Federal Institute for Risk Assessment (BfR)

UV-Filters in Sun Protection Products

Opinion of the Federal Institute for Risk Assessment, 6th August 2003

Background

The Federal States Baden-Württemberg and Bayern have reported several problems related to UV filters in sun protection products. Questions have been raised in particular concerning

1. combined effects of UV filters and a summation limit value for UV filters,
2. a limitation for the sun protection factor,
3. the photostability of UV filters and
4. the oral toxicity of UV filters in lipsticks and lip care products.

UV filters and their combinations have frequently been a subject matter of deliberations within the Committee for Cosmetic Products (Cosmetics Committee) at the Federal Institute for Risk Assessment (BfR). The questions and proposals of the Federal States were discussed at the 64th meeting of the Cosmetics Committee.

Result

1. BfR recommends using combinations of UV filters and ingredients in the formulations of cosmetic products in a manner that enables to keep the amount of individual filters and also the sum of the filters used for the protection aimed as low as possible. The permitted maximum concentrations for the individual UV filters must not be exceeded. Furthermore, UV filters added should contribute considerably to the sun protection factor of the finished product. The health safety and the skin tolerance of the finished products must be guaranteed. At present there are no hints with respect to a concrete risk for cumulative toxic effects or increased skin penetration in products with a UV filter combination.

2. BfR further recommends a limitation for the sun protection factor, SPF, in sun protection products for healthy skin. Along the lines of precautionary consumer protection BfR is of the opinion that even a lower maximum SPF than the maximum SPF of 50+ discussed in the Cosmetics Committee could be favourable. In Australia and in the USA protection factors are restricted to 30+. A restriction to a SPF of 30+ would also be beneficial with respect to the difficulties in reproducibility of high SPFs and the correspondingly long exposure time for volunteers when determining high SPFs. The declared SPF should also be achieved under application conditions.

   Products with high UVB protection should also provide high UVA protection. In order to determine UVA protection, a uniform international harmonised method should be elaborated for the wavelength range of 320 to 400 nm. The declaration of UVA protection should be comprehensible for the consumer. A declaration as a percentage of the filtered UVA rays, for example, could help to avoid confusion with the SPF, which is a time-based protection factor. Until the establishment of an internationally accepted determination method, the declaration of UVA protection should include a reference to the determination method.

3. Since the combination of various UV filters and the formulation play a decisive role for photostability, BfR generally recommends testing the stability of the UV filters in finished products under conditions which are as close as possible to application ones. This is within the responsibility of manufacturers.

4. According to current knowledge it can be assumed that the use of decorative lipsticks and lip care sticks with UV protection only leads to a minor increase in systemic exposure of consumers to UV filters. The margin of safety (MOS) for all evaluated UV filters is at least 100 in sun protection products. In the case of additional exposure to UV filters in lipsticks and lip care sticks, the MOS according to current knowledge, falls only below 100 in the case of one filter (4-methyl benzylidene camphor).

   The margin of safety is based on the assumption of daily, lifelong exposure. For sun protection products application throughout the year must be assumed. It is not currently felt that there is a risk to the consumer through additional exposure to UV filters in lipsticks and lip care sticks. For reasons of precautionary consumer protection, however, 4-methyl benzylidene camphor should not be used in lipsticks, lip care sticks or skin care products.

Further recommendations

Sun protection products do not offer complete protection against UV rays. Their use should not lead to extended exposure to the sun nor replace sun protection through clothes. This applies in particular to children. Infants and babies should not be exposed to direct sunlight at all.

Explanation

UVB rays (wavelengths of approx. 290 to 320 nm) encourage the formation of melanin in the melanocytes of the deepest epidermal layers and therefore also the darkening of the skin through delayed pigmentation. UVB is largely involved in the development of inflammatory reactions (sunburn). Even low doses of UVB rays lead to an immunosuppressant effect. UVA rays (wavelengths of approx. 320 to 400 nm) penetrate the horny layer and reach the epidermis and dermis. They have a comparatively low effect on the triggering of sunburn but may trigger pathological light reactions. UVA rays mainly lead to an immediate pigmentation by means of reversible oxidation of melanin precursors.

The light-related ageing of the skin and the formation of tumours can be attributed both to UVB and UVA rays. The rate of UV-ray-related tumours decreases with increasing wavelength up to 350 nm. There are, however, indications that rays in the range of 380 nm may also induce a higher rate of tumours (Rünger 1999).

Because of an expanding exposure of the majority of the population to the sun, UV protection takes on an increasingly important role. UV filters are, therefore, not only used in sun protection products but to an increasing degree in hair and facial care products and in decorative cosmetics.

UV filters in cosmetics require marketing authorisation. Their use is regulated in accordance with Directive 76/768/EEC (Cosmetics Directive) and in the German Cosmetics Regulation (KVO). Permitted UV filters are listed in Annex VII of the Cosmetics Directive and in Annex 7 of the KVO. The maximum concentrations and application restraints are also listed there. Moreover, manufacturers must guarantee the health safety of their products.

UV protection can be afforded by both organic and physical filters (titanium dioxide, zinc oxide). At present, 25 organic sun protection filters are listed (KVO, Annex 7, or Cosmetics Directive, Annex VII). The use of coated microfine titanium dioxide and coated, microfine zinc oxide as UV filters is admissible in accordance with § 3b KVO up to 31 December 2003.

Furthermore, titanium dioxide is also authorised pursuant to the Cosmetics Directive in relative maximum amounts up to 25 %.

1. Combined effects of UV filters and sum limitation value for UV light filter agents

Organic UV filters absorb light quants in a specific wavelength range and convert energy into infrared rays; physical filters (titanium dioxide and zinc oxide) scatter, reflect and absorb UV rays. In order to offer protection over the entire spectrum of relevant wavelengths of 290 to 400 nm, several UV filters with different absorption maxima must be combined. By choosing a suitable combination of organic and physical filters, the content of organic filters can be reduced whilst offering the same UV protection. This is desirable since in particular photounstable organic UV filters, depending on their concentration in the finished product, can trigger phototoxic and photoallergenic reactions.

The combination of UV filters can, moreover, influence photostability. The organic UVB filters octocrylene and methylbenzylidene camphor are known to stabilise the photounstable organic UVA filter butyl methoxydibenzoylmethane. Furthermore, a possible recrystallisation of dissolved UV filters can largely be prevented by a suitable combination with liquid filters.

The galenic auxiliary substances used in the formulation also play a major role in sun protection products. They should guarantee the stability of the UV filters and may, under certain circumstances, also influence their penetration to deeper skin layers. For UV protection it is, however, necessary for the filter substances to remain and act in the horny layer. The efficiency of a sun protection product does not, therefore, depend solely on the filters used but to a large degree on the composition of the overall formulation.

Fears have repeatedly been voiced that the combination of organic UV filters could lead to interactions in the formulations and to an addition or potentiation of toxic effects. However, the BfR has received no information or data, supporting this hypothesis. The authorised filters have mostly been assessed by the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) and must have a margin of safety (MOS) of at least 100 between the exposure in man achieved under application conditions and a dose which does not lead to any adverse effects in animal experiments (SCCNFP/0321/00/Final: *Notes of guidance for testing cosmetic ingredients for their safety evaluation*). The assessment of UV filters also takes into account the special situation of children. Compared with adults, children have a three-fold higher ratio of body surface to body weight. This problem has been extensively discussed by SCCNFP. SCCNFP came to the conclusion that a MOS of more than 100 is sufficient to guarantee the safety of children when exposed to UV filters (SCCNFP/0557/02/Final: *Position Statement on the Calculation of the Margin of Safety of ingredients incorporated in cosmetics which may be applied to the skin of children*).

From data provided by the surveying authorities, BfR knows that sun protection products with combinations of between two and six UV filters are on sale on the market. The sum of the UV filters may amount to 10 to 20 mass percent. Sun protection products for children may also contain several organic filters. Adverse reactions caused by products with UV filter combinations have not been reported to BfR up to now. The BfR Cosmetics Committee has discussed the combination of UV filters in sun protection products on several occasions. The experts do not currently see a concrete risk based on the cumulative toxic effects or a higher skin penetration in conjunction with UV filter combinations.

Recommendation

BfR recommends that UV filters and ingredients should be combined in the formulations in such a way that the number of filters as well as the relative amount of filters used for the

protection claimed is kept as low as possible. The permitted maximum concentrations for the individual UV filters must not be exceeded. Furthermore, the added UV filters should contribute to the sun protection factor of the finished product. The health safety and skin tolerance of the finished products must be guaranteed.

2. Limitation of the sun protection factor and UVA protection

The declaration of the sun protection factor serves as an indicator for the consumer related to the efficiency of the individual product to protect against sunburn. The SPF stated on the products describes UVB protection and indicates the time period were a stay in the sun should not lead to skin reddening when using the corresponding product (sunburn or erythema protection factor or erythema threshold value). With the principle of the SPF the individual skin type of the consumer is taken into account.

A limitation of the sun protection factor was deemed necessary by the experts of the Cosmetics Committee since use of sun protection products with a high SPF may encourage consumers to an extended stay in the sun. A limitation to a maximum SPF of 50+ with a minimum SPF of 60 was discussed by the Committee. An SPF of 60 implies arithmetically that individuals with sensitive skin (skin types I to II) could spend up to 10 hours in the sun without becoming sunburnt, individuals with insensitive skin (skin types III to IV) up to 30 hours. However when calculating the time periods protection is claimed for the following factors additionally have to be considered:

1. Even protection products with a high SPF do not completely filter UVB rays (sun protection products with an SPF of 20 approximately filter 95 %, products with an SPF of 50 approximately 98 % of the UVB rays).

2. The SPF is determined under standardised conditions in the laboratory by applying 2 mg of the product per cm^2 skin (Colipa Sun Protection Factor Test Method. Brussels; The European Cosmetic, Toiletry and Perfumery Association-COLIPA, 1994). If a smaller amount of the product is applied under application conditions, the declared SPF will not be achieved. Also the sun protection product may become rubbed off by clothing or towels with the consecution of a reduced protection.

3. Since the biological endpoint for the determination of the SPF is the UV erythema, the SPF is no indicator for a protection against UV-caused skin aging, tumour development or immunosuppression. High protection factors in the UVB range may give a false feeling of safety, as skin reddening as an alarm signal is delayed. Consumers therefore may become encouraged to a prolonged stay in the sun. In the consequence the exposure to UVA is increased, if the product does not offer UVA protection.

The determination methods for the SPF have widely been harmonised world-wide since 1999 and SPF declarations on products therefore are mainly comparable. At present, there is no harmonised method for the determination of UVA protection. The Australian Standard (AS/NSZ 2604, 1997) is the only standardised method so far and frequently used all over the world. Here the transmission spectrum of the product is determined at wavelengths of 320 to 360 nm. In order to comply with the standard, more than 90 % of the rays must be filtered. Further specification on UVA protection are derived from tanning determination *in vivo*, e.g. applying the Immediate Pigment Darkening Method (IPD) or the Persistent Pigment Darkening Method (PPD, the industrial standard in Japan since 1996). For these purposes test persons were exposed to rays with specific UVA doses and skin tanning is determined after several minutes (IPD) or several hours (PPD), respectively. Depending on the method used the numerical value given for the same protection may vary considerably. A comparison of UVA protection by different products is possible only to a limited degree.

Declarations, which also include UVB protection are the critical wavelength (at which 90 % of the area under the absorption curve is reached in the range of 290 to 400 nm) and the ratio of UVA to UVB protection.

For an additional qualitative description of sun protection products, the burden quotient was introduced. It is an index for the galenic quality of the product and describes the ratio of the overall amount of UV filters and the sun protection factor. However, it can only serve as additional information and not replace the declaration of efficiency on sun protection products.

Recommendation

BfR recommends a limitation for the SPF in sun protection products for healthy skin. Along the lines of precautionary consumer protection BfR is of the opinion that even a lower maximum SPF than the maximum SPF of 50+ discussed in the Cosmetics Committee could be favourable. In Australia and in the USA protection factors are restricted to 30 +[1]. A restriction to an SPF of 30+ would also be beneficial with respect to the difficulties in reproducibility of high SPFs and the correspondingly long exposure time for volunteers when determining high SPFs. The declared SPF should also be achieved under application conditions.

Products with high UVB protection should also provide high UVA protection. In order to determine UVA protection, an international harmonised method should be elaborated for the wavelength range of 320 to 400 nm. The declaration of UVA protection should be comprehensible for the consumer. A declaration as a percentage of the filtered UVA rays, for example, could help to avoid confusion with the SPF, which is a time-based protection factor. Until the establishment of an internationally accepted determination method, the declaration of UVA protection should include a reference to the determination method.

3. Photostability of UV filters

High sun protection factors imply long-lasting protection. However, this is only guaranteed when the UV filters remain stable over the protection period claimed or if their metabolites have a comparable protective effect. Various studies confirm differing photostability of permitted UV filters (e.g. Herzog and Sommer, 2000, Schwack and Rudolph, 1996, Johncoock, 1999). In order to standardise photostability tests for UV filters, corresponding methods for UVA and UVB filters were published by the umbrella association of the European cosmetics industry *Comité de Liaison des Associations Européennes de l'Industrie de la Parfumerie, des Produits Cosmétiques et de Toilette* (COLIPA), (Gonzenbach et al 1996). According to this method dissolved filters are applied under defined conditions to a glass surface, dried and exposed to UV rays. Subsequently the recovery of the amount of UV filter applied is analytically determined and absorption is measured and compared to a non-irradiated sample.

Recommendation

Since the combination of various UV filters and the formulation play a decisive role for photostability, BfR generally recommends testing the stability of the UV filters in finished products under conditions which are as close as possible to application ones. An appropriate method is currently being developed by COLIPA.

4. Oral toxicity of UV filters in lipsticks and lip care products

[1] In the USA sun protection products are considered to be over-the-counter drugs whose efficiency and safety must be proven. Products may be declared with a higher SPF than 30+ if the effect was previously proven.

Lips react more sensitively to UV rays than the rest of the facial skin. Therefore UV filters are increasingly being added to decorative lipsticks and lip care sticks. Even if no clinical studies are available to confirm the prevention of pre-cancerosis on the lip through UV filters in lip care products, it can be assumed that the sun protection for the skin also protects the lips. In this context various filter combinations are possible and the protective properties of the individual products differ. It is assumed that the relative amount of UV filters in these products is 10 % on average. From surveillance, however, also higher amounts of UV filters in lipsticks and lip care products were reported (in individual cases up to 27 %).

Exposure and Assessment

Usually the amount of lip care products applied is 10 mg per application according to estimates of SCCNFP (SCCNFP/0321/00/Final: *Notes of guidance for testing cosmetic ingredients for their safety evaluation*). For products with a high pigment content as much as 15 mg per application may be applied. In the case of daily four-fold application up to 60 mg of the products were applied to the lips. For lip care products 100 % systemic intake through swallowing is assumed. Under these preconditions for lip care products with a high pigment content and a relative amount of UV filters of 10 % a daily intake of 0.1 mg UV filter per kg body weight for adults (60 kg body weight) and 0.6 mg UV filter per kg body weight for children (10 kg body weight) can be expected.

It is difficult to estimate the systemic intake of UV filters via the skin from skin care and sun protection products. The intake depends on e.g.

- the frequency of application of products containing UV filters,
- the amount used,
- the relative amount of the filter(s),
- the filter combination and the galenics of the formulation as well as
- the ability of the UV filters to penetrate the skin.

The daily amount of skin care products applied (leave-on products: facial cream, body lotion, deodorant and hair products) amounts to 13.5 g according to estimates of SCCNFP (SCCNFP/0321/00 final: *Notes of guidance for testing cosmetic ingredients for their safety evaluation*). Skin care products may contain UV-absorbing agents both for product protection as well as for skin protection. Therefore consumers may additionally be exposed to UV filters through the daily use of these products.

The highest exposure to UV filters is certainly linked to the application of sun protection products. However, BfR has no data about the amounts of sun protection products used. It is generally assumed that 0.5 to 1.5 mg sun protection agent is used per application per cm^2 skin. Taking into account the skin penetration rates obtained in experiments and the filter-specific maximum concentration in conjunction with single application to the entire body surface (18,000 cm^2, application 1 mg/cm^2), systemic exposure was estimated for the individual filters by the Scientific Committee on Cosmetology (SCC) or by SCCNFP in conjunction with marketing authorisation (cf. selection in Table 1).

The estimated exposure to UV filters from decorative lipsticks and lip care sticks is estimated to be 0.1 mg per kg body weight for adults. Table 1 lists the estimated exposure from sun protection products for a selection of UV filters, which are also frequently used in lipsticks and lip care sticks and for which opinions are available from SCC and/or SCCNFP. For these UV filters the MOS was calculated in conjunction with parallel application of sun protection products and lip care products containing UV filters based on the assumption that the same filter is used in both products.

UV filter	amount in product [%]	dermal absorption [%]	filter $_S$ [mg/kg KG/d]	filter $_L$ [mg/kg KG/d]	NOAEL [mg/kg KG/d]	MOS $_S$	MOS $_{SL}$
S27	10	4,4	1,32	0,1	200	152	141
S28	10	2	0,6	0,1	450	750	643
S32	10	0,08	0,021	0,1	175	8333	1446
S60	4	1,9	0,228	0,1	25	110	**76**
S66	5	0,56	0,084	0,1	200	2381	1087
S69	5	1,5	0,23	0,1	1150	5000	3485

Table 1: Additional exposure of adults to UV filters in lipsticks and lip care sticks and changes in the margin of safety

S27: Isoamyl p-methoxycinnamate; S28:Octyl methoxycinnamate; S32:Octocrylene; S60: 4-Methyl benzylidene camphor; S66: Butyl methoxydibenzoyl methane; S69:Octyltriazone

Filter $_S$: estimated amount of UV filters taken up from sun products per kg body weight and day;

Filter $_L$: estimated amount of UV filters taken up from lipsticks and lip care sticks per kg body weight and day;

MOS_S: Margin of Safety for UV filters in sun protection products;

MOS_{SL}: Margin of Safety for UV filters, when used in parallel in sun protection products and lipsticks or lip care sticks

The margin of safety for all authorised UV filters is at least 100 when used in sun protection products. In the case of additional exposure of adults to the corresponding UV filters in lipsticks and lip care sticks, the MOS falls below 100 only in the case of one filter (4-methyl benzylidene camphor[2]). For children who have a three-fold higher ratio of body surface to body weight than adults, the MOS could be even lower under unfavourable conditions. Further exposure is possible from body care products, which may also contain UV filters.

The margin of safety for UV filters is based on the assumption of daily, life-long exposure. This should not, in principle, apply to sun care products although a year-round use must be assumed, as sun protection products may be used not only in summer but probably also during holidays and when using solariums.

Recommendation

It is not felt that there is a fundamental risk to the consumer through additional exposure to UV filters in lipsticks and lip care sticks. However, for reasons of precautionary consumer protection 4-methyl benzylidene camphor should not be used in lipsticks, lip care sticks or skin care products.

5. Further recommendations of BfR

Sun protection products do not offer complete protection against UV rays. Their use should therefore not lead to extended exposure to the sun nor replace sun protection through clothes.This applies in particular to children since data of the American Academy of Dermatology confirm that 80 % of sun damage takes place before the age of 18. Infants and babies up to the age of 2 should not be exposed, if at all possible, to direct sunlight.

[2] Consultations at SCCNFP are currently underway about UV filters with regard to possible bioaccumulation and the interpretation of thyroid effects in animal experiments.

References

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