§ 352.76 Determination if a product is water resistant or very water resistant.

The general testing procedures in §352.72 shall be used as part of the following tests, except where modified in this section. An indoor fresh water pool, whirlpool, and/or jacuzzi maintained at 23 to 32 °C shall be used in these testing procedures. Fresh water is clean drinking water that meets the standards in 40 CFR part 141. The pool and air temperature and the relative humidity shall be recorded.

(a) Procedure for testing the water resistance of a sunscreen product. For sunscreen products making the claim of “water resistant,” the label SPF shall be the label SPF value determined after 40 minutes of water immersion using the following procedure for the water resistance test:

(1) Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).

(2) 20 minutes moderate activity in water.

(b) Protocol.

(1) Test subjects shall be oriented to the use of sunscreen products and the nature of the testing procedures.

(2) Test subjects shall be oriented to the manner, duration, and activity of testing.

(c) Procedure.

(1) 20 minutes moderate activity in water.

(d) Determination of equivalency. The test product’s SPF value and PCD. Use data from at least 20 test subjects with n representing the number of subjects used. First, for each subject, compute the SPF value as stated in §352.73(b) and (c). Second, compute the mean SPF value, \( \bar{x} \), and the standard deviation, s, for these subjects. Third, obtain the upper 5-percent point from the t distribution table with n-1 degrees of freedom. Denote this value by t. Fourth, compute \( ts/\sqrt{n} \). Denote this quantity by A (i.e., \( A = ts/\sqrt{n} \)). Fifth, calculate the SPF value to be used in labeling as follows: the label SPF equals the largest whole number less than \( \bar{x} - A \). Sixth and last, the drug product is classified into a PCD as follows: if \( 30 + A < \bar{x} \), the PCD is High; if \( 12 + A < \bar{x} < 30 + A \), the PCD is Moderate; if \( 2 + A < \bar{x} < 12 + A \), the PCD is Minimal; if \( \bar{x} < 2 + A \), the product shall not be labeled as a sunscreen drug product and shall not display an SPF value.
(3) 20-minute rest period (do not towel test sites).
(4) 20 minutes moderate activity in water.
(5) Conclude water test (air dry test sites without toweling).
(6) Begin solar simulator exposure to test site areas as described in §352.73.

(b) Procedure for testing a very water resistant sunscreen product. For sunscreen products making the claim of “very water resistant,” the label SPF shall be the label SPF value determined after 80 minutes of water immersion using the following procedure for the very water resistant test:
(1) Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).
(2) 20 minutes moderate activity in water.
(3) 20-minute rest period (do not towel test sites).
(4) 20 minutes moderate activity in water.
(5) 20-minute rest period (do not towel test sites).
(6) 20 minutes moderate activity in water.
(7) 20-minute rest period (do not towel test sites).
(8) 20 minutes moderate activity in water.
(9) Conclude water test (air dry test sites without toweling).
(10) Begin solar simulator exposure to test site areas as described in §352.73.

§ 355.3 Test modifications.
The formulation or mode of administration of certain products may require modification of the testing procedures in this subpart. In addition, alternative methods (including automated or in vitro procedures) employing the same basic procedures as those described in this subpart may be used. Any proposed modification or alternative procedure shall be submitted as a petition in accordance with §10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative procedure provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in part 20 of this chapter.