Health

External Audience Protocol (EAP)

Sunscreens

©2021 Consumer Reports, Inc. This document is the property of Consumer Reports and is intended for the recipient’s internal use only. You may not republish this document or provide copies to third parties or authorize anyone else to do so without Consumer Reports’ prior written consent. You may not use or authorize any third party to use Consumer Reports' names, ratings or trademarks (i) in any form of advertising, marketing or promotion; (ii) in any manner that may be construed as an endorsement by Consumer Reports; or (iii) in any manner inconsistent with CR’s No-Commercial Use Policy without Consumer Reports’ prior written consent.

This document’s contents may not be used in connection with any legal proceedings (including but not limited to litigation involving warranties, marketing claims, product liability, market share, injury or property), regulatory standard setting, administrative investigations or enforcement proceedings, or in connection with any other type of proceedings to which Consumer Reports is not a party. This document is otherwise subject to the terms of Consumer Reports’ User Agreement. Learn more at CR.org.
OVERVIEW

1. CR includes sprays, foams, creams, gels, lotions, sticks and lip balm. In light of the fact that the FDA has asked the industry or the public to provide them with data pertaining to whether sprays are safe and effective, we may not test spray sunscreens marketed specifically for use on children.

2. CR only tests water resistant sunscreens (after 40 or 80 minutes immersion) sold in the United States for full body and facial application.

3. Products must be SPF 30 or greater.

4. Products must claim to provide broad spectrum protection.

Tests

CR conducts the following tests for inclusion in the Ratings:

- In-vivo SPF after water immersion\(^1\,^2\)
- In-vitro UVA protection\(^2\)
- In-vitro eye irritation (Only if a product specifically claims not to irritate eyes).\(^2\)
- Sensory characteristics assessed by the CR Sensory Department.\(^3\)
- Whether or not the products stain fabrics. (Only products that do not specifically warn that they may stain clothing or fabrics are tested.)\(^3\)

\(^1\)We only test water resistant products whose SPF is 30 or higher. Products have water immersion times of either 40 minutes or 80 minutes depending on the claims made by the specific product. Most products we test claim to resist 80 minutes of immersion in water.

\(^2\) A contract laboratory conducts the sunscreen efficacy tests. The tests are not performed on CR’s premises.

\(^3\) CR conducts this test.

Wherever possible, CR purchases samples that represent three manufacturing lots of each product. If that is not feasible, the three samples may represent one or two manufacturing lots.

The three samples of each product are blind-coded and provided to the test lab as follows:

- Sample A – For in-vitro UVA testing and in-vivo SPF testing
● Sample B - For in-vitro UVA testing and in-vivo SPF testing
● Sample C – For in-vitro UVA testing and in-vivo SPF testing

1. SPF

CR uses the following test procedure to evaluate how well the products protect against erythema-inducing radiation.

CR patterns this test after test methods in the Federal Register 21 CFR Parts 201 and 310 Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use 2011 FDA Final Rule for Labeling and Effectiveness Testing of Sunscreens

The test initially starts with three subjects. If necessary, we add two to three subjects (in some cases up to six additional subjects) if there is a great deal of variation in the results with respect to subjects or claims. In past projects, this approach has worked well. This differs from the number of test subjects stipulated in the 2011 FDA Final Rule that requires 10-13 human subjects for SPF testing. We test three products on each subject. Initial tests make use of 3 subjects per model with Fitzpatrick’s skin types I, II & III.

We conduct tests according to a statistical design that randomizes the order of testing of models.

To minimize process variation, which could affect data, the same two outside lab personnel apply all product throughout the project and document this in all test reports.

The lab personnel apply the product at an application rate of 2 mg per sq cm on a 5cm x 8cm (40 cm²) rectangle on the subject’s back. Note: If a product is in spray or pump form, the product is expelled it into a clean container and then applied according to the prescribed application rate of 2 mg per sq cm.

The next step is water immersion, which begins 15-30 minutes after sunscreen application:

● For models that claim to be water resistant (40 minutes), personnel perform an SPF test after 40 minutes of immersion in water (20 minute immersion, 15 minutes out of water and 20 minutes immersion). Results are for post immersion SPF.

● For models that claim to be water resistant (80 minutes) personnel perform an SPF test after 80 minutes immersion in water (20 minute immersion-15 minutes out of water-20 minutes immersion-15 minutes out of water-20 minutes immersion-15 minutes out-20 minutes immersion). Results are for post immersion SPF.
After water immersion and air drying, the lab personnel irradiate the treated sites on the subject’s back with five or six doses (each in different locations within the 40 cm² area) of simulated sunlight that bracket the product’s claimed SPF. The five or six irradiation doses used for this test follow the FDA's 15% dosage brackets.

24 hours after irradiation, laboratory personnel score the amount of sunburn on each of the irradiated subsites. They compare that information to similar information for the subject’s untreated skin (MED) and use it to compute the SPF for the tested product.

CR bases the SPF score on the mean tested SPF, not how close the tested SPF is to the claimed SPF.

2. **UVA In-vitro PFA (UVA Protection Factor)**

CR uses the following test procedure to evaluate how well the products protect against UVA radiation.

CR patterns this test after the test method in *ISO 24443 First edition 2012-06-01 Determination of sunscreen UVA photo protection in vitro.* [Note: There is no PFA test in the 2011 FDA sunscreen Final Rule.]

Note: Consumer Reports is on record in our 2014 comments to the FDA that we believe PFA tests are a better measure of UVA protection than the 2011 Final Rule’s critical wavelength test. Therefore, we have based our UVA protection score on how well it performed in a test patterned after the ISO 24443 in-vitro PFA test.

Lab personnel apply the sunscreen to molded PMMA (polymethylmethacrylate plastic) plates with one side roughened. Personnel test four plates for each product and use all three samples of each sunscreen model for this test.

For all of the in-vitro UVA tests, the lab uses a 1.3 mg/sq. cm. application rate.

Lab personnel leave the sunscreen to “dry” for 30 minutes and then pre-irradiate the plates with ultraviolet radiation.

After pre-irradiation, the laboratory uses solar simulators that transmit light at the proper wavelengths through the sunscreen-coated PMMA plates and the amount of UV transmission is measured. Personnel compute the level of UVA protection as stipulated by ISO 24443 and adjust the absorbance curve to achieve an in-vitro SPF equal to the product’s labeled SPF.

CR bases a product’s UVA score on the average of the four test results (2 from sample A and
one each from samples B and C) divided by the claimed SPF. To verify test results, lab personnel test one additional plate using a reference sunscreen with a computed PFA that must be between 10.7 and 14.7.

In addition to the PFA score, lab personnel compute an ISO 24443 critical wavelength.

3. Sensory Based Skin Feel and Odor

Sensory panelists evaluate sunscreens taking into consideration the attributes of Thickness/Integrity of Shape, Absorbency, Whitening, Amount of Residual, Residual feel, Sensations, Gloss on skin, Aroma Intensity, Aroma Description, and make note of any attribute outside of the ones described above.

CR blind codes all models and performs the test in random order. Panelists evaluate each model one time on either their right or left forearm. Prior to testing, a short training session takes place to expose testers to a few products and references in order to clarify some skin feel and aroma attributes. For the sprays, testers dispense one short spray on the top and bottom sides of the forearm and for the lotions and creams, apply 1/4 teaspoon to the forearm. Unless noted, testers do not rub in the sprays, but leave them alone to dry/absorb. Testers rub each of the lotion and cream samples into the skin using the opposite hand. They take the time required to rub the lotion in from elbow to wrist on the front and back of the forearm until it is rubbed in or within a 2-minute period. If it takes longer than 2 minutes, panelists indicate that it takes longer than the set time. Just after application, panelists evaluate the key attributes for odor and skin feel. Ten minutes after initial rub-in, panelists re-evaluate odor and skin feel.

After each arm has been used for testing (session), testers wipe the tested area with paper towels (if a lot of residual) followed by wiping with pre-moistened wipes. Finally, testers wipe the area with an unscented soap, rinse the area with water and pat it dry with soft paper towels. Panelists take a 15 minute break in between sessions to prevent excessive irritation to the test areas.

4. Staining

In the past, CR has found that many sunscreens leave a stain on common clothing materials. CR tests each sunscreen model that does not specifically caution that it may stain clothing for its potential to stain or damage four common types of white warm-weather fabrics:

- 100% cotton material (white and black)
· 100% polyester material (white and black)

Personnel test one sample (container) of each sunscreen model. Testers apply approximately 1/8 tsp of each sunscreen to two separate randomized portions of the fabric to create a visible mark approximately one and a half inches in diameter. Testers express spray-type products into a container before measuring them for placement on the fabric. They leave fabric swatches out at room temperature in the laboratory to dry for approximately 24 hours. They then scrape excess dried sunscreen remaining on the surface of the material off the swatches. Testers launder the fabric swatches twice using Tide 2X with bleach alternative detergent, using CR tap water in a warm wash and cold rinse. They air dry the fabric swatches so as not to heat-set any persisting stains. After drying, testers record any visual staining or damage to the material.

5. **Eye Irritation**

Only products that specifically claim not to irritate eyes are tested.

An outside lab conducts this test using MatTek Corporation’s EpiOcular in-vitro toxicity testing system to approximate the results of a Draize rabbit eye irritation score. The lab uses Prell Shampoo and Johnson’s Baby Shampoo as controls.