Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Safety Review of Benzophenone

July 2025

Contents

Introduction

Benzophenone is concluded by International Agency for Research on Cancer (IARC) Working Group as a possibly carcinogenic to humans (Group 2B). It is a known potential degradant of sunscreens containing octocrylene. Although USP monograph for octocrylene has limits for organic impurities in the raw material, the monograph does not specify a safe limit for benzophenone as a degradant in finished products. Therefore, the TGA has been reviewing available information to establish a safe permitted daily exposure and a limit for benzophenone as a degradant in therapeutic sunscreens.

In August 2023, the TGA held a public consultation to discuss safe levels of benzophenone in listed medicines. The consultation document proposed to amend the requirements for the use of benzophenone and octocrylene in these medicines. However, the decision to introduce a regulatory limit for benzophenone was deferred pending further consultation to develop a sunscreen exposure model specific to the Australian context.

In July 2024, the TGA conducted a subsequent public consultation to establish the Australian Sunscreen Exposure Model (ASEM), which more accurately estimates regular sunscreen exposure for Australians. The ASEM calculates a highest estimated average daily sunscreen exposure amount based on the highest use scenarios in the most vulnerable population (toddlers aged 1-2 years), ensuring it is applicable for general therapeutic sunscreens meant to be used by the whole population.

This updated safety review uses the ASEM to assess the risk of benzophenone as a degradant in sunscreens.

What is this chemical

Benzophenone is an aryl ketone and it is the simplest member of the class of benzophenones (Figure 1). Substituted benzophenones such as oxybenzone and dioxybenzone are frequently used in sunscreen.

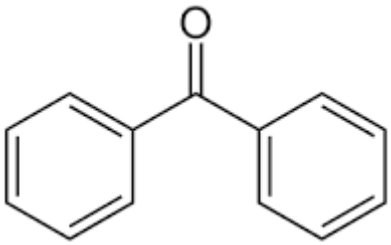

Figure 1: Benzophenone, Cas 119-61-9, synonymous: Diphenylmethanone, benzoylbenzene

Benzophenone is a naturally occurring compound used in flavouring and perfumes. It is used as fixative for heavy perfumes in soaps, detergents, and room deodorizers. It is used as a flavouring agent, ultraviolet absorber in inks and coatings, and as a polymerization inhibitor for styrene. It is used in the manufacture of antihistamines, hypnotics, and insecticides. Concentrations of benzophenone in food products range from 0.57 ppm in nonalcoholic beverages to 3.27 ppm in frozen dairy products.

The presence of benzophenone in sunscreen arises from two main sources:

(1) benzophenone contamination in the octocrylene, active ingredient in a high number of sunscreen products marketed in Australia, and
(2) accumulation of benzophenone from the degradation of octocrylene as the product ages (aminolysis and hydrolysis of octocrylene in the skin may result in the formation of benzophenone) (Figure 2).

Recently Downs and colleagues (2021) found benzophenone in 17 commercial sunscreens tested (ranging from 0 to 227.9 ppm) and after accelerated stability incubation of 6 weeks, the lowest concentration of benzophenone was 6.3 ppm and the highest was 461.4 ppm).

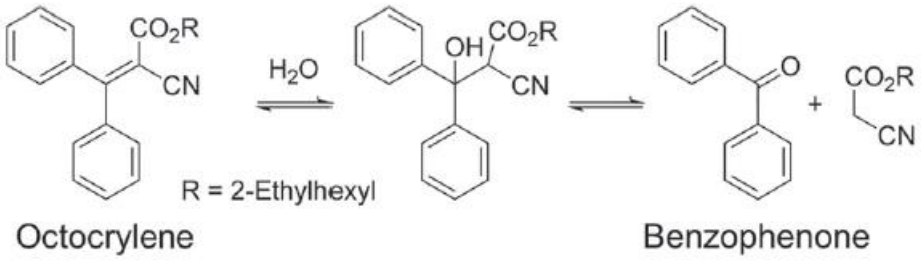

Figure 2: Degradation of Octocrylene (from Downs C.A et al. Chem. Res. Toxicol. 2021, 34, 1046-1054)

Current restrictions in Australia and overseas

Australian regulations

Benzophenone is available for use in medicines, biologicals and medical devices. For listed and over the counter medicines, benzophenone is only permitted to be used in combination with other permitted ingredients as a fragrance, where the total fragrance concentration in a medicine must be no more than 1%. As of 17 September 2024, Benzophenone is currently being used as fragrance in four listed medicines, four registered medicines and two other therapeutic goods.

The Australian Industrial Chemicals Introduction Scheme (AICIS) completed a Human Health Tier II assessment for benzophenone on 1 September 2015. While showing low acute toxicity in rabbits following dermal exposure (LD_{50} of >2000 mg/kg bw), AICIS concluded that benzophenone was a potential oral carcinogen.

International regulations

Effective from November 17, 2023, benzophenone has been added to Annex II of Regulation (EC) No. 1223/2009, which lists substances prohibited in the formulation of cosmetic products within the European Union (EU). The EU has also implemented new requirements and transition periods for octocrylene and notes that 'Benzophenone as an impurity and/or degradation product of Octocrylene shall be kept at trace level', however, a numerical limit has not been specified.

In 2009, EFSA assessed benzophenone as a food contact material (EFSA, 2009). The report indicated that the margin of exposure was low and recommended that more data on the occurrence of the substance in foods should be provided as well as appropriate toxicity data corresponding to the level of exposure to enable a full risk assessment. The EFSA Panel also concluded that benzophenone was not genotoxic but caused kidney adenoma, including hyperplasia and nephropathy in rats at the lowest dose level tested of 15 mg/kg bw/day in a carcinogenicity study, and established a Tolerable Daily Intake (TDI) of 0.03 mg/kg bw/day, equating to 1.5 mg/day for a 50 kg person). The TDI is in the same order of magnitude as the chronic dietary exposure of adults and children to benzophenone in Europe (i.e. 10-20 µg/kg bw/day) for added flavouring substances. The toxicity of benzophenone was re-evaluated by EFSA in 2017 (EFSA, 2017) and the TDI established by EFSA in 2009 was re-confirmed.

In 2018, the US FDA amended its food additive regulations to no longer allow the use of benzophenone (and other substances) in food. However, the FDA stated that this removal was only a matter of law, and concluded that these substances do not pose a risk to public health under the conditions of their intended use. As of late 2020, its use in food products or food packaging was banned in the US. Under California Proposition 65, there are no legal provisions for safe levels of benzophenone in any personal care products, including sunscreens, anti-aging creams, and moisturisers.

The current USP monograph for octocrylene has general organic impurity limits, however benzophenone is not a specific impurity mentioned or considered. The impurity limits for octocrylene are based on data submitted before the monograph became official. The USP monograph can potentially be revised if new information becomes available however is subject to consideration by USP's Expert Volunteers, noting the monograph only applies to quality limits on the raw material – not safety limits when octocrylene is used in sunscreen products.

The Health Canada Natural Health Product Ingredients Database has a TDI for benzophenone of 0.03 mg/kg bw/day when the route of administration is oral for medical use, or up to 3.27 ppm for oral non-medicinal use as a flavour enhancer. In January 2021, Health Canada undertook a Screening Assessment for benzophenone to determine whether it presents a risk to the environment or to human health. Although benzophenone was found to be non-genotoxic, chronic oral exposure to benzophenone induced kidney adenoma and leukemia in male rats, liver tumours in male and possibly female mice, and histiocytic sarcomas in female mice. The assessment also indicated that dermal studies on the carcinogenicity of benzophenone performed on mice and small groups of rabbits showed no carcinogenic potential. However, the assessment could not verify the quality of the studies given the limited information provided in the published reports, and the extent of the histological examinations appears to have been limited. The Health Canada assessment concluded that benzophenone meets the human health criterion for a toxic substance and, subsequently, proposed to make an Order to add benzophenone as a toxic substance to Schedule 1 of the Canadian Environmental Protection Act (the List of Toxic Substances) in April 2022.

Literature search summary

Human studies

No epidemiology studies related to benzophenone exposure in humans were found in the literature.

Animal studies

Percutaneous absorption

The percutaneous absorption of benzophenone was measured *in vivo* in monkey. [^{14}C]-benzophenone was applied to 1 cm^2 area of abdominal skin at a concentration of 4 µg/cm^2. In rhesus monkeys, percutaneous absorption of benzophenone was found to be 44% and 69% for unoccluded and occluded sites, respectively (Bronaugh et al., 1990).

A more recent study determined the in *vitro* dermal absorption of radiolabelled benzophenone in different preparation through human skin. [^{14}C]-benzophenone was added to two commercial sunscreen formulations and an acetone vehicle. Each preparation (containing 0.1 g/L benzophenone) was applied (approximately 2 µL/cm^2) to dermatomed human skin mounted in static diffusion cells, and the receptor fluid was collected up top 24 hours following application. All samples were analysed by liquid scintillation counting. The authors note that the study was compliant with Good Laboratory Practice, with OECD Test Guideline No. 428 and OECD Guidance Document No. 28. The results indicated that after 24 hours, the amount of benzophenone in the two spiked sunscreen formulation that was absorbed was (mean±SD) 9.04 ± 2.61% and 10.02 ± 2.40%, respectively. The absorption of benzophenone in the acetone vehicle through human skin was documented as 5.19% of the applied dose. The [^{14}C]-benzophenone mass balances were considered low: 81.5%, 85.3% and 8.02%, respectively, with losses due to [^{14}C]-benzophenone volatility (Ejaz et al, 2024).

A dermal absorption value of the mean percent plus one standard deviation was calculated for the calculation of the maximum concentration of benzophenone in therapeutic sunscreen products. Using the highest dermal absorption value from the second spiked sunscreen preparation, a dermal absorption value of 10.02% + 2.4% = 12.42% was determined (Ejaz et al, 2024).

Acute toxicity

The median lethal (LD_{50}) doses of benzophenone given by oral, intraperitoneal, and dermal routes of administration were calculated and the result suggested that benzophenone is only slightly toxic.

The LD_{50} in an acute rat oral study was 1,900 mg/kg/day. The LD_{50} in an acute mice oral study was 2,895 mg/kg/day. The LD_{50} in an acute i.p. mice study was 727 mg/kg/day and the LD_{50} in an acute rabbit dermal was 3,535 mg/kg/day (National Toxicology Program, 2006).

Sub chronic and chronic feeding studies

There are sub-chronic and chronic feeding studies and a 2-generation reproductive gavage study of benzophenone in rodents. There are extensive mutagenicity and endocrine activity data for benzophenone. Long-term studies of toxicity and carcinogenicity were published on benzophenone.

In a sub-chronic feeding study, benzophenone was administered in the diet to both male and female Sprague-Dawley (SD) rats at 0, 20, 100 and 500 mg/kg bw/day. The low-dose group was treated for 13 weeks, while the mid- and high-dose groups were treated for 28 days (Burdock et al. 1991). Treatment-related changes, including altered haematological and clinical biochemistry endpoints, increased liver and kidney weights, and increased hepatocellular hypertrophy, occurred in both sexes of rats at mid- and high-dose levels. A No-Observed-Adverse-Effect Level (NOAEL) of 20 mg/kg bw/day was derived from this study (Burdock et al, 1991; ECHA, 2018).

In the reproductive study benzophenone caused liver hypertrophy in the rats at the lowest dose level (~6 mg/kg/day), but it was considered an adaptative response and not an adverse event (EFSA, 2017).

The one long-term study of toxicity and carcinogenicity will be analysed below (Carcinogenicity of Benzophenone).

Mutagenicity of Benzophenone

Benzophenone showed no evidence of mutagenicity *in vitro* or *in vivo*. Benzophenone (1 to 1,000 µg/plate) did not induce mutations in *Salmonella typhimurium* strains TA98, TA100, TA1535, or TA1537, with or without induced rat liver metabolic activation enzymes. Intraperitoneal injections of 200 to 500 mg benzophenone/kg body weight (three injections at 24-hour intervals) did not induce micronuclei in bone marrow PCEs of male B6C3F mice.

No increases in the frequencies of micronucleated NCEs were seen in peripheral blood of male or female B6C3F1 mice administered benzophenone for 14 weeks (1,250 to 20,000 ppm) (EFSA, 2017).

Carcinogenicity of Benzophenone

In 2006 The National Toxicology Program (NTP, 2006) studied the effects of benzophenone on male and female F344/N rats and B6C3F1 mice to identify potential toxic or carcinogenic hazards to humans. Groups of 50 mice (male and female) were fed benzophenone for 2 years at 40, 80 and 160 mg/kg bw per day in males and 35, 70 and 150 mg/kg bw per day in females. The higher concentration at 160 mg/kg bw, was based on the minimum toxicity observed at this level in a previous 14-week study). The corresponding doses in rats were 15, 30 and 60 mg/kg bw per day in males and 15, 30 and 65 mg/kg bw per day in females.

The target organs of toxicity in the 2-year studies were liver, kidney, nose, and testes. Neoplastic responses occurred in the kidney, liver, and hematopoietic system. The conclusion of the panel of NTP was:

- ‘Administration of benzophenone in feed resulted in increased incidences and/or severities of nonneoplastic lesions in the kidney and liver of male and female rats and in the liver, kidney, nose, and spleen of male and female mice’.

- 'There was some evidence of carcinogenic activity of benzophenone in male rats based on increased incidences of renal tubule adenoma; mononuclear cell leukemia in male rats may have been related to benzophenone exposure.'
- 'There was equivocal evidence of carcinogenic activity of benzophenone in female rats based on the marginally increased incidences of mononuclear cell leukemia and histiocytic sarcoma.'
- 'There was some evidence of carcinogenic activity of benzophenone in male B6C3F1 mice based on increased incidences of hepatocellular neoplasms, primarily adenoma.'
- 'There was some evidence of carcinogenic activity of benzophenone in female B6C3F1 mice based on increased incidences of histiocytic sarcoma; the incidences of hepatocellular adenoma in female B6C3F1 mice may have been related to benzophenone exposure.'
- The incidences of hepatocellular adenoma in the male mice showed a positive trend. No NOAEL could be identified for incidences of adenoma (the low dose of 40 mg/kg/day is the LOAEL with regard to this change).
- In rats, no NOAEL could be identified for incidence of renal tubule hyperplasia in males and females and the low dose corresponding to 15 mg/kg/day was considered a LOAEL. No NOAEL could be identified in relation to chronic progressive nephropathy for its severity in male rats and the LOAEL was the low-dose (15 mg/kg/day). In female rats the NOAEL for the severity of chronic nephropathy was the low dose.

In summary, in 2-year studies in rats and mice administered benzophenone in the feed, neoplastic responses were reported in kidney, liver and haematopoietic system. Species- and sex-specific differences in effects were observed. Effects were seen in all dose groups and no NOAEL was identified.***Table*** 1 below shows a summary of the 2-year carcinogenic study in rodents.

Table 1 Summary of the 2-year carcinogenesis and genetic toxicology studies of benzophenone

Text	Male F344/N Rats	Female F344/N Rats	Male $B6C3F_1$ Mice	Female $B6C3F_1$ Mice
Decreased incidences	None	Mammary gland: Fibroadenoma (27/50, 24/50, 15/50, 7/50)	None	None
Level of evidence of carcinogenic activity	Some evidence	Equivocal evidence	Some evidence	Some evidence
Genetic toxicology				
Salmonella typhimurium gene mutations:	Negative in strains TA98, TA100, TA1535 and TA1537 with and without S9			
Micronucleated erythrocytes:				
Mouse bone marrow *in vivo*	Negative			
Mouse peripheral blood *in vivo*	Negative			

The potential for dermal carcinogenicity has also been studied (Stenbäck and Shubik, 1974 as reported by ECHA). Treated groups of female Swiss mice received (on 1-inch square of the dorsal skin between the flanks, which was shaved regularly) concentrations of 5, 25, and 50%

benzophenone in acetone in a total volume of 0.2 ml, twice a week for a period of up to 110 weeks (the number of animals in the test groups, in the vehicle and positive control groups was 50/group, and additional untreated control group consisted of 150 animals). Although there is a lack of data on the vehicle control, and this study was conducted in 1974 (and not according to GLP/OECD guidelines), no significant difference in dermal carcinogenic effects was observed between control groups and treated groups in this study.

The potential carcinogenicity of benzophenone was also evaluated by several Regulatory Agencies and Expert Panels and the conclusions were similar to the conclusions reached by the NTP:

- The International Agency for Research on Cancer (IARC, 2012) evaluated the carcinogenic risk of several chemical present in industrial and consumer products, foods and drinking-water, including benzophenone and the conclusion was that 'benzophenone is possibly carcinogenic to humans' and it was classified in group 2B (which means that there is strong evidence that it can cause cancer in humans, but at present it is not conclusive).
- In 2009 benzophenone was evaluated as a food contact material by the European Food Safety Authority, and it was re-evaluated in 2017. The Panel concluded that benzophenone caused kidney adenoma, including hyperplasia and nephropathy in rats. Based on an NTP study (2006), the Panel established a Tolerable daily intake (TDI) of 0.03 mg/kg bw per day. The TDI is in the same order of magnitude as the chronic dietary exposure of adults and children to benzophenone in Europe (10–20 µg/kg bw per day) for added flavouring substances.

The Joint Expert Committee of Food Additives (JECFA, 2011) noted that histiocytic sarcomas occurred only in female mice and rats and only at dose levels inducing toxicity and possibly affecting hormonal balance. A NOAEL was not identified. The sex specificity of renal pathology in rats was suggested by JECFA to be due to differences in renal clearance of metabolites and more severe ageing chronic nephropathy in males compared to females, possibly due to higher concentration of proteins, primarily α-2µ-globulin, in male rats. A conclusion from JECFA was that the increasing severity of ageing chronic nephropathy is largely responsible for the renal tubular proliferation in male rats in most strains, including F344/N, and that this mode of action is not relevant to human renal carcinogenesis.

Calculation of maximum allowable concentration

The maximum allowable concentration of benzophenone, in general therapeutic sunscreens, was established based on the:

- Permitted Daily Exposure (PDE),
- Amount of sunscreen applied (daily), and
- Dermal absorption

As per **Equation 2**.

A PDE amount was calculated for benzophenone, using **Equation 1**, to account for risks posed to the whole population, including the most vulnerable group (toddlers aged 1-2 years).

The NOAEL obtained in different studies ranged from 20 mg/kg to 300 mg/kg. In some of the studies it was not possible to obtain a NOAEL or LOAEL. The lower NOAEL of 20 mg/kg/day was obtained in a 13-week oral study in rats (Burdock et al, 1991; ECHA, 2018) and was used to calculate the maximum allowable concentration of benzophenone.

Equation 1*: Formula to calculate the PDE

$$PDE = \frac{NOAEL \times \ body\ weight}{F1 \times F2 \times F3 \times F4 \times F5}$$

$$PDE = \frac{20\ mg/kg\ bw/day \times 50\ kg}{5 \times 10 \times 5 \times 2.5 \times 1}$$

$$PDE = 1.6\ mg/day$$

$$PDE = 0.032\ mg/kg\ bw/day$$

*Equation 1 is based on the method described in Appendix 3 of the ICH Guideline Q3C (R8) on impurities; guideline for residual solvents (EMA/CPMP/ICH/82260/2006[1]. Modifying factors of **5** (F1) for interspecies variability, **10** (F2) for variability between individuals, **5** (F3) for the short-term study (~3 months) to obtain the NOAEL of 20 mg/kg/day in rats, **2.5** (F4) for the possibility of non-genotoxic carcinogenic effects, and **1** (F5) if a no-effect level was not established, are used in the calculation. As per ICH Q3C (R8), an adult body weight of 50 kg is used in this calculation.

ASEM established the highest average daily sunscreen exposure value, which was used in **Equation *2*** to calculate the maximum allowable benzophenone concentration in general therapeutic sunscreens. The value for the dermal absorption 12.42% was selected from a recently published paper (Ejaz et al, 2024).

Equation 2: Formula to calculate maximum allowable benzophenone concentration

$$Benzophenone\ conc\ = \frac{PDE\ (mg/kg\ kg/day)}{Amount\ of\ applied\ sunscreen\ (mg/kg\ bw/day) \times DA\ (\%)}$$

$$= \frac{0.032\ mg/kg\ bw/day}{673\ mg/kg\ bw/day \times 12.42\ \%}$$

$$= \ 0.000383$$

Converting to a percentage or ppm

$$= 0.0383\ \%$$

$$= \mathbf{383\ ppm}$$

[1]ICH Guideline Q3C (R8) on impurities; guideline for residual solvents (EMA/CPMP/ICH/82260/2006) https://www.tga.gov.au/sites/default/files/2024-07/International-Scientific-Guideline-ICH-guideline-Q3C-R8-impurities-guideline-residual-solvents-adopted.PDF

Recommendation

To mitigate the risk from chronic exposure to benzophenone it is recommended that the Poisons Standard be amended to include a new entry for benzophenone, and:

- benzophenone is limited to a maximum concentration of 383 ppm as a potential degradant in therapeutic sunscreen containing octocrylene.
- benzophenone is not permitted to be added as a fragrance, as a precautionary approach, noting the EU has also prohibited the inclusion of benzophenone as an ingredient in cosmetic products.

When proposing risk management strategies, consideration should be given to the following:

- The safety review concluded that the maximum allowable benzophenone concentration in therapeutic sunscreens should not exceed 383 ppm (0.0383%).
- The 383 ppm concentration has been calculated for exposure from therapeutic sunscreen only. This value does not include benzophenone from other sources like cosmetics or fragrances in therapeutic or non-therapeutic goods. Because octocrylene is a common active ingredient used as a UV filter in therapeutic and cosmetic sunscreens and as a photo-stabiliser in other cosmetics, consumers might use multiple products, or a product could contain both octocrylene and benzophenone with the latter acting specifically as a fragrance. Consideration should be given to potential exposure different consumer products.
- Restrictions should ensure allowable limits of benzophenone as an impurity or degradation product are required to be maintained until the end of shelf life, not at release for supply of a product.
- The conditions under which octocrylene is more likely to degrade into benzophenone, such as excessive temperatures, and whether products have appropriate labelling for storage conditions e.g. therapeutic sunscreens are required to comply with mandatory wording for storage conditions in the Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92).

Conclusion

Skin cancer is a major health issue in Australia. The Australasian College of Dermatologists recommends that daily sun protection should be used in Australia, particularly during the spring and summer months, where the UV index is often 3 or higher for nearly the entire day. In addition, the Cancer Council recommends Australians use SPF50 or SPF50+, broad-spectrum, water-resistant sunscreen. Given the widely recognised public health importance of sunscreens, Australians should continue to use sunscreens along with other sun protective behaviours when the UV index is 3 or more. The 5 SunSmart S's - slip, slop, slap, seek, slide are protective measures include seeking shade, wearing a hat, wearing protective clothing and eyewear and using sunscreen. This approach clearly supports the benefits of optimal sunscreen use, benefits which are substantial, and balanced against any theoretical risks.

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