

What Makes a Sunscreen Water-Resistant?



A Division of



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INTRODUCTION

Swiss-American is the manufacturer of EltaMD® sunscreens and has been asked to provide a position paper on the question of what makes a sunscreen water-resistant?

The answer to this question has two elements: the ingredient element and the legal element. But before defining these elements, it's important to understand the definition of water-resistance for sunscreens. This comes from the FDA's most recent version of the sunscreen monograph.¹ This document indicates that:

The water-resistance test indicates that a sunscreen product's labeled SPF protection is retained for a certain period of time after immersion in water.¹

The FDA has created three levels of water-resistance claims:

1. Not water-resistant, hence an SPF claim only
2. Water-resistant to 40 minutes
3. Water-resistant to 80 minutes

The test methodology to evaluate the 80-minute water-resistance of a sunscreen is as follows:

The water-resistant SPF value is determined by the product's ability to resist an 80-minute period of water immersion, achieved through the following test regimen:

After application of the sunscreen product followed by the waiting period, a total of 80-minutes of water immersion are scheduled; Four each 20 minute intervals in the water, followed by 15 minute rest intervals (without towel drying). Immersion is achieved indoors in a circulating whirlpool maintained at 23 to 32 degrees C for these testing procedures. The pool and air temperature and the relative humidity are recorded. At the conclusion of the water immersion/rest period cycle, the test sites are allowed to air-dry without toweling prior to exposure from the solar simulator.

Sixteen to twenty-four hours post-exposure, the subjects are instructed to return to the facility for evaluation of delayed erythemic (skin reddening) responses.¹

The FDA set these time limits based on research done in 1978 that indicated that swimmers in the pool or the ocean, spend an average of 21 minutes in the water and go in the water an average of 3.6 times on any given day.¹

The Ingredient Element:

To make a sunscreen water-resistant, ingredients have to be added that will allow the sunscreen formulation to adhere to skin when submerged in "swirling water". This can be done with waxes, oils, or a type of polymer such as dimethicone. Because accepted sunscreen active ingredients are either some form of liquid chemical compound or a fine mineral powder, they do not generally adhere to human skin. The formulator's objective is to mix ingredients into the sunscreen that will:

1. Help the sunscreen active ingredients adhere to skin when immersed in water.
2. Not negatively affect the balance of the sunscreen formulation, causing it to separate.
3. Not inhibit sunscreen ingredients from achieving desired SPF levels.
4. Not fill and plug skin pores.

Adding ingredients that cause sunscreen to adhere to the skin can be difficult because they must be compatible with the rest of the sunscreen formula, and not negatively affect the quality of the feel of the product; e.g., making it too oily, too sticky, or too thick.

The Legal Element:

The ability to claim a water-resistant capability is solely dependent on a product's performance in a water-resistance test described above. The protocol for this test was designed by the FDA to simulate actual swimmer behavior.

The SPF of a product being tested is recorded as many as three times during water-resistant testing:

1. At the beginning without submersion
2. At the end of the second submersion or 40 minutes in the water
3. At the end of the fourth submersion or 80 minutes in the water

A manufacturer can consider each of these three SPF readings and choose which one they want to use on the label of their product. For example, EltaMD UV Sport scored an SPF 58 without the water testing and an SPF 53 after the fourth submersion (80 minutes). This product could have been labeled as SPF 58, but then water-resistance could not have been mentioned on the label. To have the "Water-Resistant (80 minutes)" added to the label, the SPF could only have been listed as SPF 53. Since UV Sport is a product that for years has been labeled SPF 50, EltaMD decided to leave the same SPF designation in place, so UV Sport was labeled SPF 50, Water-Resistant (80 minutes).

EltaMD UV Physical was tested in two ways that resulted in different SPF ratings:

1. Without submersion = SPF 47
2. After submersion (40 minutes) = SPF 41

Because EltaMD chose to label UV Physical as "Water-Resistant (40 minutes)", it was required to use the lower rating of SPF 41 resulting after the submersion test.

Some Final Notes:

The water-resistant issue that this testing protocol does not directly address is that of sweating. Generally speaking sweating produces a 98%-water liquid, and because sweat emerges from within the skin it has the possibility of washing sunscreen away as it leaves the skin's pores.² While this could happen, its impact on overall sunscreen protection is very negligible. Skin pores range in size from 500-700 microns in diameter, and vary in their distribution over the body.³ For example, a standard accepted pore distribution on the forehead is 175-200 pores per cm².⁴ These dimensions suggest that on the forehead, skin pores only represent .2% of the skin's surface. The performance of a sunscreen that has been tested for water-resistance would not be affected due to sweat from such a small portion of the overall skin. What can happen, however, is that a sweating person can wipe sweat off of their body or face, which would also wipe off their sunscreen.

In the past the FDA has sanctioned the use of the terms "Water-Resistant" and "Very Water-Resistant". These have now been replaced with their new versions that reference specific times; "Water-Resistant (40 minutes)" and "Water-Resistant (80 minutes)". The FDA does not allow manufacturers to claim that sunscreens are "waterproof" or "sweat proof".

REFERENCES

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