EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Consumer Products

SCCP

OPINION ON

Benzophenone-3

COLIPA n° S38

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

The SCCP adopted this opinion at its 18th plenary of 16 December 2008

About the Scientific Committees
Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCP
Questions concerning the safety of consumer products (non-food products intended for the consumer).
In particular, the Committee addresses questions related to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, domestic products such as detergents and consumer services such as tattooing.

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1. BACKGROUND

Submission I on the UV-filter Benzophenone-3 or Oxybenzone (INN) with the chemical name 2-hydroxy-4-methoxybenzophenone was submitted by COLIPA[1] in December 2005.

SCCP adopted at its 10th plenary meeting on 19 of December 2006 an opinion (SCCP/1069/06) on Benzophenone-3 with the conclusion:

"It is the opinion of the SCCP that insufficient data are presented to calculate the Margin of Safety of Benzophenone-3 under the proposed conditions of use.
The following additional information is required:
- A dermal absorption study with Benzophenone-3 under its in-use concentrations (up to 10%) according to OECD Guideline 428 combined with SCCP/0970/06.
These data are requested before end of March 2007."

The substance is currently regulated in the Cosmetics Directive in Annex VII, part 1 ("List of permitted UV filters which cosmetic products may contain") in a concentration up to maximum 10%. The regulation demands a warning on the label "contains oxybenzone" due to the photo-allergenic potential of the substance.

By the current dossier, submitted in December 2007, the applicants apply for a maximum allowed concentration up to 6%.

2. TERMS OF REFERENCE

1. *Does the SCCP consider Benzophenone-3 safe for use as an UV-filter in cosmetic products in a concentration up to 6.0% taken into account the scientific data provided?*

2. *And/or does the SCCP have any further scientific concerns with regard to the use of Benzophenone-3 as an UV-filter in cosmetic products?*

[1] COLIPA - European Cosmetics Toiletry and Perfumery Association

3. OPINION

3.1 HISTORICAL BACKGROUND

In its 2006 opinion (SCCP/1069/06), the SCCP discussed the physicochemical properties and the major part of the toxicological dossier of Benzophenone-3 (BP-3):

- BP-3 is a widespread UV-filter for which over the years a large amount of data have been generated, many of them between 1970 and 1988. This is reflected in the identification and physicochemical data section. The majority of the data are statements from the technical and material data sheets. Also the quality of the toxicological dossier suffers from the fact that studies are often outdated and/or only available as publications in journals, with the result that on several occasions batch number and purity of the test substance are not mentioned, compositions of tested formulations are unknown, etc. Nevertheless the SCCP was of the opinion that the submission summary provided a comprehensive and well-structured overview of the available test descriptions and publications.

- BP-3 displays a low acute toxicity profile with oral and dermal LD_{50}-values exceeding the classification limit of 2000 mg/kg. It is not considered as being irritating to the skin and the eyes. The UV filter has been extensively tested for its photoirritating potential *in vitro* during the validation of the 3T3 NRU PT test and was found negative in the majority of cases.

- With regard to the sensitising potential of the compound, both a guinea pig Magnusson Kligman Maximisation test and a LLNA indicated that BP-3 is non-sensitising in these experimental models. In addition, the 2005-submission contained a number of reports of clinical trials with regard to the photoallergenic potential of UV-filters in general. In each of those, a number of clear positive reactions to BP-3 were described. The SCCP added a number of references and emphasized that, looking at the positive photoallergic reactions to BP-3, one must keep in mind that the study population in all tests consisted of patients with a suggested history of photocontact allergy. Taking all the information together, the SCCP concluded that BP-3 can cause photoallergic reactions.

- As far as the dermal absorption of BP-3 was concerned, diverging *in vitro* (and *in vivo*) results were obtained and the SCCP requested a new, well-performed *in vitro* study.

- After repeated oral administration of BP-3 in rats and mice, the most frequently encountered adverse effects consisted of unspecific signs of systemic toxicity in the form of reduced food consumption and retarded body weight gain, together with effects on the identified target organs being the kidney and the liver. These effects were partly associated with changes in clinical chemistry. Very often the most susceptible parameter was the increase in liver weight. The latter, however, without any histopathological correlate, is not considered by the submission authors to reflect an adverse effect per se but should be considered as an adaptive metabolic response which is known to be reversible. Therefore, according to the 2005-submission, the oral NOAEL corresponded to 411 mg/kg bw/day. With regard to the results of the dermal repeated dose studies, a dermal NOAEL of 200 mg/kg bw/day was put forward, on the assumption that deviations without dose-response relationship and without correlated histopathological findings (e.g. the decreased reticulocyte count, increased relative kidney weight, increased platelet count and whole blood cell count in the 90d dermal study in rat) should not be taken into account.

- A teratogenicity study in rat showed BP-3 to be non-teratogenic under the conditions of the test. Only at the highest dosage level, which also caused maternal toxicity, some

skeletal aberrations were noted. The NOAEL-value for maternal and developmental toxicity was 200 mg/kg bw/day. A NOAEL value of 400 mg/kg bw/day for reproductive toxicity was extracted from subchronic toxicity studies involving additional reproductive toxicity parameter measurements.

- Toxicokinetic studies indicated that BP-3 was readily biotransformed into its three major metabolites and that excretion in the rat primarily occurs via the urine, while in the mouse the faecal route appears to be equally important.

- As far as the (photo)mutagenic/(photo)genotoxic potential of BP-3 was concerned, the presented *in vitro* and *in vivo* assays indicated that the substance did not possess (photo)mutagenic of (photo) genotoxic properties.

The SCCP was unable to calculate the Margin of Safety for BP-3 as no scientifically acceptable dermal absorption study was available in the submission.

3.2 DATA INTRODUCED

The current submission contains the following documents:

- COLIPA letter stating that the use level of BP-3 as a UV-filter does not exceed 6% for COLIPA members.

- An *in vitro* dermal absorption study with 4 sunscreens containing BP-3 either at 2% or at 6% [1].

- A PhD work covering 4 *in vivo* dermal absorption studies in human volunteers with BP-3 containing sunscreens [2-3].

- Additional literature data on (i) toxicokinetics and cytotoxicity of BP-3 [4-6], (ii) the effect of the concurrent use of an insect repellent and BP-3 on the dermal absorption of the compound [7-10] and (iii) some case reports about (photo-)allergic reactions to BP-3 [11-17].

- A full submission summary, combining the information discussed in the previous SCCP opinion (SCCP/1069/06) and the newly provided information.

The newly introduced data are discussed on the following pages.

3.2.1 *In vitro* dermal / percutaneous absorption - pig skin

Guideline:	Draft OECD TG 428: Percutaneous Absorption: *in vitro* Method (2000) + SCCP/0970/06
Date of test:	Jul - Oct 2007
Test system:	Pig ear skin (split-thickness, 400µm) on a flow through diffusion cell
Test substance:	BARNE-40: o/w[2] sunscreen emulsion with BP-3 at 2% BARNE-41: o/w sunscreen emulsion with BP-3 at 6% BARNE-42: w/o[3] sunscreen emulsion with BP-3 at 2% BARNE-43: w/o sunscreen emulsion with BP-3 at 6% (Compositions of sunscreens available in report)
N° of samples:	BARNE-40: 16 samples from 16 donors, (9 evaluable samples) BARNE-41: 14 samples from 14 donors (10 evaluable samples)

[2] oil in water
[3] water in oil

	BARNE-42: 18 samples from 18 donors (10 evaluable samples) BARNE-43: 24 samples from 24 donors (12 evaluable samples)
Batch:	N° 352
Purity:	98% (measured through GC)
Applied amount:	10 µl/cm² (~ 10 mg/cm²), in contact with skin for 24h (no occlusion), rinsed off after 24 hours with either an aqueous solution (BARNE-40-41) or methanol (BARNE-42-43)
Receptor fluid:	20% ethanol in phosphate buffered saline (PBS)
Sampling times:	0.5, 1.0, 2.0, 4.0, 6.0, 8.0 and 24 hours
Duration of study:	48 hours
GLP/QAU:	In compliance

BP-3 was investigated *in vitro* for its absorption and penetration properties on viable porcine skin by making use of two o/w and two w/o standard sunscreen formulations, containing either 2% or 6% of the UV-filter.
The performing laboratory initiated 3 independent experiments per formulation, each experiment involving measurements on 6 skin samples (18 samples per formulation).
Fresh dermatomed pig ear skin samples, with a thickness of 400 ± 80 µm, were treated with 10 µl/cm² of test formulation for 24 hours under dynamic and non-occluded conditions. Blank samples (at 0 hours) were collected immediately after filling the donor chambers at the maximal flow rate of the pump prior to application of the test items. As a measure of skin integrity, the conductivity across the skin samples was determined before treatment and after the last sampling. In addition, positive and negative controls with Benzoic Acid and Basic Red 12, respectively, were used to check the performance of the skin penetration system (historical data, checked every 3-4 months).
Washing solutions consisted of either an aqueous solution (for the o/w sunscreens: water + 0.2% acetic acid) or a methanol-based solvent (for the w/o sunscreens: methanol + 0.2% acetic acid). The receptor solution (20% ethanol in PBS) was slowly pumped through the receptor chambers with a flow rate of 0.5 to 2 ml per hour and fractionated 0.5, 1, 2, 4, 6, 8 and 24 hours following the application of each test item. The *stratum corneum* was separated by tape stripping (2 x 5 strips per sample) from the lower skin layers. Analysis for the presence of BP-3 was carried out by HPLC. The use of this HPLC technique for the quantification of BP-3 in various sunscreens was implemented and validated by determining linearity of standard curves, accuracy and precision, sensitivity, specificity and selectivity and stability in the matrix.

Results
Integrity checks of all skin samples lead to the use of skin samples within the acceptable conductivity range of ≤900 µS/cm only. No major impairment of the skin layer was detectable after incubation with the tested sunscreens.
The validation study of the HPLC method revealed a LOD[4] of 2.0 ng/ml and a LLOQ[5] of 2.5 ng/ml in 20% EtOH in PBS and the eluent mixtures. The solubility of BP-3 in the receptor solution was shown to be up to 5 µg/ml.
After the application period of 24 hours, BP-3 was detected in the skin extracts and in the receptor solution samples. The vast majority, however, was found in the wash solution, irrespective of the investigated test item (o/w or w/o sunscreen). The solubilisation of the test items after the application period was noted to be the most critical step regarding an acceptable recovery. Due to the observation that there was an impaired recovery, primarily within the first two experiments, the wash off and extraction procedure was optimized to guarantee a higher recovery in the repetition experiments. As such, 31 samples were excluded from the calculations due to a low recovery (< 85%).

With regard to the measurements in the receptor fluid over time, the amount of BP-3 penetrated during the first 0.5 – 1.0 hours appeared to be negligible (near the LOD of

[4] Limit of Detection
[5] Lower Limit Of Quantitation

2.0 ng/ml). Thereafter, there was a constant increase in the portion penetrated through the skin for all formulation types.
Throughout the assay, there was no indication of saturation and no relevant differences were observed with respect to the composition of the test items (o/w versus w/o). The amounts measured at the end of the study in the different compartments are presented in µg/cm² or in % of the applied dose in Table 1 and Table 2, respectively.
As 31 of the 72 samples failed to generate a BP-3 recovery of 85% at the end of the test, the results presented originate from 9 to 12 evaluable samples (each sample coming from a different donor) per formulation tested.

Table 1: Results expressed in µg/cm²

Amount of BP-3	2% BP-3, o/w (n=9)	6% BP-3, o/w (n=10)	2% BP-3, w/o (n=10)	6% BP-3, w/o (n=12)
Applied dose	200 ± 10	583 ± 42	201 ± 10	612 ± 37
Receptor fluid	4.5 ± 2.8	6.9 ± 2.1	2.3 ± 0.8	5.9 ± 3.1
Stratum corneum (tape stripping)	1.0 ± 0.7	4.9 ± 10.4	1.3 ± 2.5	8.0 ± 20.0
Epidermis + dermis (24 hours)	3.4 ± 1.6	11.3 ± 11.7	4.4 ± 4.9	13.4 ± 20.5
Washing solution	178 ± 12	512 ± 42	177 ± 14	543 ± 64
Recovery	187 ± 10	535 ± 36	185 ± 10	571 ± 43
Bioavailable portion (RF + epidermis + dermis)	7.9 ± 3.7	18.3 ± 11.3	6.7 ± 4.6	19.3 ± 21.6

Table 2: Results expressed as a % of the applied dose

Amount of BP-3	2% BP-3, o/w (n=9)	6% BP-3, o/w (n=10)	2% BP-3, w/o (n=10)	6% BP-3, w/o (n=12)
Applied dose	100	100	100	100
Receptor fluid	2.3 ± 1.4	1.2 ± 0.4	1.2 ± 0.4	1.0 ± 0.6
Stratum corneum (tape stripping)	0.5 ± 0.4	0.8 ± 1.7	0.6 ± 1.2	1.3 ± 3.2
Epidermis + dermis (24 hours)	1.7 ± 0.8	1.9 ± 1.9	2.2 ± 2.3	2.2 ± 3.2
Washing solution	89.1 ± 4.5	87.8 ± 5.7	88.3 ± 7.6	88.8 ± 9.6
Recovery	93.6 ± 3.9	91.8 ± 4.1	92.3 ± 5.3	93.3 ± 5.0
Bioavailable portion (RF + epidermis + dermis)	4.0 ± 2.0	3.1 ± 1.9	3.3 ± 2.2	3.1 ± 3.4

Conclusion

The study authors conclude that, under the experimental conditions reported, around 3-4 % (between 7-18 µg/cm²) of BP-3 (depending on the concentration in the formulation) penetrated the skin samples during 24 hours and therefore can be considered as bioavailable.

Ref.: 1

Comment

The mean value plus 2 standard deviations will be used for the calculation of the Margin of Safety.

3.2.2 *In vivo* dermal absorption / photostability - human volunteers

The submission contains a PhD work covering four different investigations on the percutaneous absorption of BP-3 and photostability of sunscreens including development and application of a specific analytical method:

1) 11 volunteers (4 women, 7 men) applied a commercially available sun-protection lotion containing 4% BP-3 over the whole body (2 m²) at 2 mg sunscreen/cm². They collected the urine subsequently over a period of 48 h and the BP-3 content was analyzed by a newly developed reverse-phase HPLC method. The investigator reported a BP-3 excretion of approximately 0.4% of the applied dose during the 48 h sampling period.
2) 25 volunteers (16 women, 9 men) followed the same application procedure but applied the respective lotion in the morning and the evening for 5 consecutive days. Urine was sampled and analyzed during the 5 days of application and for 5 days thereafter. One group (11 volunteers) received no UV radiation, while the other group was exposed to UV-A (400-707 J/cm²) and UV-B (0.46-2.0 J/cm²) at lunchtime. The investigator stated as mean total excretion an amount of 3.7% (1.2-8.7%) of the applied BP-3 after 10 days.
3) Methodological development and application of the analytical method covering solid phase extraction followed by reverse HPLC on urine analyses regarding conjugated/non-conjugated BP-3 and its conjugated/non-conjugated metabolite dihydroxy-benzophenone (DHB). The linearity of the assay with detection limits of 0.01 µmol BP-3/l and 0.16 µmol DHB/l was reported including large variation in the excretion patterns among the volunteers.
4) Study of the photostability of 7 commercial sunscreens by means of absorption spectrophotometry before/after artificial UV radiation and before/after natural UV radiation by the sun. BP-3 occurred in 2/7 sunscreens and was reported as "quite photostable" according to the newly developed calculation and grading scheme.

In the submission summary, the applicant states the following remarks questioning the reliability and validity of the reported investigations:

- No information on the composition of the BP-3 containing sunscreens is supplied.
- No individual or summary values were supplied but predominantly graphs with the exception of a tabulated overview of spectrophotometric measurements. Consequently, no reliable evaluation of the reported results was possible.
- The application was performed by the volunteers and not under controlled conditions. Thus, neither the applied amount nor the application areas are precisely known or were verified.
- The urine samples were taken, the volumes were measured and the probes were supplied by the volunteers without any control measure on good practice. Only a questionnaire was used. Consequently, the verification on the exact urine amount was impossible (e.g. no information on spillage) as prerequisite for precise analysis since concentration has to be related to volume.
- Within the analytical method not urine but methanol/filtered water was used for the standards and this is regarded as a methodological shortcoming.
- Photostability was investigated by means of spectrophotometer but no information on the suitability, acceptability or validity was available. Moreover, instead of the recommended amount for application of 2 mg/cm² only 0.5 mg/cm² was placed between silica plates. In addition, due to limited number of silica plates, the simultaneous exposure to natural sunlight was not possible and the spectrophotometer had no integrated sphere limiting the accuracy of the analysis.

Therefore, the applicant considers the presented thesis (and a publication resulting from it) of questionable reliability and validity due to several methodological shortcomings and numerous deficiencies and inconsistencies in reporting and assessment.

Ref.: 2, 3

Comment
As pointed out by the applicant, the presented PhD study contains too many shortcomings to generate scientifically acceptable results for the current risk assessment of BP-3.

3.2.3 Additional literature data

(i) Toxicokinetics and cytotoxicity of BP-3

In a first study, five commonly used sunscreen agents (avobenzone, octinoxate, octocrylene, BP-3 and padimate O) were added to human keratinocyte cultures in order to define their IC_{50}-values. Therefore the log sunscreen concentrations were plotted versus the reduction percentage of DNA synthesis (measured via radiolabelled thymidine uptake).
Subsequently the penetration of those 5 sunscreen agents through human skin was evaluated after application in mineral oil to isolated human epidermal membranes. Following 24h of human epidermal exposure, detectable amounts of all sunscreens were present in the stratum corneum and viable epidermis with epidermal penetration most evident with BP-3.
The concentrations of each sunscreen found in human viable epidermis after topical application, adjusting for skin partitioning and binding effects, were at least 5-fold lower, based on levels detected in viable epidermal cells, than those appearing to cause toxicity in cultured human keratinocytes. The IC_{50} value of BP-3 was 28.8 µM. The authors concluded that the human viable epidermal levels of sunscreens were too low to cause any significant toxicity to the underlying human keratinocytes.

Ref.: 4

The percutaneous absorption and urinary excretion after a whole body topical application of highly concentrated sunscreen was investigated in 32 volunteers (15 young males and 17 postmenopausal women) treated with 2 mg/cm² of a basic cream formulation on a daily basis for 4 days during the first week, followed by the same treatment regime with a sunscreen containing 30% of UV-filters in total (10% 4-Methylbenzylidene Camphor, 10% BP-3 and 10% Ethylhexyl Methoxycinnamate) during the second week.
Blood concentrations were measured at 0, 1, 2, 3, 4, 24 and 96 h and urine concentrations at 0, 24, 48, 72 and 96 h. Almost all three sunscreens were undetectable in plasma and urine before the first application. One to 2 h after the first application, all three sunscreens were detectable in plasma. The maximum median plasma concentrations were 187 ng/ml for BP-3 for females and 238 ng/ml BP-3 for men. In the females, urine levels of 44 ng/ml and in men 81 ng/ml BP-3 were found. Thus, all three compounds were detected in their parent forms both in plasma and urine, showing dermal bioavailability.

Ref.: 5

The effect of 3 UV filters on the hypothalamic- pituitary-thyroid axis in humans after whole body topical application was investigated in a 2-week single-blinded study. In this study 15 young men and 17 postmenopausal women were assigned to daily whole-body topical application (2 mg/cm²) of a basic cream in week 1 and with a mixture of the three sunscreens each at 10% (w/w) including BP-3 in week 2. The daily mean amount of cream applied over 4 days for each subject was 40 g for men and 35 g for women. All subjects were healthy and not taking any regular medication. The thyroid and postmenopausal status was verified about 4 weeks prior to treatment and hormone levels were measured. There was no biologically significant effect on hormone levels (TGB, TSH, T_4 total, T_4 free, T_3 total, T_3 free), indicating that the concentrations of sunscreen compounds absorbed were not capable of disturbing the homeostasis of thyroid hormones in humans.

Ref.: 6

(ii) Sunscreens containing a combination of insect repellent and BP-3: effect on dermal absorption

In vivo and *in vitro* studies were performed to investigate dermal absorption profiles of sunscreen preparations containing as well BP-3 as the insect repellent DEET (N,N-diethyl-m-toluamide). Both compounds showed to penetrate the skin and combined use showed to enhance the penetration percentages due to mutual enhancement effects (' synergistic percutaneous permeation'). The observed penetration profiles were dependent upon the type of formulation, application sequence and application proportion.
Human skin appeared to be less permeable than artificial membranes but comparable to pig skin.

Ref.: 7, 8, 9, 10

(iii) Case reports on (photo)-allergic reactions to BP-3

The current submission contains a number of additional scientific papers dealing with case reports or large population patch testing. They supplement analogous publications discussed in SCCP/1069/06 and thus confirm the statement made previously by the SCCP that BP-3 can be considered to display photoallergic properties.

Ref.: 11, 12, 13, 14, 15, 16, 17

(iv) Miscellaneous

Finally, a recently published study shows that BP-3 can be considered as photostable in a sunscreen, either as sole UV-filter or in combination with other filters. The compound also showed to enhance the photostability of Vitamin A.

Ref.: 18

As BP-3 is commonly used in personal care and other consumer products, Calafat et al. conducted an exposure study in a representative sample of the USA general population above 6 years of age. In total, 2517 urine samples were collected. as part of the 2003–2004 National Health and Nutrition Examination Survey. BP-3 was detected in 96.8% of the samples with a mean value of 22.9 µg/l. The authors conclude that exposure to BP-3 was prevalent in the general U.S. population during 2003–2004. Differences by sex and race/ethnicity were noticed and appeared to reflect differences in the use of personal care products containing BP-3.

Ref.: 19

3.2.4 Safety evaluation (including calculation of the MoS)

BP-3 as a UV-filter in sunscreens up to 6%

Dermal absorption (6% formulation): 9.9% [mean (3.1%) + 2 SD (2*3.4%)]
Applied dose (sunscreen): 18 g/day
Typical human body weight: 60 kg
No observed effect level NOAEL (terato-rat): 200 mg/kg bw/day

Systemic exposure dose (SED) = (18.10^3 mg/day * 6/100 * 9.9/100) / 60 kg
= 1.78 mg/kg bw/day

MoS = NOAEL / SED = 112

BP-3 as a UV-filter at 0.5% to protect cosmetic formulations against sunlight

Dermal absorption (2% formulation): 8.0% [mean (4.0%) + 2 SD (2*2.0%)]
Applied dose (all cosmetic products): 17.79 g/day
Typical human body weight: 60 kg
No observed effect level NOAEL (terato-rat): 200 mg/kg bw/day

Systemic exposure dose (SED) = ($17.79.10^3$ mg/day * 0.5/100 * 8.0/100) / 60 kg
= 0.119 mg/kg bw/day

MoS = NOAEL / SED = 1686

3.2.5 Discussion

A detailed discussion on the general toxicological profile of BP-3 was given in SCCP/1069/06 and taken over under section 3.1 of the current opinion.

The major shortcoming in the dossier was the absence of a sound dermal absorption study, allowing the calculation of the Margin of Safety for the UV-filter.
The newly provided *in vitro* dermal absorption study is considered scientifically acceptable and shows a mean dermal absorption level of 19.3 µg/cm² or 3.1% of the applied dose for a sunscreen (o/w or w/o) containing the maximum requested BP-3 concentration of 6%.
The available teratogenicity study in the rat generated a NOAEL-value for maternal and developmental toxicity of 200 mg/kg bw/day, which was used to calculate the MoS under section 3.2.4.
For both requested use patterns (as a UV filter up to 6% in sunscreens and as a UV filter to protect formulations up to 0.5% in all types of cosmetics), the MoS of BP-3 is above 100.

The additional literature references provided in the most recent submission and summarized under 3.2.3, support the statements of SCCP/1069/06 and do not introduce new discussion points.

4. CONCLUSION

The SCCP is of the opinion that the use of benzophenone-3 as a UV-filter up to 6% in cosmetic sunscreen products and up to 0.5% in all types of cosmetic products to protect the formulation does not pose a risk to the health of the consumer, apart from its contact allergenic and photoallergenic potential.

5. MINORITY OPINION

Not applicable

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