CTPA Guidance Note on Durability Claims for Sunscreens

October 2018
Acknowledgements

The Cosmetic, Toiletry and Perfumery Association (CTPA) wishes to thank the members of the CTPA Sun Products Working Group for their time, advice and support in the preparation of this document:

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Ms Sandra Browne, Edgewell Group
Dr Jack Ferguson, Skinnovation
Ms Atoshi George, L’Oréal UKI
Mr Richard Keightley, Acheson & Acheson
Dr Monica Lundervold, Procter & Gamble UK
Ms Martyna Myka, Beiersdorf UK
Ms Clare O’Connor, Walgreens Boots Alliance
Ms Debra Redbourn, Godrej UK
Mr Mike Salmon, LF Beauty (UK)

The CTPA would also like to thank Caroline Rainsford, Scientific Affairs Manager at CTPA, for the compilation of this document and her input.

The CTPA Sun Products Working Group welcomes comments, questions or suggestions for improvements to this guideline. These should be addressed to Dr Emma Meredith, Director of Science, at the CTPA Secretariat via email to: info@ctpa.org.uk.
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Introduction

Sun protection products are an important part of a sunsafe regime. They need to be applied generously and it is recommended that they should be re-applied frequently to maintain the protection. However, for some people, frequent reapplication can be difficult. For example, people participating in outdoor sports or who work outdoors may not be able to re-apply sunscreen and there are also some people who would prefer not to have to re-apply frequently if possible.

Durable sunscreens (sometimes referred to as ‘extended wear’ or ‘once a day’ products) have been formulated to stay on the skin longer while maintaining their sun protection. Manufacturers of durable sunscreens comply with the same safety and claim substantiation requirements as for traditional sunscreens and will carry out robust testing to ensure the product will provide the expected level of protection during use.

This CTPA guide provides some key considerations that companies manufacturing such products should take into account.

1. Legislation

In the UK and EU, sun protection products are classed as cosmetic products and are covered by the EU Cosmetic Products Regulation ((EC) No. 1223/2009), hereafter the Cosmetics Regulation. The main aim of the Cosmetics Regulation is to ensure human safety.

The Cosmetics Regulation requires that any claim made by a product must be substantiated; and SPF (Sun Protection Factor) numbers, UVA protection, ‘water resistant’ or a durability claim on a sunscreen product are to be considered product claims.

2. EU Commission Recommendation

In 2006 the European Commission issued a Recommendation (2006/647/EC) on the efficacy of sunscreen products and their claims for primary sun protection products. This is in the process of being updated to refer to the Cosmetics Regulation (which replaced the European Cosmetics Directive (76/768/EEC) in 2013) and to reference the International Organisation for Standardisation (ISO) testing methods which are now the industry best practice for substantiating SPF and UVA claims.

The European Commission recommends that a sun protection product should provide both UVA and UVB protection.

The Recommendation lists the SPF numbers that should be used and states there should also be an indication of the type of protection the sunscreen offers i.e. low, medium, high or very high, alongside the SPF and labelled at least as prominently as the SPF.

The UVA protection that a sunscreen provides will be evident on the label. In the UK and across Europe, UVA protection is indicated on-pack by a logo showing the letters ‘UVA’ in a circle. The UVA logo is used throughout Europe to show that a product contains at least the recommended minimum level of UVA protection for a sunscreen (at least one third of the SPF). This level is also noted in the Recommendation. The Recommendation suggests a uniform way of communicating UVA protection to the consumer and, as mentioned above, the accepted industry practice is the UVA logo.
The Recommendation also provides other labelling requirements and warnings. However, it does not make any reference to water resistance or other durability testing.

While the Recommendation is seen as industry best practice for primary sunscreens in Europe, the Recommendation has no legal standing.

3. Testing Methods

The Cosmetics Regulation does not specify what test must be carried out to substantiate any claim. For the European market CTPA advises, and it is industry best practice, to use the following ISO methods for the SPF and UVA:

- SPF - ISO in vivo SPF Test Method (24444)
- UVA - ISO UVA in vitro Test Method (24443)

The British Standards Institution (BSI) online store, for the purchase of the methodology, may be accessed here.

3.1 Water Resistance

ISO is currently working on two international standards for water resistance testing: Water resistance – water immersion procedure; and Determination of percentage of water resistance.

In the UK/EU it is best practice to use the water resistance testing guidelines issued by Cosmetics Europe, the European personal care association. These guidelines are available to download from the Cosmetics Europe website:


3.2 Durability Claims

There is no recommended testing protocol for durability claims. However, manufacturers of such sunscreens should have developed their own robust protocols to substantiate such claims made on their products. These products are designed to incorporate ingredients such as film formers to help protect the UV filters from being rubbed and/or washed off.

This CTPA guidance note highlights some important aspects to consider when embarking on the development and testing of durable sun protection products.
4. **Ethical Considerations**

Studies involving human volunteers must respect sound ethical principles and be based on informed consent by the participants, consistent with the type of study under consideration. The person conducting the study must have appropriate training and experience in the field of the proposed study.

5. **Durability Claims – Key Considerations**

When developing a sunscreen with durability claims it is important to consider certain factors that may affect the protection that a product claims to provide over the anticipated period of time. A combination of challenges may be appropriate to support certain durability claims.

Key to all durability sun protection claims is longevity of the product remaining on the skin. Durable sun products should therefore show durability of skin protection over the time in which the product claims protection. Technologies for ensuring the sunscreen remains on the applied area for the period of time claimed, for example film former etc., should be considered during the development of the product.

Since it is anticipated that durable sunscreens will be used for a longer period of time, kinetic testing should be factored into the development and testing process and timeline. It is vital that manufacturers know how their durable sunscreen will work over time.

Since water resistance claims are themselves an indication of durability, it is recommended that water resistance testing be performed on any durable sunscreen product and that it should meet the ‘very water resistant’ criteria from the standard protocol.

Products promoted for active people may need to consider perspiration durability during exercise, for example by using a tailored sweat resistance protocol.

The photostability of the UV filters intended to be used must also be considered in any formulation. The ISO *in vitro* UVA test method gives an indication of this.

Another aspect of the testing regime should be to mimic some ‘real life’ situations, e.g. days out, water parks, outdoor workers, and build in some ‘real life’ assaults into the testing regime on the sunscreen to mimic usual use conditions.

A summary of testing factors to be considered for durable sunscreen products:

- SPF and UVA testing using ISO 24444 and ISO 24443 respectively.
- Pass ‘very water resistant’ test (Cosmetics Europe test method, 2005).
- Photostability of the sunscreens over the time period relating to the claim.
- Durability of protection over a set time period suitable to support the specific claim.
- Additional specialised testing to include ‘real life’ usage situations and challenges, such as sweating during exercise or heat challenge.
- Consideration should be given as to circumstances in which re-application would be recommended.
6. Validation

With the number of variables involved, as with any new testing protocol, it is vital that the durability testing is standardised and validated. If the testing is not to be conducted in-house then manufacturers should discuss this with their testing house as early in the process as possible and factor the testing into the development process. It takes time to validate a new testing process, potentially several months. Sun protection has significant health implications, therefore making sure the process is tested thoroughly to ensure it provides the claimed SPF and protects for the claimed time period is imperative.

7. User Evaluation

End user evaluations can provide useful support data on the durability perceived by the majority of users during normal use. Participants are asked to use the finished product according to the instructions for use and follow their usual routine before giving feedback.

8. Labelling

It is apparent that there is confusion among consumers when it comes to sunscreen labelling. Therefore the labelling of sun protection products must be as clear as possible to ensure correct use and compliance, especially where a new benefit such as durability is being claimed.

The European Commission Recommendation on sunscreen products provides guidance on labelling and claims. In Section 2, Part 5. (b) the Recommendation states:

“No claim should be made that implies the following characteristics: no need to re-apply the product under any circumstances (such as ‘all day prevention’).”

This does not mean that durable products are banned. However, the labelling of durable sunscreens must explain how much product should be initially applied and how the product must be applied as well as under what circumstances it should be re-applied, such as after excessive perspiring, swimming or towelling or after a given period of time.

Therefore, the consumer must be made aware that the protection claimed is dependent on proper application and on following the use and re-application instructions along with other sun safe messaging, which can be found in the EU Commission Recommendation.

9. Further Information

Sunscreens and sun protection, including durable products, have dedicated sections on the CTPA consumer website www.thefactsabout.co.uk, where there is a Sunscreens page.

The EU cosmetics legislation is available from the CTPA website, www.ctpa.org.uk, in the section How are cosmetics regulated?
References


2 Royal Pharmaceutical Society (RPS) Survey into sunscreen, 2015