

# Guidance Note on Durable Claims for Sunscreens

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**CTPA Role:**

The Cosmetic Toiletry and Perfumery Association (CTPA) is the trade association for the UK cosmetic and personal care industry.

The Association's role is to advise manufacturers, distributors and suppliers about the strict legal framework for cosmetics, to represent industry views to UK government, and external stakeholders and help promote information to the media on issues relating to the safety of cosmetic products. The CTPA acts as the voice of the UK industry and provides the most up-to-date interpretation of, and guidance on, regulatory matters affecting cosmetic products in the United Kingdom and internationally.

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The CTPA Sun Products Working Group welcomes comments, questions or suggestions for improvements to this guideline. These should be addressed to Caroline Rainsford, Head of Scientific Services, at the CTPA Secretariat via email to: [info@ctpa.org.uk](mailto: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. Within the EU, cosmetics are regulated by the EU Cosmetic Products Regulation ((EC) No. 1223/2009) and within the UK, cosmetics are regulated by Schedule 34 of the Product Safety and Metrology Statutory Instrument. Both frameworks are based on the same principles and are very closely aligned. The main aim of these Cosmetics Regulations is to ensure human safety.

The UK and EU Cosmetics Regulations require 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)<sup>1</sup> on the efficacy of sunscreen products and their claims for primary sun protection products. Although some aspects of the Recommendation have been superseded; for example, references to the Cosmetics Directive and references to previous testing methods for substantiating SPF and UVA claims, the principles within the Recommendation remain best practice in the UK and EU.

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 the UK and 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 the UK and Europe, the Recommendation has no legal standing.

### 3. Testing Methods

The Cosmetics Regulation does not specify which test must be carried out to substantiate particular claims. For the UK and European market CTPA advises, and it is industry best practice, to use the following International Organisation for Standardisation (ISO) methods for the determination of SPF and UVA:

- ISO 24444:2019 - *In vivo* determination of the sun protection factor (SPF)
- ISO 24443:2021 - Determination of sunscreen UVA photoprotection *in vitro*

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

#### 3.1 Water Resistance

Two ISO Standards are available for water resistance testing:

- ISO 16217:2020 - Water immersion procedure for determining water resistance
- ISO 18861:2020 - Percentage of water resistance

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

#### 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 using ISO 16217 and ISO 18861.
- 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<sup>2</sup>. 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<sup>1</sup> 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](http://www.thefactsabout.co.uk), where there is a [Sunscreens](#) page.

The UK and EU cosmetics legislation is available from the CTPA website, [www.ctpa.org.uk](http://www.ctpa.org.uk), in the sections for [UK Cosmetics Regulation and Amendments](#) and [EU Cosmetics Regulation and Amendments](#).

## References

<sup>1</sup> Commission [Recommendation](#) of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC)

<sup>2</sup> Royal Pharmaceutical Society (RPS) Survey into [sunscreens](#), 2015

