Cosmetics Europe
the personal care association

COSMETICS EUROPE:

N° 16: WATER RESISTANCE LABELLING

APRIL 2005

COLIPA RECOMMENDATION N°16
- Approved by PCPM -

Date: 07 April 2005 (updated July 2006)
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Water resistance labelling

Introduction

The method used to determine the water resistance of a sunscreen product is described in the Colipa Guidelines for Evaluating Sun Product Water Resistance (published December 2005 by Colipa).

Determination of the water resistance

The sun protection factor value on an individual subject for any product either before or after immersion is defined as the ratio of the minimal erythemal dose (MED) on protected skin to the MED on unprotected skin of the same subject. MED and SPF are determined according to the current International SPF test method (May 2006).
SPF measurements before and after water immersion (static and wet SPF) must be determined in the same laboratory on the same panel of volunteers as part of the same test sequence.

Mean Static SPF (SPFs)

The static SPF (SPFs) is calculated as the mean of the total individual static SPF values (SPFis), determined on all subjects completing the procedure. A corresponding 95% bilateral confidence interval (95%CI) should also be calculated. A test will be considered acceptable if the 95% confidence interval on the mean static SPF (SPFs) is within ± 17% of the mean static SPF (SPFs).

Determination of the percentage of water resistance retention

An individual Percentage Water Resistance Retention ($\%WRR_i$) value shall be calculated for each individual subject according to the formula below:

$$\%WRR_i = \frac{(SPF_{iw} - 1)}{(SPF_{is} - 1)} \times 100$$

Where: SPF_{iw} = individual wet SPF after water immersion
SPF_{is} = individual static SPF

The mean percentage water resistance retention (%WRR) is expressed as the arithmetic mean of the 'n' individual %WRR values ($\%WRR_i$).
The n value is determined according to the statistical criteria on the static SPF.

The confidence in the value for the mean percentage water resistance retention (%WRR) is expressed by way of a unilateral 90% confidence interval. The 90% unilateral lower confidence limit for the mean %WRR is calculated as:

$$\text{mean } \%WRR - d$$

with d calculated as:

$$d = \frac{t_u \times s}{\sqrt{n}}$$

where s = standard deviation
n = total number of volunteers in test
t_u = t value from the 'one-sided' Student-t distribution table at a probability level p=0.10 and with n-1 degrees of freedom

n	10	11	12	13	14	15	16	17	18	19	20
t_u values	1.383	1.372	1.363	1.356	1.350	1.345	1.341	1.337	1.333	1.330	1.328

Water resistance claim

If the 95% CI of the mean static SPF is within ± 17% of the mean static SPF and the mean %WWR – d is ≥ 50% then a product will be considered **water resistant**.

Very water resistance claim

Products which are designed to provide extra water resistance shall be tested by adding a further two twenty-minute water immersion periods. The condition for having a very water resistant claim are the same as above:

With two additional twenty-minutes water immersion, if the 95% CI of the mean static SPF is within ± 17% of the mean static SPF and if the mean %WWR - d is ≥ 50% then a product will be considered **very water resistant**.

Implementation is expected by January 2007, with a transition period of two years. All labelling should comply by 31 December 2008.

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