SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

Final Opinion on Benzophenone-3 in Cosmetic Products

1. Introduction

1.1. Benzophenone-3 (2-Hydroxy-4-methoxybenzophenone; oxybenzone; CAS No. 131-57-7; see figure 1) is currently included on the list of substances permitted for use as an UV filter in cosmetic products up to a concentration of 6% within Annex VI (Entry 4) of the Cosmetic Products Regulation UK No 1223/2009 (as amended). Benzophenone-3 may also be used in concentrations not greater than 0.5% to protect the product formulation.

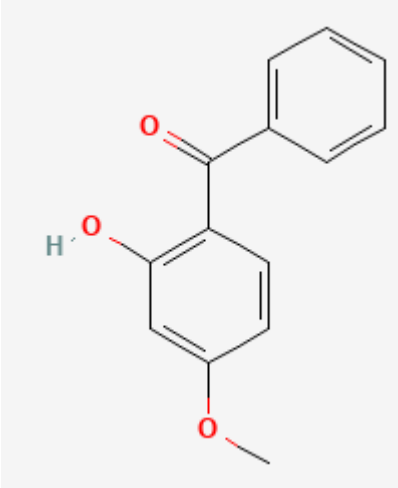

Figure 1: Structure of Benzophenone-3, CAS No. 131-57-7 (PubChem 2023)

1.2. Benzophenone-3 does not have any human health related harmonised classifications under the GB Classification, Labelling and Packaging (CLP) regulation No 1272/2008 (as amended). Currently no EU harmonised or GB mandatory classification and labelling entries exists for benzophenone-3

(databases accessed December 2022). However, it is suspected of being an endocrine disruptor (DK-EPA, 2014).

1.3. In April 2022, OPSS released a call for data on the safety of cosmetic ingredients with suspected endocrine disrupting properties in which benzophenone-3 was included. Several responses were submitted to OPSS to support the safe use of benzophenone-3 as a UV filter up to a concentration of 6% in cosmetic products and up to maximum concentration of 0.5% in cosmetic products to protect the product formulation. OPSS requested that the SAG-CS review the safety of benzophenone-3 intended to be used as a UV-filter in cosmetic products.

2. Background

Intended function and uses of benzophenone-3:

2.1. The predominant use of benzophenone-3 is as a broad band UV-filter in sunscreen products. Benzophenone-3 may also be used to protect product formulations in other cosmetic products.

2.2. Additional consumer exposure to benzophenone-3 may result from coating products, fillers, putties, plasters, modelling clay and finger paints.

3. Potential Endocrine Disrupting Properties

3.1. For the purposes of this assessment the SAG-CS are using the WHO/IPCS definition for endocrine disruption[1] (WHO/IPCS, 2002).

3.2. *In vitro* studies (OECD Conceptual Framework levels 1 and 2): A range of *in vitro* assays providing information on potential endocrine mechanisms and pathways are available. However, the available data are not conclusive with respect to potential endocrine-related activity; data are at best equivocal.

3.3. *In vivo* studies (OECD Conceptual Framework levels 3 and 4): A range of *in vivo* assays (19 studies) providing information on potential endocrine mechanisms and pathways, as well as adverse effects on endocrine-relevant endpoints are available. However, the available data are not conclusive with respect to potential endocrine-related adversity; data are contradictory and at best equivocal.

4. Regulation of Benzophenone-3 in Other Jurisdictions

4.1. In Australia, benzophenone-3 is currently allowed for use up to a maximum concentration of 10% in sunscreen products.

[1] *'An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.'*

4.2. In Canada, benzophenone-3 is currently allowed for use up to a maximum concentration of 6% in sunscreen products.

4.3. In the European Union, benzophenone-3 is currently allowed for use up to a maximum concentration of 6% in cosmetic products and up to maximum concentration of 0.5% in cosmetic products to protect the product formulation.

4.4. In Japan, benzophenone-3 is currently allowed for use up to a maximum concentration of 5% in cosmetic products.

4.5. In the United States, benzophenone-3 may be used up to 6% in over-the-counter sunscreen products. Local regulations may vary.

5. Previous Scientific Opinions on Benzophenone-3

5.1 Benzophenone-3 was initially listed as a permitted UV filter up to a concentration of 10% (w/w) in Annex VII of the EU Cosmetics Directive 76/768/EEC. Under this regulation, a warning statement of 'contains oxybenzone' was required to protect the consumer owing to the photo-allergenic potential of benzophenone-3.

5.2 In 2001, the SCCNFP reviewed the potential estrogenic effects of benzophenone-3. A No Observed Effect Level (NOEL) of 100 mg/kg bw/day was estimated from a 90-day feeding study in rats, based upon a benzophenone-3 dose of 0.1% in the diet. When using a Systemic Exposure Dose (SED) of 0.3 mg/kg bw/day as estimated from a percutaneous absorption value of 1% from Nohynek and Scharfer (2001) a Margin of Safety (MoS) of 333 was calculated. Another MoS calculation was undertaken using a NOEL of 937 mg/kg bw/day as determined in a uterotrophic assay in rats by Schlumpf *et al.* (2001). In combination with an estimated SED of 0.30 mg/kg bw/day, a 'screening MoS' was determined at 3123, which was deemed acceptable (Nohynek and Scharfer, 2001; Schlumpf *et al*., 2001; SCCNFP, 2001).

5.3 In 2006, the Scientific Committee of Consumer Products (SCCP) reviewed a submitted dossier that aimed to defend use of benzophenone-3 up to a maximum concentration of 10% in cosmetic products. The SCCP determined that the data provided were insufficient to calculate a Margin of Safety (MoS) and requested submission of a dermal absorption study using benzophenone-3 at in-use concentrations and according to OECD Test Guideline no. 428 (SCCP, 2006, OECD,2004).

5.4 In 2008, the SCCP reviewed a submitted dossier that aimed to defend use of benzophenone-3 up to a maximum concentration of 6% in cosmetic products. The SCCP were supplied with the above requested dermal absorption study and, in combination with a no observed adverse effect level (NOAEL) of 2000 mg/kg bw/day from a rat teratogenicity study, were able to calculate MoS values of 112 and 1686 for benzophenone-3 as a UV-filter in sunscreens up to

6% and as a UV-filter at 0.5% to protect cosmetic formulations against sunlight, respectively. The SCCP regarded that benzophenone-3 did not pose a risk to consumer health when used 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 (SCCP, 2008).

5.5 Following their call for data on substances with potential endocrine disrupting properties in 2019, the Scientific Committee of Consumer Safety (SCCS) was mandated by the European Commission to perform a safety assessment for benzophenone-3 considering the data received. Within this assessment, the SCCS performed MoS calculations with a revised NOAEL of 67.9 mg/kg bw/day from a rat oral prenatal and postnatal developmental study. When factoring in a maximum benzophenone-3 concentration of 6%, MoS values were found to be insufficiently protective for sunscreen body cream, aerosolised spray, and pump spray, at 38, 36, and 38, respectively. The SCCS therefore concluded "that use of benzophenone-3 up to a maximum concentration of 6% in sunscreen products, either in the form of body cream, sunscreen propellant spray or pump spray is not safe for the consumer" and revised the maximum use concentration to 2.2%. Sunscreen face creams (MoS = 447), hand creams (MoS = 317), and lipsticks (MoS = 1257) were found to have sufficiently protective MoS values at 6% benzophenone-3 and were considered to be within acceptable safety margins for consumers at this usage level. The SCCS also concluded that use of benzophenone-3 up to 0.5% in cosmetic products to protect the cosmetic formulation is within acceptable safety margins for the consumer, however, if benzophenone-3 is used to protect the product formulation at up to 0.5% in sunscreen body cream, aerosolised spray, and pump spray, the maximum use level of benzophenone-3 as a UV filter in these products should not exceed 1.7% (i.e. a total maximum of 2.2%).

5.6 The SCCS determined that the evidence presented with respect to endocrine disrupting properties was inconclusive and warrants further investigation (SCCS, 2021).

6. Presentation and Discussion by the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

6.1 At their July 2022 meeting, the SAG-CS discussed a paper which focussed on risks posed to health by benzophenone-3 when used as a UV filter in cosmetic products.

6.2 The regulatory background of benzophenone-3 and previous opinions from other risk assessment bodies were discussed (sections 4 and 5).

6.3 Members discussed analytical methods for detection and quantification of benzophenone-3. Although few methods are reported, it is not anticipated that such analyses should present difficulty. Members suggested that manufacturers may be able to provide suitable methods of analysis that are not available in the open literature.

6.4 Genotoxicity data for benzophenone-3 were discussed. A wide range of *in vitro* and *in vivo* studies are available, all of which were negative. Photomutagenicity studies also presented negative results (European Chemical Agency (ECHA) 2022).

6.5 The *in vitro* dermal absorption study by Jäger (2007) using pig skin samples, which was conducted according to OECD Test Guideline no. 428 (OECD, 2004) and GLP, was the most appropriate study to derive a dermal absorption value. Overall, the study (Jäger, 2007) does not comply with all the requirements of the SCCS basic criteria as overall recovery of benzophenone-3 was not within the range of 85-115% for all replicates or experiments. In addition, very high variability across all replicates and experiments exists. Therefore, the mean plus two standard deviations should be used as a dermal absorption value in the safety assessment calculations. The dermal absorption value for a sunscreen formulation containing 2% benzophenone-3 is 8% (4% + 2 x 2%). The dermal absorption value for a sunscreen formulation containing 6% benzophenone-3 is 9.9% (3.1% + 2 x 3.4%).

6.6 Members highlighted a potential interaction between benzophenone-3 and ketoprofen, namely that cross reactivity between the immune response to ketoprofen could lead to allergenic reaction to benzophenone-3 in individuals who had already been sensitised to ketoprofen, resulting in photo-contact allergenic reactions (Leroy et al, 1997).

6.7 In several studies investigating the endocrine disrupting properties of benzophenone-3, no dose-response behaviour was observed, and effects were observed only at very high doses. These doses were deemed unrepresentative of predicted human exposure. Members noted the presence of *in silico* and *in vitro* effects, but these were deemed not relevant *in vivo* given the absence of effects at relevant dose levels in *in vivo* studies. Members considered that benzophenone-3 was shown to be endocrine active in some assays but there is inadequate evidence to determine endocrine disruptive effects and there was no conclusive evidence available to derive an endocrine-specific Point of Departure (PoD).

6.8 Members considered a No Observable Adverse Effect Level (NOAEL) of 67.9 mg/kg bw/day from a pre- and postnatal developmental toxicity study in rats as a sufficient PoD to cover other human health endpoints (Nakamura *et*

al., 2015). Members considered an impact on testosterone levels during a sensitive developmental period but noted that this was at high-doses only and showed no dose-response relationship.

6.9 Members highlighted the necessity to consider aggregate exposure. The following SED and MoS values were calculated using the SED calculations given in the SCCS Notes of Guidance (2023). A more detailed breakdown of the calculations can be found in the appendix:

Table 1. SED and MoS calculated for cosmetics containing 6% benzophenone-3

Product Type	Route of Exposure		SED (mg/kg bw/day)	MoS
6% UV Filter in Cosmetic Products	**Dermal**	***-Full body***	**1.234**	**55**
	Dermal	*-Face cream*	0.106	643
	Dermal	*-Hand cream*	0.148	458
	Inhalation	*-Propellant spray*	0.090	752
	Inhalation	*-Pump spray*	0.001	75230
	Oral		0.054	1257
	Sunscreen spray (dermal + inhalation)	***-Propellant spray***	**1.234 + 0.09 = 1.324**	**51**
	Sunscreen spray (dermal + inhalation)	***-Pump spray***	**1.234 + 0.001 = 1.235**	**55**
	Lotion/cream sunscreen + lip salve		**1.234 + 0.054 = 1.288**	**53**
	Sunscreen spray (dermal + inhalation) + lip salve	***-Propellant spray***	**1.234 + 0.090 + 0.054 = 1.378**	**49**
	Sunscreen spray (dermal + inhalation) + lip salve	***-Pump spray***	**1.234 + 0.001 + 0.054 = 1.289**	**53**
0.5% UV Stabiliser in Cosmetic Products	Dermal		0.099	683

SED – systemic exposure dose. MoS – margin of safety.
Inhalation - exposure to benzophenone-3 (6%) in sunscreen products (propellant or pump sprays) only.
Oral – exposure to benzophenone-3 (6%) in lip products only.
Dermal absorption value of 9.9% used in calculation (for a formulation containing 6% benzophenone-3).

6.10 Given that the aggregate exposures to benzophenone-3 would result in an exceedance of the margin of safety, recalculation of the maximum concentration of benzophenone-3 that met acceptable safety margins when the cosmetic products are used in combination (Table 2) was necessary. This acceptable concentration was found to be 2.2%, provided that there is no additional exposure to benzophenone-3 when used as a UV stabiliser (at 0.5%). If benzophenone-3 is used in a cosmetic product as a UV stabiliser (at 0.5%), the concentration added for UV filtration purposes must not exceed 1.7% (i.e. a total of 2.2% in the cosmetic product).

Table 2: (Overleaf) SED and MoS calculated for cosmetics containing 2.2% benzophenone-3

Product Type	Route of Exposure		SED (mg/kg bw/day)	MoS
2.2% UV Filter in Cosmetic Products	Individual product use			
	Dermal	*-Full body*	0.453	150
	Dermal	*-Face cream*	0.039	1754
	Dermal	*-Hand cream*	0.054	1250
	Inhalation	*-Propellant spray*	0.033	2052
	Inhalation	*-Pump spray*	0.0003	205171
	Oral	*- lip salve*	0.020	3429
	Sunscreen spray (dermal + inhalation)	*-Propellant spray*	0.453 + 0.033 = 0.486	140
	Sunscreen spray (dermal + inhalation)	*-Pump spray*	0.453 + 0.0003 = 0.4533	150
	Aggregated product use			
	Lotion/cream sunscreen (dermal) + lip salve (oral)		0.453 + 0.020 = 0.455	149
	Sunscreen spray (dermal + inhalation) + lip salve	*-Propellant spray*	0.453 + 0.033 + 0.020 = 0.506	134
	Sunscreen spray (dermal + inhalation) + lip salve	*-Pump spray*	0.453 + 0.0003 + 0.020 = 0.4733	143
	Face cream + hand cream + sunscreen spray (dermal + inhalation) + lip salve	*-Propellant spray*	0.039 + 0.054 + 0.453 + 0.033 + 0.02 = 0.599	113
	Face cream + hand cream + sunscreen spray (dermal + inhalation) + lip salve	*-Pump spray*	0.039 + 0.054 + 0.453 + 0.0003 + 0.02 = 0.566	120

SED – systemic exposure dose. MOS – margin of safety.
Inhalation - exposure to benzophenone-3 (2.2%) in sunscreen products (propellant or pump sprays) only.
Oral – exposure to benzophenone-3 (2.2%) in lip products only.
Dermal absorption value of 8% used in calculation (for a formulation containing 2% benzophenone-3).

6.11 Members noted that the consideration of environmental effects is outside the remit of the group.

7. SAG-CS Conclusions

Members agreed that benzophenone-3 is acceptable when used as a UV-filter in cosmetic products up to a maximum concentration of 6% when used:

- *In face cream.*
- *In hand cream.*
- *In lip products.*

Members also agreed that benzophenone-3 is acceptable when used as a UV-stabiliser in cosmetic products up to a maximum concentration of 0.5%.

However, benzophenone-3 does not meet acceptable safety margins as defined in the SCCS Notes of Guidance (2023) when used as a UV-filter in cosmetic products up to a maximum concentration of 6% when applied to the full body; consequently benzophenone-3 also does not meet acceptable safety margins when applied to the full body in combination with other products. Members reviewed calculations that confirm those undertaken by the SCCS. These show that when applied to the full body, a maximum use concentration of 2.2% benzophenone-3 in the proposed cosmetic products meets the acceptable margin of safety of 100.

When benzophenone-3 is present as a UV-stabiliser, the concentration added for UV filtration purposes must not exceed 1.7% (i.e. a total of 2.2% in the cosmetic product).

The Committee were of the opinion that a full risk assessment in children and adolescents should be conducted when adequate data and an appropriate methodology become available.

Members considered that the available data were inconclusive regarding endocrine disruption according to the WHO definition and the information is not sufficient to conclude that the observed effects in the one-generation reproductive toxicity study were as a result of an endocrine mode of action.

Members noted potential interactions between ketoprofen and benzophenone-3.

Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

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Appendix – Safety Assessment Calculations

SED_{dermal} and Margin of Safety (MoS) calculations using the methodology outlined in the SCCS Notes of Guidance 2023.

Table 3: Full calculations for dermal exposures to benzophenone-3

Product type/application	**Sun protection cream with 2.2% Benzophenone-3 - body**	**Sun protection cream with 2.2% benzophenone-3 - face**	**Sun protection cream with 2.2% benzophenone-3 - hand**	**All products when used at 0.5% for non-UV filter purposes**
Daily exposure to product (mg/d)[1]	18000	1540	2160	17400
Concentration Benzophenone-3 (%)	2.2%	2.2%	2.2%	0.50%
Calculated daily exposure to Benzophenone-3 (mg/d)	396	33.88	47.52	87
$E_{product}$/bw (mg/kg bw/d)	257.14	22.00	30.86	248.57
Retention Factor[2]	100%	100%	100%	100%
Dermal Absorption (%)[3]	8.0%	8.0%	8.0%	8%
Skin surface area (cm^2)	17500	565	860	
Dermal absorption per application (DA_a*SSA*0.001)	1.40	0.05	0.07	
Frequency of application (/day)	1	1	1	1
Body weight (kg)	70	70	70	70
SED_{dermal} (mg/kg bw/d)	**0.453**	**0.039**	**0.054**	**0.099**
PoD (mg/kg bw/d)[1]	67.9	67.9	67.9	67.9
Oral absorption (%)[2]	100%	100%	100%	100%
$PoD_{systemic}$ (mg/kg bw/day)[4]	67.9	67.9	67.9	67.9

MoS	**150**	**1753**	**1250**	**682**
Acceptable MoS	100	100	100	100
Conclusion	**Acceptable MoS**	**Acceptable MoS**	**Acceptable MoS**	**Acceptable MoS**

[1] – Default use levels from the SCCS Notes of Guidance, 2023. Total body exposure to sunscreen of 18,000 mg/day was used as stated in section 3-3.4.2.1.

[2] – Default values from the SCCS Notes of Guidance, 2023.

[3] – Derbal absorption derived from Chemie Wirtschaftsforderungs GmbH (Jäger, 2007) by the SCCS, 2021. Dermal absorption of 8% calculated from the mean of 4% + 2SD (2*2%) derived from the study using 2% BP3.

[4] – POD derived from pre- and postnatal developmental toxicity study in rats (Nakamura *et al*., 2015).

Table 4: Inhalation exposure	Propellant spray	Pump spray
Amount per application (mg/application)[1]	15000	9000
Content BP3 in non-propellant (%)	2.2%	2.2%
Proportion non-propellant[1]	0.6	1
Airborne fraction[1]	1	0.2
Potential amount inhaled (mg/application)	198	39.6
Box 1 volume (L)[2]	1000	1000
Duration in box 1 (min)[1]	2	2
Inhalation rate (L/min)[1]	13	13
Potential amount inhaled in box 1 (mg/application)	5.148	1.029
Box 2 volume (L)[2]	10000	10000
Duration in box 2 (min)[1]	10	10
Inhalation rate (L/min)[1]	13	13
Potential amount inhaled in box 2 (mg/application)	2.574	0.5148
Retention fraction in lungs (25% exhaled)[1]	0.75	0.75
Respirable fraction[1]	0.2	0.01
Frequency of application (/day)	2	2
Body weight (kg)	70	70
$SED_{inhalation}$ (mg/kg bw/d)	**0.033**	**0.00033**
PoD (mg/kg bw/d)1	67.9	67.9
Oral absorption (%)2	1	1
$PoD_{systemic}$ (mg/kg bw/day)	67.9	67.9
MoS	**2051**	**205171**
Safe MoS	100	100
Conclusion	**Acceptable**	**Acceptable**

[1] - Default values from the SCCS Notes of Guidance, 2023.

[2] - Box 1 is near field of exposure, around the head. Box 2 is the far-field of exposure, e.g the bathroom. Based on default estimates from the SCCS Notes of Guidance, Appendix 11 (2023).

3 - POD derived from pre- and postnatal developmental toxicity study in rats (Nakamura *et al*., 2015).

Table 3: Aggregate SED and MoS calculations.

Component	Propellant spray	Pump spray
SED Sun protection cream - body	0.452	
SED Sun protection cream - face	0.0387	
SED Sun protection cream - hand	0.0543	
SED Lip salve with sun protection	0.0198	
SED Inhalation	0.0331	0.00033
SED Non-UV filter uses; dermal (0.5%)	0.0994	
PoD (mg/kg bw/day)[1]	67.9	
Oral absorption (%)[2]	100%	

PoD systemic (mg/kg bw/day)	67.9	
Total SED (mg/kg bw/day)	**0.598**	**0.566**
MoS	**113**	**120**
Safe MoS	100	100
Conclusion	**Acceptable**	**Acceptable**

[1] - POD derived from pre- and postnatal developmental toxicity study in rats (Nakamura *et al*., 2015).

[2] - Default values from the SCCS Notes of Guidance, 2023.

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