

ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

APPENDIX 3

COSMETIC LEGISLATION AND OTHER GUIDANCE WITH WHICH DERMATOLOGICAL PRODUCTS MUST COMPLY

Note: All products must comply with the European Regulation on Cosmetic Products (Regulation (EC) 1223 / 2009) which will replace the existing Cosmetics Directive (78/768/EEC) by 2013.

1. SUNSCREENS

1.1 SUN PROTECTION FACTOR

International Sun Protection Factor (SPF) Test Method

Ref: Colipa Guidelines - May 2006

<http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association/guidelines.html?view=item&id=21>

This document describes the testing procedure that must be followed when assessing the degree of protection offered against UVB radiation. Any products being submitted for ACBS approval must have evidence of having been tested against this standard with this method

1.2 UVA PROTECTION

Method for the *in vitro* determination of UVA protection provided by sunscreen products

Ref: Colipa Guidelines - 2009

<http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association.html?view=item&id=33>

This methodology describes the agreed European standard for determining the level of UVA protection offered by sunscreen products. Any products being submitted for ACBS approval must have evidence of having been tested against this standard with this method

1.3 WATER RESISTANCE

Guidelines for evaluating sun product water resistance

Ref: Colipa Guidelines - December 2005

<http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association/guidelines.html?view=item&id=18>

Protection against sunburn using any product is transitory and it is important to know whether or not products retain their effectiveness after submersion in water. This guideline offers an agreed mechanism whereby products can be tested to establish the effectiveness of sunscreens when they are used in the sea or swimming pools. Evidence that this methodology has been used must be produced when making any water resistance claims in the course of an application for ACBS approval.

1.4 COMPATIBILITY

Product test guidelines for the assessment of human skin compatibility

Ref: Colipa Guidelines - Edition of 1997

<http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association/guidelines.html?view=item&id=24>

This document provides guidance about various aspects of assessing whether or not products are compatible with human skin. This includes ethical requirements, testing approaches to be followed and information which will be required as part of the testing procedures. These procedures must be observed and evidence will have to be produced when requesting ACBS approval.

2. COSMETIC PRODUCTS

In addition to the EC regulation (see above) the following should also be consulted:

NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 7TH REVISION

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_004.pdf