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Water immersion does not alter the minimal erythema dose

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Synopsis

To determine the water resistance of a sunscreen, the COLIPA method requires the determination of two minimal erythema doses (MEDs): a static MED (MED_{US}) and a wet MED (MED_{UW}) (1). The MED_{US} is used in calculating the static SPF; the MED_{UW} is used in calculating the SPF after water immersion. Herein, we report that in the 107 subjects examined, the mean MED_{US} (21.0±0.55 mJ) is not different from the mean MED_{UW} (21.0±0.61 mJ). This shows that water immersion does not alter the minimal erythema dose and strongly suggests that the determination of two MEDs is unnecessary and that one should be eliminated. Eliminating one of the two MED determinations would increase the benefit/risk ratio of the COLIPA sunscreen water-resistance efficacy testing without harm to efficacy.

INTRODUCTION

Any clinical trial should maximize the benefit/risk ratio. One method is to reduce the risk to the subjects in the clinical trial. Another method is to increase the benefit for the subjects or for a greater population. To that end, sunscreen efficacy testing maximizes the benefit because millions of consumers receive the benefit from the subjects participating in the sunscreen testing.

To determine the water resistance of a sunscreen, the COLIPA method requires the determination of two minimal erythema doses (MEDs): a static MED (MED_{US}) and a wet MED (MED_{UW}) (1). The MED_{US} is used in calculating the static SPF; the MED_{UW} is used in calculating the SPF after water immersion.

The World Health Organization (2) and the US Department of Health and Human Services–National Toxicology Program (3) have declared that UV radiation is a carcinogen. Thus, clinical trials that involve UV radiation could increase their benefit/risk ratio by reducing the risk of exposure to UV radiation. Reducing the number of unprotected MED determinations would reduce the risk of sunscreen efficacy testing during the COLIPA water resistance testing.

Gambichler *et al*. reported no difference between MED_{US} and MED_{UW} in 12 subjects (4). Herein, we report that in the 107 subjects tested, the mean MED_{US} is not different from

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the mean MED_{UW}. This strongly suggests that the determination of two MEDs is unnecessary that and one should be eliminated. Eliminating one of the two MED determinations would increase the benefit/risk ratio of the COLIPA sunscreen water resistance efficacy testing without harm to efficacy. While this would not benefit the millions of sunscreen users, it would benefit the subjects in the clinical trial.

METHODOLOGY

Multiport solar simulators (Solar Light Company, Philadelphia, PA) are maintained by the Metrology Department at Consumer Product Testing Company, Inc. Data from 59 subjects were generated from 150-W multiport solar simulators; data from 48 subjects were generated from 300-W multiport solar simulators.

The MED, the minimum amount of energy required to produce a uniform, clearly demarcated erythema response in each subject, was determined according to COLIPA methodology (1). In the COLIPA methodology, 15 to 30 minutes after application the test sites are immersed in water for 20 minutes, dried for 15 minutes, immersed again for 20 minutes, and then air dried for 15 minutes or until completely dry before UV exposure.

RESULTS

In testing sunscreens using the COLIPA guidelines, this testing facility has generated 107 MED_{US} and MED_{UW} on identical subjects. For the 107 subjects, the means of the MED_{US} and MED_{UW} are identical:

	MED_{US}	MED_{UW}
Mean	21.0 mJ	21.0 mJ
STDEV	0.55 mJ	0.61 mJ

In 106 cases, the MED_{US} equaled the MED_{UW}. In only one of 107 instances did the MED_{US} not match the MED_{UW}, and in that instance the MED_{US} was slightly higher. From this data, we conclude that the MED_{US} is equivalent to the MED_{UW}.

Because the MED_{US} and MED_{UW} are equivalent, we propose that determination of the MED_{UW} be eliminated from the COLIPA guidelines for SPF testing. The MED_{UW} serves no useful purpose and increases the exposure of the subject to UV radiation.

CONCLUSION

Data from 107 subjects shows that water immersion does not alter the minimal erythema dose because there is no difference between the MED_{US} and MED_{UW}. Thus, the MED_{US} and MED_{UW} as required by the COLIPA method for water-resistant sunscreen testing are redundant and unnecessary. Eliminating the MED_{UW} would increase the benefit/risk of the clinical trial while maintaining quality in test methodology.

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