does not actually protect people from the sun also immorally deprives these consumers of money that they could have spent on more useful, necessary items; and

f) Holding sunscreen producers and manufacturers accountable—to Plaintiffs, Florida Subclass members, and Illinois Subclass members, and other sunscreen consumers—for SPF misrepresentations would deter future misrepresentations, with no perceivable drawbacks.

142. Accordingly, Plaintiffs seek damages on behalf of themselves, Florida Subclass members, and Illinois Subclass members in the full amount of the Product or, at the very least, the amount of money paid for the Product as represented in excess of what a consumer reasonably would have paid for the Product as delivered.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek a judgment against Defendant as follows:

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

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

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

D. For prejudgment interest on all amounts awarded;

E. For an order of restitution and all other forms of equitable monetary relief;

F. For injunctive relief as pleaded or as the Court may deem proper; and

G. For an order awarding punitive damages, reasonable attorneys' fees, and costs to counsel for Plaintiffs and the Classes.

DEMAND FOR TRIAL BY JURY

Plaintiffs demand a trial by jury on all causes of action and issues so triable.

Dated: October 10, 2025

Respectfully submitted,

/s/ James J. Reardon, Jr.
James J. Reardon, Jr. (ct13802)
REARDON SCANLON LLP
45 South Main Street, 3rd Floor
West Hartford, CT 06107
Tel.: (860) 955-9455
Fax: (860) 920-5242
james.reardon@reardonscanlon.com

Frank S. Hedin*
Elliot O. Jackson*
HEDIN LLP
1395 Brickell Ave., Suite 610
Miami, Florida 33131-3302
Telephone: (305) 357-2107
Facsimile: (305) 200-8801
fhedin@hedinllp.com
ejackson@hedinllp.com

Counsel for Plaintiffs and Putative Classes

**Pro Hac Vice application forthcoming*

EXHIBIT A

CONSUMER PRODUCT TESTING COMPANY
cptclabs.com

FINAL REPORT

SPONSOR:

Hedin LLP
1395 Brickell Ave, Ste 610
Miami, FL 33131

ATTENTION:

Frank Hedin

TEST:

Clinical Evaluation of Static Sunscreen Efficacy with the Sun Protection Factor (SPF) Assay and Calculation of the Label SPF following FDA Final Rule 2011 and Final Administrative Order 2021
Protocol: HAQS01-001
Protocol Date: 05/05/2025

TRIAL NUMBER:

S25-2125.03

TEST MATERIAL:

Product C

8/5/25
Approved By:
Michael Traudt, Ph.D.
Vice President,
Clinical and Photobiology Services

Michael B. Lutz 04 Aug 2025
Approved By:
Michael B. Lutz
Technical Director,
Clinical, Photobiology & Bioinstrumentation

Report Date: July 31, 2025

FDA Registration# 1000151293
DEA Registration# RC0199744 Schedule I-V
US EPA/NJ DEP Registration# NJD982726648
ISO/IEC 17025:2017 Accredited

Office: +1 (973) 808-7111 Fax: +1 (973) 808-7234 70 New Dutch Lane Fairfield, NJ 07004-2514

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor any member of its staff, may be used in connection with the advertising or sale of any product or process without authorization. Results indicated in this Report apply only to the items tested.

CONSUMER PRODUCT TESTING COMPANY
cptclabs.com

FDA Registration# 1000151293
DEA Registration# RC0199744 Schedule I-V
US EPA/NJ DEP Registration# NJD982726648
ISO/IEC 17025:2017 Accreditation # 80071

QUALITY ASSURANCE UNIT STATEMENT

Trial Number: S25-2125.03

The Consumer Product Testing Company, Incorporated (CPTC) Quality Assurance Unit (QAU) is responsible for auditing the conduct, content and reporting of all clinical trials that are conducted at CPTC.

This trial has been conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, CPTC Standard Operating Procedures, and the approved protocol.

The CPTC QAU has reviewed all data, records, and documents relating to this trial and also this Final Report. The following QAU representative signature certifies that all data, records, and documents relating to this trial and also this Final Report have been reviewed and are deemed to be acceptable, and that the trial conforms to all of the requirements as indicated above.

All records and documents pertaining to the conduct of this trial shall be retained in the CPTC archives for a minimum of five (5) years. At any time prior to the completion of the fifth archival year, a Sponsor may submit a written request to the CPTC QAU to obtain custody of trial records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, trial-related records shall be destroyed at the end of the CPTC archive period with no further notice in a manner that renders them useless.

Quality Assurance Representative

8-5-25
Date

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor any member of its staff, may be used in connection with the advertising or sale of any product or process without authorization.

Background Information

An over-the-counter sunscreen product in a form suitable for topical administration is generally recognized as safe and effective if it meets the requirements found in the Final Rule issued by the Food and Drug Administration (reference 1). This trial was designed to evaluate the Sun Protection Factor (SPF) of a test material as a sunscreen product, in accordance with the requirements delineated in this methodology.

Trial Objective

The primary objective of this trial was to determine the static SPF of a test material using the methodology described in the Final Rule (SPF) Test Method (reference 1) and in the 2021 Final Administrative Order (reference 2).

Trial Schedule

Initiation Date:
May 29, 2025

Completion Date:
July 16, 2025

Test Material

Product C
(Expected SPF = 50)

Standard

A control standard, 7% Padimate O/3% Oxybenzone was run concurrently with the test material to verify proper and consistent performance of test equipment and procedures. The control standard has a mean SPF of 16.3 with a standard deviation of 3.43.

Storage

Test materials were stored at ambient temperature and humidity in the container in which they were received by CPTC.

The control standard was stored at ambient temperature and humidity.

Disposition

At the conclusion of the trial, all remaining test material is retained by CPTC for 60 days and then discarded in accordance with local, state, and federal laws and regulations unless the Sponsor has arranged for a different disposition in writing.

The control standard will be used in additional trials until the entire control standard has been used or the expiration date has been reached.

Selection and Withdrawal of Subjects

Number of Subjects

A minimum of 10 valid results were required for the panel. An initial assessment of 1 - 3 subjects was conducted to evaluate a preliminary SPF value. Additional subjects were added to the initial 1 - 3 subjects to form a complete panel of 10 subjects. A maximum of 3 individual results were permitted to be excluded from the calculation of the mean SPF but each exclusion was justified in accordance with the "Rejection of Data" section, appearing later in this Report. Additionally, the Principal Investigator may decide to exclude the results observed to evaluate the preliminary SPF value.

Subjects who meet all of the inclusion criteria and none of the exclusion criteria qualified for the trial.

Inclusion Criteria

1. Subjects who read, signed and dated an Informed Consent Form that included a HIPAA statement;
2. Subjects who were aged 18 to 65 years, inclusive.
3. Subjects who had a Fitzpatrick skin type I, II or III (described below), or an ITA° ≥28° :

Skin Type	Sunburn and Tanning History
I	Always burns easily; never tans
II	Always burns easily; tans minimally
III	Burns moderately; tans gradually

4. Subjects were considered dependable and capable of understanding and following directions.

Exclusion Criteria

1. Subjects who were in ill health, as determined by the Principal Investigator;
2. Subjects who were taking medication, other than birth control, that, in the opinion of the PI, could have influenced the purpose, integrity, or outcome of the trial;
3. Subjects who used any prescribed or OTC anti-inflammatory, antihistamine, corticosteroid, immunosuppressant, or antibiotic drug within 7 days prior to trial initiation;
4. Female subjects who were pregnant, planning to become pregnant or lactating during the trial;
5. Subjects with any visible disease, sunburn, suntan, uneven skin, scars, excessive tattoos, nevi, blemishes, moles, etc., that might be confused with a skin reaction to the test material or, as determined by the PI, might have interfered with the evaluations;
6. Subjects who had a history of abnormal response to sunlight, such as lupus erythematosus or skin cancer;
7. Subjects who were unwilling to have excessive hair clipped;

8. Subjects who exposed themselves to sunlight (natural or artificial) on the test site; or

9. Subjects who participated in testing procedures within previous 2 months that precluded a sufficient area being clear of all previous skin tanning.

Methodology

Potential subjects reported to the Testing Facility and completed an Informed Consent Form to become subjects. The informed consent process fully appraised each potential subject of the risks and benefits associated with the research clinical trial and of the confidentiality requirements relating to the subject's clinical trial records. If the potential subject agreed to participate in the research clinical trial, then the potential subjects executed the Informed Consent Form (ICF). Staff who conducted the informed consent process also executed the form, after which the potential subject entered the clinical trial as a subject. Each subject received a signed copy of the fully executed ICF.

If at any time during the clinical trial the subject had questions, the ICF directed the subject to a Subject Rights Advocate, whose contact information was in the Informed Consent Form.

Subjects completed a Medical History Form to determine initial qualification.

Instrumentation

Multi-port xenon arc solar simulators (300 W) equipped with WG320 and UG11 filters were used as the source of full spectrum UV radiation (Solar Light Company, Philadelphia, PA). This instrument, described in detail (reference 3), provided a continuous spectral output in the UVB range (290 nm – 320 nm), the UVAII range (320 nm – 340 nm) and the UVAI range (340 nm – 400 nm) that is similar to sunlight.

The performance of the solar simulators depends on their spectral output. Therefore, the solar simulator spectral output specification is less than 1500 W/m^2 for the total irradiance range of 250 nm to 1400 nm and a beam uniformity of 20% (reference 2). The maximal irradiance was confirmed to avoid excessive heat feeling during the SPF test. Irradiance for UVAII and UVAI equaled or exceeded 20% and 60%, respectively, of the full spectrum UV radiation.

The erythemal effectiveness of each wavelength band is expressed as a percentage of the total erythemal effectiveness from less than 290 nm to 400 nm, or as the Percent Erythemal Contribution (%EC). The following table indicates the %EC acceptable output limits for the solar simulators.

	% Erythemal Contribution	
Wavelength Range (nm)	Lower Limit	Upper Limit
<290		<0.1
290-300	1.0	8.0
290-310	49.0	65.0
290-320	85.0	90.0
290-330	91.5	95.5
290-340	94.0	97.0
290-400	99.9	100.0

Solar simulators were provided an appropriate warm-up period, after which, they were expected to have no significant time-related fluctuations in radiation emissions. Each solar simulator had good beam uniformity in the exposure plane. To ensure that the solar simulators deliver the appropriate spectrum of UV radiation, their spectral output is measured biannually with an accurately calibrated spectroradiometer.

The lamp output was measured after warm-up with a UV intensity meter (Model PMA2100, Solar Light Company, Philadelphia, PA) equipped with the appropriate detector before and after the test period. The delivered dose to each subsite was within 10% of the expected dose.

Determination of Preliminary MED of Unprotected Skin

Methodology

Prior to the test material phase, the MEDu of each subject was determined by a progressive sequence of UV radiation exposures, each of which was graduated incrementally by 25% over that of the previous exposure. In certain instances, the Principal Investigator determined the validity of utilizing a historical preliminary MED.

Evaluation

The test sites were evaluated for erythema according to the MED Scoring Scale, described below. The MEDu is the smallest UV dose that produces perceptible redness of the skin (erythema) with clearly defined borders at 16 to 24 hours after UV exposure (Score of at least 1 on the MED Scoring Scale). The MEDu test site was in close proximity to the MEDp test sites.

Score	Description
0	No erythema present
0.5	Ambiguous erythema, and/or no clear border, and/or not filling more than 50% of the exposure subsite
1	Perceptible unambiguous erythema with defined borders filling more than 50% of the exposure subsite
2	Moderate to intense erythema

Test Phase

Test Sites / Area

A sufficient number of 40 cm^2 test sites were outlined with a surgical marking pen on the subject's back between the scapulae and the beltline, lateral to the midline. There was a minimum distance of 1 cm between the borders of adjacent test sites.

These test sites were designated for each test material being tested, control standard, and MEDu (unprotected skin). The position of the test sites was randomly distributed on the back over the entire panel of subjects according to a Testing Facility generated Randomization Schedule.

Application of Test Material(s) and Control Standard

The test material(s) and control standard were evenly spread / applied to the appropriate test sites over 35 ± 15 seconds, using a gloved finger, at an application rate of approximately 2 mg/cm^2. The seconds utilized to complete application, application completion time, and actual weight applied were recorded on the CRF.

The test sites were allowed to air dry for at least 15 minutes after application.

UV Exposures

All test sites were divided into 6 subsites, used for a progressive sequence of timed UV radiation exposures. The area of each subsite was at least 0.5 cm^2 with a minimum of 0.8 cm distance between each adjacent subsite border.

The preliminary MEDu evaluation score along with the expected SPF of test material(s) was used to determine UV exposure for each subsite. The UV exposure for the Control Standard and MEDu was based on the expected SPF of 16.3 and 1, respectively.

For 6 subsites, UV exposures were divided as follows where X is the expected SPF:

Expected SPF	% Increments	Subsite 1	Subsite 2	Subsite 3	Subsite 4	Subsite 5	Subsite 6
<8	25%	0.51X	0.64X	0.80X	1.00X	1.25X	1.56X
8-15	20%	0.58X	0.69X	0.83X	1.00X	1.20X	1.44X
>15	15%	0.66X	0.76X	0.87X	1.00X	1.15X	1.32X

Evaluation of Immediate Responses

After completion of UV exposure, the control standard and test materials were gently removed using a cotton pad with a mild lotion such as makeup remover or other similar product, when neccessary.

Immediate reddening, darkening/tanning, and generalized heat responses were recorded on CRFs.

Prior to dismissal, each subject was instructed to shield the test sites from further UV radiation until evaluation of the subsites the following day.

Evaluation of Erythema 16-24 Hours Post UV Exposure

Each subsite was evaluated 16 to 24 hours after exposure to determine a final MED, using the previously listed scoring scale.

Evaluations were performed in sufficient illumination (tungsten or warm white fluorescent lighting) with at least 450 lux.

The qualified evaluator was not be the same person who applied the test material or delivered the UV radiation.

Statistical Methods

Rejection of Data

Test data from a subject was considered invalid and rejected for the following reasons:

- If the exposure series failed to elicit a MED response (erythema) on any of the subsites for either the treated or unprotected test sites;
- If the exposure series elicited a MED response (erythema) on all subsites for either the treated or unprotected test sites;
- If the MED response (erythema) on any test site (treated or unprotected) was inconsistent with the UV exposure series; or
- If the subject was noncompliant (*e.g.*, subject withdrew from the test due to illness or work conflicts, subject did not shield the exposed test sites from further UV radiation until the MED was evaluated, etc.).

SPF Calculation for Test Material on a Subject (SPFi)

The SPF is defined as the ratio of the energy of exposure to full spectrum UV, 290 nm – 400 nm, to produce erythema in human skin in the presence of a test material (or control standard), applied at 2 mg/cm^2, to that in its absence and is calculated as follows:

$$SPFi = \frac{\text{MED Protected Skin}}{\text{MED Unprotected Skin}}$$

SPF Calculation for a Test Material on the Panel

The SPF of the test material is defined as the arithmetic mean of the individual (SPFi) values obtained from the total number (n) of subjects used, expressed to one (1) decimal point:

$$SPF = (\sum SPFi) / n$$

Its standard deviation, s, is:

$$s = \sqrt{[(\sum SPFi^2) - ((\sum SPF\ i)^2 / n)) / (n-1)]}$$

The standard error (SE) is:

$$SE = s / \sqrt{n}$$

The SPF for the test material is the largest whole-number less than *x*-A, where *x* is the mean SPF value of all valid data.

Calculation of A: $A = \frac{(t)(s)}{\sqrt{n}}$

Where n = number of subjects,
t = upper 5% point from the t distribution with n-1 degrees of freedom and
s = standard deviation.

For the SPF determination of the test material to be considered valid, the SPF value of the control standard must fall within the standard deviation range of the expected SPF (i.e., 16.3±3.43).

Amendments

There were no amendments.

Deviations

There were no deviations.

Adverse Events

There were no adverse events.

Test Results

Of the 13 subjects who enrolled into the trial, 13 qualified, and 13 completed the trial.

Overall results were based on data from 10 subjects.

- Data for Subject # 1 were not included in the final results due to erythema in all subsites of the test material treated area.
- Data for Subject # 3 were not included in the final results due to erythema in all subsites of the control material treated area.
- Data for Subject # 8 were not included in the final results due to erythema in all subsites of the test and control material treated areas.

SPF calculations for each subject are shown in Table 1.

Conclusion

Under the conditions of this clinical trial, the average Sun Protection Factor (SPF) of test material, Product C was calculated to be 22.8 (SPF Label Value = 20).

References

1 Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Federal Register 2011:76;35620-35665.

2 Final Administrative Order (OTC000006); Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use (Posted September 24, 2021)

3 Berger DS. Specification and design of solar ultraviolet simulators. *J Invest Dermatol* 1969;53:192-199.

Table 1

Individual SPF Values

Subject #	ID#	Age	Gender	Skin Phototype	ITA°	MED (mJ/cm²) Untreated	Standard	Test Material	Control Standard	Product C
1	18972	58	F	II	58	19.0*	269.8*	<312.1*	14.2*	<16.4*
2	32121	58	F	III	34	22.4	345.5	609.3	15.4	27.2
3	13283	63	F	II	57	15.3*	<164.0*	289.4*	<10.7*	18.9*
4	96660	55	F	II	50	31.0	352.0	619.9	11.4	20.0
5	96707	33	F	III	33	34.8	493.5	801.3	14.2	23.0
6	94576	50	F	III	47	24.8	351.6	570.0	14.2	23.0
7	96161	54	F	II	41	17.7	314.4	444.0	17.8	25.1
8	96185	18	F	III	28	38.5*	<412.5*	<506.4*	<10.7*	<13.2*
9	43838	46	F	III	31	34.8	429.0	606.0	12.3	17.4
10	90518	42	M	III	28	48.2	546.1	770.4	11.3	16.0
11	6472	63	M	II	58	15.3	188.8	405.0	12.3	26.5
12	36287	60	M	II	57	15.3	249.5	352.4	16.3	23.0
13	42116	64	F	II	56	7.9	128.7	208.8	16.3	26.4
Average SPF									14.2	22.8
Number of Subjects (n)									10	10
Standard Deviation									2.27	3.87
Standard Error									0.72	1.22
t (one-tail)									1.833	1.833
A									1.31	2.24
SPF Value									12	20

Notes: Anticipated SPF 50.
Subject #s 1 - 4 tested at SPF 25.
Subject #s 5 - 13 tested at SPF 20.

* = Data not included in calculations.
< = Data invalid; erythema present in all subsites.