Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Australian Sunscreen Exposure Model

Consultation on an exposure model for assessing the safety of sunscreen ingredients in Australia

Version 1.0, July 2024

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All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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About this consultation

This consultation is about creating a model that more accurately estimates how much sunscreen Australians are exposed to on a regular basis. The model will enable the Therapeutic Goods Administration (TGA) to calculate the safe concentration of ingredients in sunscreens based on Australian conditions and the latest scientific information.

Stakeholders have an opportunity to provide feedback on the best way to estimate sunscreen use in Australia, as well as any positive and negative impacts the proposals may have on businesses, professionals and consumers.

The feedback will be used to help inform the Government's decision on implementing an appropriate proposal.

We invite you to provide your feedback by answering the questions in this consultation paper at the TGA consultation hub by 13 August 2024.

If you have questions about the proposals or this consultation, please email: sunscreen.consultation@health.gov.au

Glossary

Abbreviation	Explanation
ABS	Australian Bureau of Statistics
AICIS	Australian Industrial Chemicals Introduction Scheme
ARGS	Australian Regulatory Guidelines for Sunscreens
ARNS	Application Requirements for New Substances in listed medicines
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARTG	Australian Register of Therapeutic Goods
ASEM	Australian Sunscreen Exposure Model
BoM	Bureau of Meteorology
MoS	Margin of Safety
NOAEL	No Observed Adverse Effect Level
PoD	Point of Departure
SCCNFP	Scientific Committee on Cosmetic and Non-Food Products intended for Consumers
SCCS	Scientific Committee on Consumer Safety
SED	Systemic Exposure Dose
SPF	Sun Protection Factor
SSA	Skin Surface Area
Sunscreen Standard	Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:2021 Amd 1:2022
TGA	Therapeutic Goods Administration
Therapeutic sunscreen	Primary and some secondary sunscreens regulated under the *Therapeutic Goods Act 1989* (see Attachment 1)
UF	Uncertainty Factor
UV	Ultraviolet

Introduction

The Therapeutic Goods Administration (TGA) regulates therapeutic sunscreens that protect Australians against the sun's harmful Ultra-Violet (UV) radiation. UV radiation is a major health concern linked to approximately 95% of melanoma cases in the country (Cancer Australia 2019).

Exposure to UV radiation is a significant risk factor and is known to cause skin cancer in humans (IARC 1992). Preventative UV radiation exposure measures, such as using sunscreens, are an effective strategy against developing skin cancer (Green et al. 2011; Olsen et al. 2015). Despite being the last recommended line of defence after other protective measures, such as seeking shade and wearing UV protective clothing, sunscreens are one of the most common methods of sun protection (Stanton et al. 2004) and suggested to be a cost-effective method for preventing skin cancer (Gordon et al. 2009; Gordon et al. 2020).

While Australians widely use sunscreen, individual application varies based on factors such as daily habits, occupational exposure and recreational activities. Australians are increasingly aware of sun safety and are using sun protection measures (Cancer Australia 2019) which may be due to increased promotion and public awareness of their importance and benefits. As such, the way sunscreens were used in the past is likely to differ to how they are used today.

This consultation proposes an Australian Sunscreen Exposure Model which has been developed as a significant advancement for performing sunscreen exposure calculations that reflect the unique conditions and practices in Australia today. It aims to calculate safe levels of new ingredients proposed for use in Australian sunscreens, as well as reassess existing ingredients when new evidence suggests potential risks. Our goal is to ensure the approval of sunscreen ingredients is based on current information and scientific best practice so that sunscreens continue to be used safely and effectively by all Australians as one of the measures to prevent skin cancer.

Why is the TGA consulting on an Australian sunscreen exposure model?

The TGA regulates therapeutic sunscreens by ensuring they are safe, efficacious and of appropriate quality. Before a sunscreen product can be marketed and supplied to consumers in Australia, the TGA must have approved its ingredients and their maximum safe concentration. Sponsors (who are product owners or manufacturers) are legally bound to adhere to these TGA-mandated concentration limits. See Attachment 1 for a detailed explanation of the regulation of therapeutic sunscreens.

Risk assessments for sunscreen ingredients typically focus on long-term exposure to the ingredient, but they also address acute safety concerns like potential skin irritation. The risks associated with use of ingredients are characterised by calculating the Margin of Safety (MoS), which compares the associated (health) hazards to the expected systemic (or internal) exposure of the ingredient. The MoS calculation helps ascertain the maximum safe concentration of an ingredient. The internal exposure dose is referred to as the Systemic Exposure Dose or 'SED', which is the amount of an ingredient absorbed through the skin into the systemic circulation.

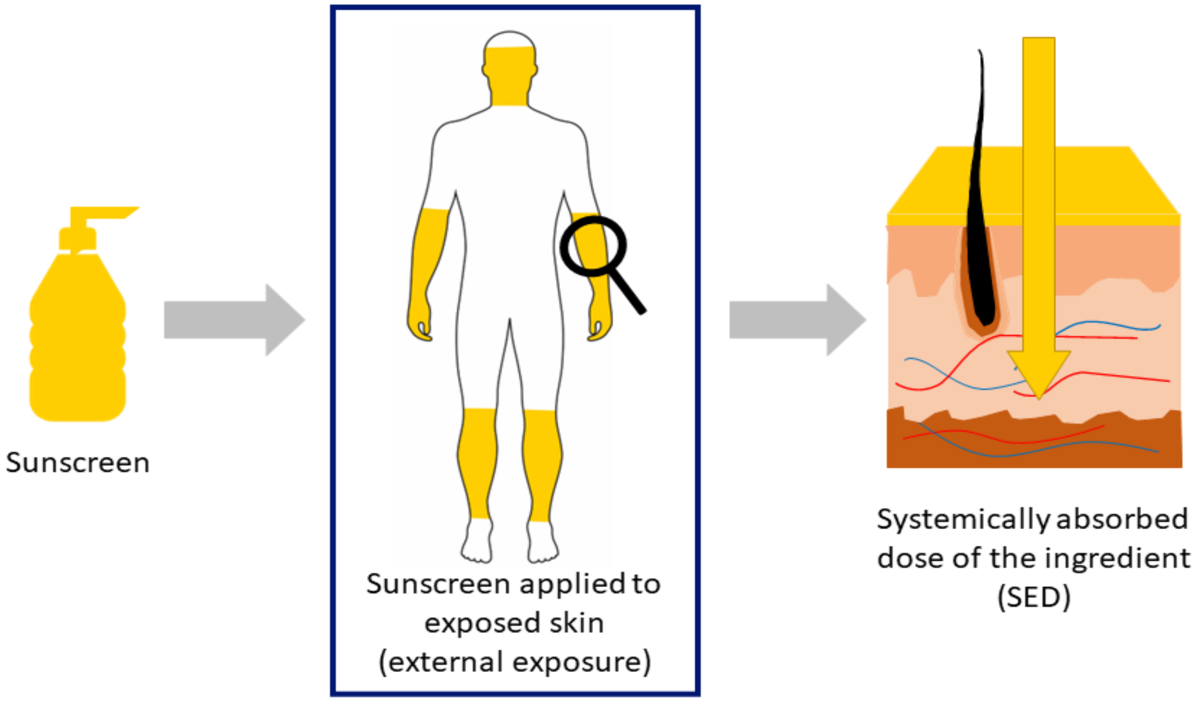
For more information about how sunscreen ingredients are approved, see Attachment 2.

Determining the SED is based on how much sunscreen is applied to the skin on a daily basis (i.e. the external exposure dose), which is variable and difficult to estimate as sunscreen usage varies greatly among individuals. **Figure 1** describes the relationship between the external exposure and systemic exposure. Actual use may not always align with recommendations for how sunscreens are to be used effectively. Moreover, different methods for calculating the external exposure component may not fully capture Australian usage patterns.

Therefore, a standardised, evidence-based approach is proposed to calculate the external exposure of a sunscreen, that takes into account the diverse ways Australians use sunscreen and ensures a realistic and safe framework for ingredient evaluation.

> This consultation addresses the challenges of determining the amount of sunscreen that could be applied to the skin (**external exposure; see Figure 1**), which in turn informs the SED and MoS calculation for sunscreen ingredients used in Australia, and presents 3 options for estimating this.
>
> For ingredients that neither absorb through the skin nor pose a risk of systemic exposure, an exposure model is not necessary since there is no SED to measure.

Figure 1: The relationship between sunscreen applied externally to skin and systemic exposure



Different approaches can be used for sunscreen ingredient risk assessments

Risk assessments for sunscreen ingredient safety that may end up being absorbed into the body, can employ various methodologies to calculate the amount of sunscreen applied to the skin. Some of these assessments may be excessively conservative or fail to consider the unique Australian context. Historically, risk assessments and approvals of ingredients by the TGA have been conducted on a case-by-case basis, with regulatory guidelines evolving over time. These assessments consider the general toxicological profile and intended use of the ingredient. The assessments have primarily relied on data provided by the applicant, along with considerations of precedents set by international regulatory bodies. The variance in exposure calculation methods can result in regulatory inconsistencies and uncertainties for applicants seeking to introduce new ingredients to the market.

A number of new sunscreen ingredient applications have utilised exposure models from the European Commission's Scientific Committee on Consumer Safety (SCCS) or the then Scientific Committee on Cosmetic and Non-Food Products intended for Consumers (SCCNFP). The current SCCS models are based on European and other country usage patterns and do not account for Australian use patterns or the amount of sunscreen application required to achieve the labelled Sun Protection Factor (SPF)[1] rating. While the SCCS uses a 60 kg bodyweight estimate in their calculations, the TGA has historically used a more conservative bodyweight estimate of 50 kg in some assessments. Further, the SCCS method shows a substantial disparity in the risk assessment calculations depending on whether data for dermal absorption of an ingredient is reported in μg/cm² or as a percentage (see Attachment 3 for example calculations for octocrylene).

Other assessments have adopted a higher exposure using a sunscreen application rate of 2 mg/cm^2 than the SCCS approach which is based on studies that observed varying rates ranging from 0.5-1.3 mg/cm^2 (p 85, SCCS 2021). Other approaches have been based on the Cancer Council Australia's guidelines of reapplying sunscreen every 2 hours for a full-body application of 35 mL for a full day. The type of information that is presented by the applicant can also contribute to inconsistent assessments.

A standardised, evidence-based approach is essential for regulatory certainty and to ensure that sunscreens are safe, effective, and reflective of actual usage patterns in Australia, rather than relying on different approaches or international assessment models. This will provide a consistent framework for evaluating the safety of therapeutic sunscreen ingredients, aligning with Australian conditions and consumer practices.

[1] The SPF is the level of protection a sunscreen offers against sunburn. It relates to the amount of time it takes for redness to appear on the skin compared to when no sunscreen is applied.

Quantifying sunscreen use (exposure) is complex

The Australian context

Australia's unique environmental and lifestyle factors underscore the need for a tailored approach to therapeutic sunscreen regulation. This is because Australia has the highest incidence of melanoma and non-melanoma skin cancer globally (Ferlay et al. 2020), a depleted ozone layer (DCCEW 2022), and a vast coastline and sunny climate that promotes a culture of outdoor activities. This is why sunscreens that protect the skin from UV radiation are integral to public health and regulated as therapeutic goods with stricter standards than in some international jurisdictions where they are deemed cosmetics. The Australian Government's commitment to reducing skin cancer's impact is evident in its longstanding investment in research and public health campaigns such as the National Skin Cancer Prevention Campaign to educate Australians on proper sunscreen use. An Australian-specific regulatory assessment model can account for these distinctive factors that ensure sunscreen regulatory requirements are appropriately tailored to the Australian context and lifestyle.

What evidence is available about sunscreen use in Australia

Daily use of sunscreen has been proven to be effective in reducing the incidence of skin cancers and protecting humans from premature skin aging (Green et al. 2011). However, definitive information on the use of sunscreens in Australia is lacking. There is some general information on sunscreen usage and application rates based upon observational studies that demonstrate users do not apply sufficient sunscreen but there is minimal robust and contemporary data on its use across the country that would aid risk assessments.

Sunscreen use varies among individuals. How much sunscreen is applied to the skin and how often will vary based on: habits, climate where you live, time spent outside vs indoors (due to occupation or recreation), cost of sunscreens, socioeconomic factors, organisational policies (such as for childcare, school or work), perception of skin cancer risk, susceptibility to sunburn and whether sunscreen is available when needed. This makes it difficult to estimate an exposure amount that covers all different situations for the Australian population that can be used for risk assessments.

The intent of this consultation relates to assessing the risk, and consequently the acceptable safety, of therapeutic sunscreen ingredients, and thus, the TGA is seeking information about sunscreen usage patterns to inform the model for these risk assessments (not efficacy).

The TGA identified the following data gaps pertaining to sunscreen use:

- the frequency of sunscreen usage, including daily reapplication
- the parts of the body that people apply sunscreen to
- the quantity of sunscreen used per application or body part
- differences in use depending on gender, body size, occupational and recreational needs
- differences in patterns of use depending on where you are in the country, the season, and the socio-economic status of the household and/or community
- what sunscreen products are used across the population.

The following information has been identified regarding Australian sunscreen use. While this provides some insight, it does not address all the identified gaps listed above.

Sunscreen use by the general population

National Sun Protection Surveys conducted by Cancer Council Australia captures Australian adults' and adolescents' sun protection behaviours on summer weekends in 2003-2017. Consistently over the years surveys were conducted, more than 40% of adults and more than 25% of adolescents used 2 or more sun protection methods, such as sunscreen (Cancer Australia 2019)[2]. However, the percentage of people who use sunscreen as one of the sun protection methods was not reported in these surveys.

[2] See Table 3 and 4 under the 'About the data' tab.

The most recent representative survey prepared for Cancer Council Australia of Australian adolescents' and adults' sun protection behaviours in 2016-17 found that on a summer weekend the most common sun protective behaviour used by adolescents was using sunscreen with an SPF of at least 15 (40%) and the most common sun protective behaviours among adults were wearing sunglasses (61%), wearing a hat (49%), and using sunscreen with SPF 15 or higher (42%) (Tabbakh and Dobbinson 2018).

A survey conducted by Cancer Council Victoria of Melbourne residents' sun-related attitudes and behaviour over 3 decades, between 1987 and 2017, shows a significant and sustained improvement in sun protection behaviour, including increased sunscreen use, after the implementation of the SunSmart program. The timing and size of the shift in preventive behaviours implies that Cancer Council Victoria's SunSmart campaign is likely to have contributed to the reduced incidence in melanoma among younger cohorts (Tabbakh et al. 2019). Conversely, a systematic review exploring the use of sun-protection by outdoor sporting participants in Australasia concluded that adequate sun-protective behaviours are lacking despite 40 years of 'Slip Slop Slap' health promotion (Morton et al. 2023).

A study of adults who participated in a skin cancer prevention trial between 1992 and 1996, found that 56% of the eligible participants applied sunscreen at least 5 days per week, although 27% used sunscreen infrequently at 2 or fewer days per week (Neale et al. 2002). Almost 50% of the participants who reported less than daily sunscreen use stated that they did not think sunscreen application was necessary given the weather conditions or their planned activities. Of these respondents, 45% reported that they generally spent almost no time outdoors during the day.

A survey conducted on 670 beachgoers in the Newcastle district found that sunscreen was the most frequently used form of sun protection (Foot et al. 1993). Among the participants, 82% applied sunscreen to at least one body area. Among these participants, 69% had applied sunscreen with an SPF value higher than 15. The authors also reported that children under the age of 15 years were more likely to have used sunscreen compared to the older age groups.

Queensland preventive health telephone surveys (QPHS 2023) conducted by Queensland Health captured summer sun protection habits of 12,500 adults and the parents of 2,500 children aged 5 through 17 years. Based on the '*Sunburn and protection*' data reported in the Queensland Survey Analytic System[3], just over 20% of adults were using, presumably, combined sun protection methods of '*broad brimmed hat, SPF 30+* [sunscreen], *clothing*' in summer between 2010 and 2020. However, the percentage of adults using sunscreen as one of the sun protection methods was not reported.

The Cancer Council Australia has advised that recent research suggests men are less likely than women to use sun protection (Cancer Council Australia 2022). Almost half (47%) of men reported they often or always spent time outdoors during peak UV radiation hours during summer. Less than one third (29%) of men reported using sunscreen (broad-spectrum with SPF 30 or higher) often or always during peak UV radiation hours during summer. Less than half (49%) of men reported often or always seeking shade to protect themselves from the sun during peak UV radiation hours during summer. More than half of respondents (55%) reported being sunburnt at least once during the summer, with the most common activity being during a walk, jog or run (15%).

Sunscreen use in children

A multi-year survey reported child-related sun protection practices from 2008, 2013 and 2018, covering 3,243 early-childhood services (i.e. childcare and/or pre-education services for infants and children aged ≤5 years) across Australia (Hunkin and Morris 2020). The authors reported significant increases over the last decade in the proportion of services requiring the use of sun-protective hats, sunscreen and protective clothing, as well as those services supplying sunscreen (98.4% of the services required the use of sunscreen in 2018). The proportion of services applying sunscreen to children 15-20 minutes before going outside and re-applying sunscreen every 2 hours while outdoors also significantly increased (in 2018, 68.3% of services required sunscreen to be applied regularly, every 2 hours if outdoors). It is noted that the percentage of services that required children to wear

[3] QPHS survey result can be visualised in Queensland survey analytic system (QSAS)

sun-protective clothing outside significantly increased from 68% (2008) to 88.8% (2018); however, the percentage of services requiring children to wear long sleeves significantly decreased from 45.1% (2008) to 17.9% (2018). The percentage of services requiring children to wear longer shorts/skirts remained below 30% throughout the survey years. The authors suggested that suboptimal UV radiation protection can result from incorrect sunscreen application in terms of amount used, time of application (relative to sun exposure) and reapplication, and therefore, appropriate sunscreen application techniques are an important target for future promotion efforts.

The unpublished report[4] of 1,189 Australian early childhood centres surveyed in the 2018 National Early Childhood Sun Protection Policy and Practice Survey (Cancer Council SA 2018), which was the most recent survey data analysed by Hunkin and Morris (2020), reported further information on sunscreen use practices in early childhood centres. The report indicated a trend in increasing sunscreen practices in children. In 2018 most services required children wear sunscreen all year, and more services applied sunscreen more frequently throughout the day, and required sunscreen when the UV index was 3 or more, rather than only part of the year. The data showed that in 2018, 49% of services across Australia applied sunscreen to children twice a day, 26% 3 times a day, and 11% more than 3 times. Western Australia had higher rates, with 40% of centres applying sunscreen 3 times daily and 20% more than 3 times. Between 2008 and 2018, there was a significant increase in the number of services providing sunscreen for children, promoting self-application, and encouraging application by parents or caregivers. There was also a rise in the practice of applying sunscreen 15-20 minutes before outdoor activities, assigning staff the responsibility of applying sunscreen to children, and regularly reapplying sunscreen. Conversely, there was a decline in the number of services that encouraged parents to provide sunscreen for their children. Moreover, over 99% of services enforced hat wearing for children and 98% for staff members. Most services followed a policy of taking infants (under 12 months) outdoors only in shaded areas (71%), while 22% limited the duration of outdoor time for this age group. The use of UV levels as a criterion for implementing sun protection measures during certain times of the year increased to 61% in 2018, up from 35% in 2008. These findings underscore the evolving practices in early childhood centres to enhance sun protection for children, reflecting a growing awareness and implementation of recommended sunscreen use.

In a survey conducted for 187 childcare services in the Hunter region, 150 centres (87%) reported that centre policy required children to wear hats, and 122 (71%) required sunscreen be applied to children before outdoor play (Parkinson et al. 2003). However, the self-reported sun protection practices were lower, and 36% of children wore a hat and 57% applied sunscreen before outdoor play.

The Queensland QPHS survey conducted in 2020 found 74.9% of children aged 5-7 frequently use sunscreens with SPF 30+ (Queensland Government 2023).[5] This percentage gradually decreases with increasing age, as 49.3% of children aged 16-17 frequently use sunscreens. Remoteness and socioeconomic status also impact sunscreen use. Children from remote areas or from disadvantaged socioeconomic backgrounds are less likely to use sunscreen frequently. The survey also found that 16% of children apply sunscreen as part of the morning routine.[6]

A study conducted with children aged 5-12 years in Queensland found that children in the youngest school grades (1 and 2) applied significantly more sunscreen than the older children (Diaz et al. 2012). The authors recommended that educational interventions may help to improve sunscreen application thickness to maximise the protection received from sunscreen. The authors also commented that sunscreen is often the only form of sun protection used by children, therefore, children may be less well protected from the sun than parents might expect.

A survey conducted with 3,655 Queensland students (in grades 7, 9 and 11) reported that negative views of sun protection measures were associated with poorer sun protective behaviour; this association was strongest among older students and in larger schools (Balanda et al. 1999). Similarly, lower perceived parental sun protective behaviour was associated with poorer sun protective behaviours and older students had poorer sun protective behaviours than younger students.

[4] Report provided to the TGA by the Cancer Council SA.

[5] 'Prevalence table' tab of Figure 3: Characteristics of sunburn and sun safety of Queensland children

[6] 'Introduction' tab of Figure 3: Characteristics of sunburn and sun safety of Queensland children

Sunscreen use by outdoor workers

An unpublished independent report commissioned by Safe Work Australia[7] conducted between January and July 2008 that comprised 4,500 telephone interviews with indoor and outdoor workers in all Australian industries, investigated the exposure to direct sunlight and the control measures provided in workplaces relating to direct sunlight exposure. Workers in northern states (QLD, NT, WA) exhibiting a 37% higher probability of high-level exposure to direct sunlight compared to southern states (NSW, ACT, SA, VIC, TAS). Male workers were 2.9 times more likely to be exposed than female workers. The disparity was more pronounced within industry sectors, with outdoor workers facing considerably higher exposure odds, being 18 times greater in agriculture, forestry, and fishing, and 8.8 times greater in construction, relative to manufacturing. The average daily exposure duration exceeded 4 hours for outdoor workers, with those in agriculture and construction experiencing upwards of 5.5 hours. Most common forms of protection were sunscreen, hats, or protective clothing. Sunscreen was reported to be provided by over half of the workers in most industries. The likelihood of sunscreen provision was 1.7 times higher in agriculture, forestry, and fishing (69% of workers provided with sunscreen), 2.4 times higher in construction (75**%**), and 6.2 times higher in government administration and defence (91%) compared to manufacturing (58%). Protective clothing followed a similar trend, with 1.9 times higher provision in construction (76% of workers provided with protective clothing) and 4.1 times higher in government administration and defence (87%) compared to manufacturing. Notably, despite the high exposure risk in agriculture, forestry, and fishing, only 68% of workers reported receiving protective clothing. The report concluded that there is limited evidence that workers exposed to longer durations of UV radiation are more likely to have access to protective controls than workers with a low level of exposure.

Another study by Girgis and colleagues investigated 184 outdoor workers' sun protection behaviour when outdoors between 11 am and 3 pm when there was no rain (Girgis et al. 1994). A body region was considered to be adequately protected if it was fully covered by clothing/hat or shaded at the time of the interview, and/or if sunscreen with an SPF 15 or higher had been applied to that region. Participants who had more than 75% of the body protected were classified as having high protection. The authors reported more than 49% participants used high level sun protection; however, the sunscreen use by outdoor workers was not reported.

Application thickness of sunscreens

There is some limited contemporary research indicating that Australians apply, on average, a thickness that was less than the 2 mg/cm^2 sunscreen needed to achieve the labelled SPF rating. The amount of sunscreen used also depends on the formulation and dispenser type, for example roll-on versus pump-pack (Diaz et al. 2012; Neale et al. 2002), and could be influenced by how much the user perceives needs to be applied based on its visual appearance and feel after application. While research indicates an approximate average application thickness between 0.5 mg/cm^2 and 0.99 mg/cm^2 (Diaz et al. 2012; Neale et al. 2002) and Diaz et al. commented that an application thickness of 2 mg/cm^2 in children was infeasible, both studies report that some participants actually applied the correct thickness of 2 mg/cm^2 or more. Further, another Australian study using spectrophotometric analysis estimated an average application thickness of 1.4 mg/cm^2, with some participants also meeting the ideal application rate of 2 mg/cm^2 (Bauer et al. 2010).

[7] Report provided to the TGA by Safe Work Australia

Correct sunscreen application

The level of protection provided by sunscreens, and therefore the ability to reduce the risk of skin cancer, is determined not only by the labelled sun protection factor (SPF)[8] rating but also by the amount of product applied and its conditions of use. As such, it is important they are safe and effective for their intended uses. The effectiveness is significantly reduced by inadequate application, infrequent reapplication, and loss of product due to sweat, swimming, or friction from clothing or towel drying. Most people do not apply enough sunscreen or reapply frequently enough which can result in an SPF that is 20-50% less than what is specified on the product label (Diaz et al. 2012; Stokes and Diffey 1997).

Current evidence-based sunscreen use guidelines

In the 1960s the risks of overexposure to UV radiation were first identified in Australia. Twenty years later, the iconic 'Slip! Slop! Slap!' campaign was launched in 1980 to raise awareness of the dangers of UV, featuring Sid the Seagull. This campaign is credited with playing a key role in changing sun protection attitudes and behaviour in Australia. In 2007, the messaging was updated to 'Slip, Slop, Slap, Seek, Slide', with which many Australians are familiar with.

The Australian Government has delivered a National Skin Cancer Prevention Campaign in partnership with Cancer Council Australia each summer since 2021-22. State and territory governments also fund skin cancer prevention activities, as do a number of non-government organisations. Funding of $15 million has been provided in the May 2024 Budget for a national skin cancer prevention campaign targeting groups most at risk, including men over 40 and young adults with activity to occur over the 2024-26 summers.

As the amount of sun protection is based on the amount of sunscreen applied, there is a concerted effort from government, researchers and other organisations through education and campaigns (such as the Cancer Council Australia's well-known SunSmart program (Cancer Council Australia n.d. - a) to encourage the correct application of sunscreen. For example, leading Australian organisations, including the Cancer Council Australia (2024a), Melanoma Institute Australia (n.d.), Australasian College of Dermatologists (2019), Safe Work Australia (2019), and Surf Life Saving Australia (2006), provide evidence-based recommendations on proper sunscreen usage to ensure effective sun protection. Consumers expect sunscreens to be safe for daily use in Australia (Cancer Council Australia 2017).

The Cancer Council Australia (n.d. - b) recommends adults use a teaspoon for the face, neck and ears; a teaspoon for each arm and leg; and a teaspoon each for the front and back of the body. It is also recommended to reapply every 2 hours or after activities that may remove the product, such as swimming, sweating or towel drying (Cancer Council Queensland n.d.). The Cancer Council Australia does not recommend sunscreen as the only method of protection even if the UV is 3 or above every day of the year and encourage the five forms of sun protection:

- slipping on sun protective clothing
- slopping on SPF 30 or above broad-spectrum water-resistant sunscreen
- slapping on a broad brim hat
- seeking shade when possible
- sliding on sunglasses.

In the 2023 position statement by Australian Skin and Skin Cancer Research Centre (ASSC) aimed at balancing the risks and benefits of sun exposure, it is recommended that sun protection behaviour should be tailored to the individual's risk of skin cancer (ASSC 2023). People who are at high risk of skin cancer (i.e. very pale skin and/or olive/pale brown skin but with other risk factors) are advised to adopt an extremely cautious approach to sun exposure including avoiding time outdoors when the UV index is ≥3. On days when the UV index is forecast to reach ≥3, irrespective of the length of time, sunscreen of at least SPF 30 should be used in the mornings as part of the usual daily routine and

[8] The SPF rating serves as a guide for consumers, indicating the level of protection a sunscreen offers against sunburn. It assists individuals to choose a product that aligns with their skin's sensitivity and expected sun exposure.

applied to all parts of the body not covered by clothing. Sun protection should also be used if these people planned to spend >2 hours (cumulatively across the day) outdoors when the UV index is between 1 and 3, and outdoor workers always use sun protection, irrespective of the UV index (ASSC 2023).

Sunscreen, often viewed as a protective measure for prolonged sun exposure during outdoor activities, but also the last line of UV radiation defence, is equally essential for daily protection against the often-overlooked incidental UV exposure that occurs during everyday tasks such as running errands or commuting. In 2019, an Australian and New Zealand evidence-based consensus statement was published recommending routine sunscreen application for adults and children on body parts not covered by clothing when the UV index is predicted to be 3 or above irrespective of their anticipated activities (Whiteman et al. 2019). This recommendation aims to reduce the incidence of skin cancer by accounting for incidental UV exposure resulting in cumulative skin damage, such as from everyday activities such as shopping, travelling to work, or household chores.

The Australian and New Zealand evidence-based consensus statement on when to apply sunscreen is relevant year-round for parts of Australia where the UV index consistently exceeds 3, such as Darwin, Brisbane, and Perth (**Table 1**) and where the UV index reaches above 3 between 11 am and 1 pm (**Figure 2**). Darwin for instance has a very high average UV index at solar noon above 8 every month of the year; however, the recommendation may not apply to lower latitudes where the sun is lower in the sky such as Kingston in Tasmania during the 4 months it experiences an average UV index below 3 (ARPANSA 2024).

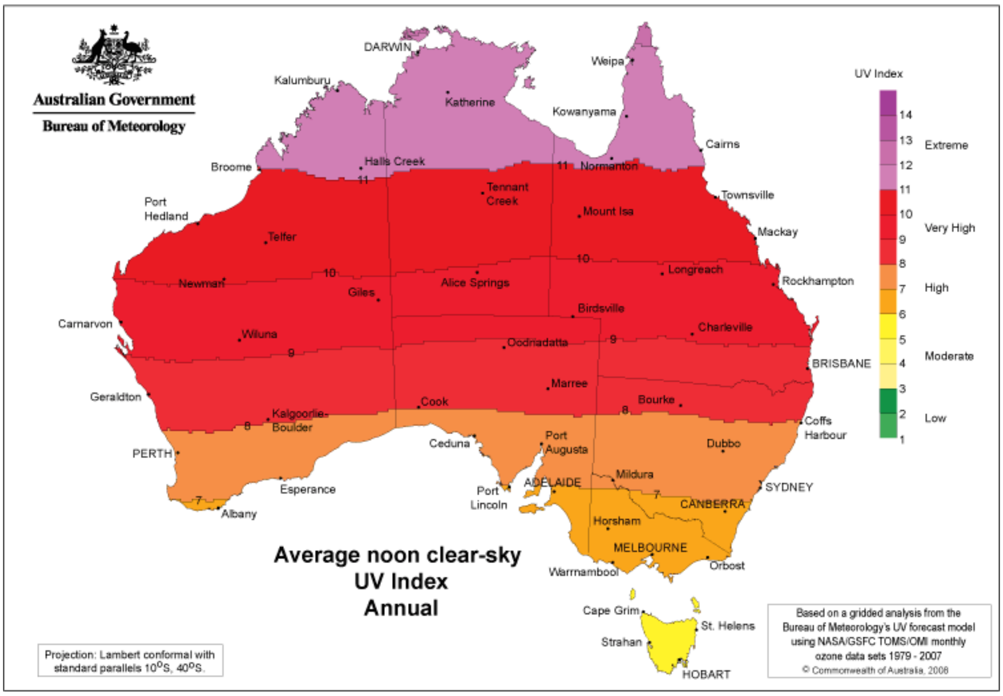
Table 1: Average daily maximum UV index for Australia by month and city, reproduced from Whiteman et al. (2019)

Table 1: Average daily maximum UV index for Australia and New Zealand, by month and city

City	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Australia												
Darwin	12	13	13	11	9	8	9	10	12	13	12	12
Brisbane	12	11	10	7	5	4	4	5	7	9	11	11
Perth	12	11	9	6	4	3	3	4	6	8	10	11
Sydney	11	10	8	5	3	2	3	4	5	7	9	10
Canberra	11	8	7	5	3	2	2	3	5	7	9	11
Adelaide	11	10	8	5	3	2	2	3	5	7	9	11
Melbourne	10	9	7	4	2	2	2	3	4	6	8	10
Hobart	8	7	4	3	1	1	1	2	3	4	6	7
New Zealand												
Auckland	10	8	7	4	2	1	2	2	3	6	8	9
Wellington	9	8	6	3	1	1	1	2	2	5	7	8
Christchurch	8	7	5	2	1	1	1	1	2	4	7	8
Invercargill	7	6	4	2	1	0	0	1	2	3	5	6

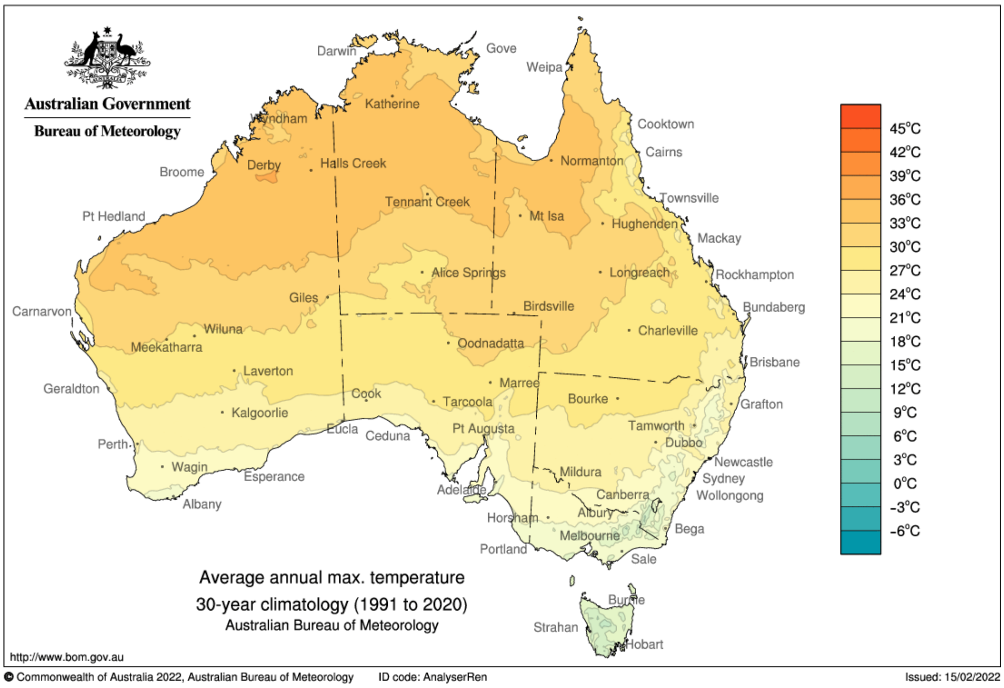
Notes:
Sunscreen should be applied to exposed body sites daily when the maximum UV index is forecast to reach 3 or more. Shaded cells show months when the average maximum UV index does not reach 3.

Figure 2: Average annual UV Index for Australia, for the period 1979-2007 under cloud-free conditions at local noon. These values are also representative of UV index expected between 11 am and 1 pm local time (12 pm and 2 pm daylight saving time) under clear skies (BOM 2024a).



Northern regions of Australia are closer to the equator and typically have warmer climates (**Figure 3**) that encourage lighter clothing and increased time outdoors. With last year ranking as Australia's equal eighth-warmest on record (BOM 2024b), and the projected trend towards warmer climates continuing (BOM 2024c), sunscreen will continue to be an important sun protection measure in the future. This geographical variance in UV exposure and climate conditions highlights the importance of a model that ensures adequate protection for all Australians, regardless of their location.

Figure 3: Average annual maximum temperatures over the period 1991 to 2020 (BOM 2024d).



How sunscreens should be used to achieve the labelled SPF rating

Therapeutic sunscreens must comply with the requirements of the Australian/New Zealand Standard for sunscreens[9]. The Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2021) (amended) (the Sunscreen Standard) was adopted into therapeutic goods legislation from 1 July 2024.

The Sunscreen Standard acknowledges that in circumstances where the dosage used in the measurement of the SPF (2 mg/cm^2) is not applied, the expected sun protection will not be achieved. This is supported by research that demonstrates reduced application thickness exponentially decreases the SPF (Faurschou and Wulf 2007; Schalka et al. 2009). The Sunscreen Standard also requires primary sunscreens to be labelled with clear and appropriate directions so the labelled claims will be achieved, advising that the instructions should state the product should be applied generously. The SunSmart 2024 guidelines also recommend applying more sunscreen than one might think is necessary to achieve adequate application (2024).

Sunscreen for infants (birth to 12 months)

Both the Australasian College of Dermatologists and Cancer Council Australia advise that infants under 12 months should not be exposed to direct sunlight when the UV Index is 3 or higher and sunscreen is not recommended for infants under 6 months (Australasian College of Dermatologists 2018; Cancer Council Australia 2024b). For infants over 6 months, sunscreen can be applied to small areas of skin not covered by clothing or hats, but it should be considered as the last line of defence after other sun protection measures, including covering as much skin as possible with clothing.

Challenge of aligning recommended sunscreen application with the risk assessment

Reflecting on the complexities involved, it is evident that calculating sunscreen exposure to effectively cater to the diverse Australian population is a complicated task. Nonetheless, it is vital to integrate the expected sunscreen application practices, which align with the current Australian recommendations, into the risk assessment of sunscreen ingredients. Further, this assessment should take into account the concerted government and community efforts to refine sun protection behaviours, ensuring that the evaluations are prepared for future sunscreen usage trends. This ensures that sunscreens not only meet the protective needs of Australians but also adhere to public health directives, thereby reinforcing the safety and integrity of sunscreen products for all Australians.

[9] *The Australian/New Zealand Standard (AS/NZS) 2604:2021 Sunscreen products – Evaluation and classification.* https://store.standards.org.au/product/as-nzs-2604-2021

Approaches differ on the appropriate exposure calculation

In August 2023, the TGA initiated a public consultation to determine the safe levels of benzophenone (a degradation impurity) in sunscreens containing octocrylene. The assessment utilised the Cancer Council's full-day sunscreen application recommendation, equating to 140 mL for a full body, to calculate the maximum worst-case sunscreen exposure.

However, while one respondent supported the approach, industry feedback indicated that this estimate was overly conservative, not reflective of actual consumer usage and failed to consider additional protective measures advised by the Cancer Council.

Industry stakeholders presented varied perspectives on the appropriate method for exposure assessment:

- Many suggested adopting the SCCS's daily usage model of 18 g/day as the best available model at the time.
- Others proposed alternative volumes such as using 50 mL instead of 140 mL, or a daily estimate of 45 mL (5 mL for face and neck, 2.5 mL for forearms and lower legs, applied once before work/school, once at morning tea/recess and once at lunch) based on the Cancer Council's policies for schools, acknowledging that the torso is not exposed most of the time and other protection measures are used.
- Others suggested based on sales data, divided by the Australian population, that consumers on average would use minimal sunscreen a year.

The diversity of opinions highlighted the need for further development of a suitable exposure model that aligns with Australian guidelines and practices. Some stakeholders have welcomed further work to consider an appropriate exposure model based on Australian guidelines.

As such, the TGA advised in December 2023 that it would consider developing a sunscreen exposure model for the Australian context with future consultation to be undertaken. The proposed changes regarding setting an acceptable regulatory limit for benzophenone were deferred pending consultation.

What options are proposed for the sunscreen exposure model?

This consultation is an important step towards achieving regulatory certainty and ensuring sunscreens continue to be used safety and effectively by all Australians. It is an opportunity for stakeholders to respond to the proposed options and contribute to the development of an exposure model that accurately represents Australian conditions and usage practices.

Each option below is about how to estimate daily sunscreen exposure (or "external exposure"; see **Figure 1**) in Australia to calculate the Systemic Exposure Dose (SED). The SED is then used to calculate the maximum safe concentration using the Margin of Safety (MoS) formula. Please see Attachment 2 for further information about how the SED and MoS are used in risk assessments.

Three options are proposed in this consultation:

- **Option 1: Australian Sunscreen Exposure Model (ASEM)**
  This model has been designed by the TGA to calculate the estimated daily sunscreen exposure more precisely, catering to the varied needs of Australians. The ASEM integrates expected sunscreen application practices in line with current evidence-based Australian recommendations, rather than relying on international models that may not be reflective of Australian usage patterns.

  The ASEM is intended to confirm the safety of sunscreen ingredients by considering the highest plausible, estimated daily sunscreen exposure among regular sunscreen users. The model considers these situations by employing 6 theoretical evidence-based Australian exposure scenarios for the most frequent users and, assessing the risk of the ingredient based on the highest exposure. This ensures that if an ingredient is deemed safe for the highest exposure, it will also be safe for all Australians.

- **Option 2: SCCS sunscreen exposure model**

  This SCCS sunscreen exposure model is a well-established approach that describes default estimated daily sunscreen exposure (e.g. 18 g/day) as detailed in the SCCS's guidance for testing cosmetic ingredients (12th revision). This model is recognised by some international regions such as Europe, where sunscreens are regulated as cosmetics and has been employed in previous TGA assessments and submitted by sunscreen ingredient applicants.

- **Option 3: Status quo**

  This option involves not adopting a specific estimated daily sunscreen exposure model and continuing to evaluate sunscreen ingredients on a case-by-case basis using various approaches.

Feedback is sought on the appropriateness of each proposal for approximating sunscreen exposure in Australia and using this to calculate the maximum safe concentration of sunscreen ingredients.

Guiding principles

The guiding principles for evaluating the proposed options are:

1. **Correct usage directions for effective sun protection**: The model should integrate evidence-based application guidelines to achieve the labelled SPF rating, ensuring sunscreen ingredients are safe and effective when used as directed. It should be future proof where possible to account for future expected sunscreen use based on current and emerging evidence-based recommendations.
2. **Highest realistic use-case**: The model should cater for the way sunscreen is used by the average Australian, as well as those who use sunscreen more frequently in realistic everyday scenarios, such as outdoor workers in northern Queensland where the UV index is very high all year round.

3. **Contemporary evidence-based information**: The exposure model should consider data reflective of the demographics that use sunscreens, such as children and adults, and the contexts in which sunscreen is applied, including areas not covered by clothing, with a preference for Australian-specific data where available.

4. **A standardised approach for regulatory certainty**: The model should offer a standardised, evidence-based methodology, that is practical for applicants and evaluators to assess ingredient risk, providing clarity and consistency for industry stakeholders and ensuring that sunscreens evaluations account for Australian use.

5. **Upholding sunscreen safety and trust**: The model should bolster the safety reputation of Australian sunscreens, ensuring consumers are confident in their evaluation by the TGA and encouraged to use them without fear or doubt.

These principles aim to ensure that the final model is robust, reflective of Australian practices, and continues to provide the necessary assurance for the safety and efficacy of sunscreen ingredients.

Option 1: Australian Sunscreen Exposure Model (ASEM)

The Australian Sunscreen Exposure Model (ASEM) is proposed to accurately calculate sunscreen use that accounts for the diverse needs of Australians and integrates the expected sunscreen application practices that align with current Australian recommendations, rather than utilising international models that do not. This ensures that sunscreen ingredients are evaluated for safety based on how they are, and recommended to be, used in Australia today.

The objective of this approach is to affirm the safety of sunscreen ingredients, considering the highest plausible sunscreen use throughout the year, for the most sensitive population. To achieve this, 6 theoretical ASEM scenarios have been developed to represent a broad spectrum of regular sunscreen usage patterns across different demographics across Australia (see **Table 3**). These scenarios provide the highest estimated daily sunscreen exposure, to calculate maximum safe concentration of a sunscreen ingredient using the SED and MoS formulas.

It is crucial to recognise that the ASEM scenarios are constructed to reflect the higher end of sunscreen usage in Australia, rather than the average Australian's usage. This approach ensures that the risk assessments for sunscreen ingredients, when based on the highest usage scenarios, will also guarantee safety for lower usage cases where less of the ingredient may be applied to the skin.

How does it work?

The TGA draws upon the same risk assessment method developed by the SCCS for cosmetic ingredients to calculate the SED and MoS (see Attachment 2). However, the ASEM utilises a different estimated daily sunscreen exposure (external exposure) than is used by the SCCS to calculate the SED and MoS.

The SCCS estimated daily sunscreen exposure is expressed in 2 ways (see Option 2):

How dermal absorption data is reported	Estimated daily exposure	Estimated daily exposure per unit body weight*
Method 1 (%)	18 g/day (i.e. 9 g of sunscreen applied twice daily)	300 mg/kg bw/day
Method 2 (μg/cm^2)	35,000 cm^2/day (i.e. 2x whole body applications daily)	583 cm^2/kg bw/day

*SCCS uses a default human body weight of 60 kg

The ASEM is a model to calculate the estimated daily sunscreen exposure using a formula, and the input into that formula is based on Australian expected sunscreen use scenarios. For the purpose of regulatory risk assessments, the TGA has established the highest estimated daily sunscreen exposure using the ASEM, that is proposed to be used to calculate SED and MoS, rather than the SCCS values above. The highest estimated daily sunscreen exposure values are expressed below depending on how dermal absorption data for the ingredient is reported:

How dermal absorption data is reported	ASEM highest estimated daily sunscreen exposure
Method 1 (%)	673 mg/kg bw/day
Method 2 (μg/cm^2)	336 cm^2/kg bw/day

The following aspects of the ASEM that establish the above highest estimated daily sunscreen exposure values are discussed below:

- ASEM formula
- ASEM scenarios
- Calculations for establishing the highest estimated daily sunscreen exposure

Real world and hypothetical examples of the SED and MoS calculations using the ASEM highest estimated daily sunscreen exposure (Option 1) and SCCS (Option 2) methodology are provided in Attachment 3 and Attachment 4.

ASEM Formula

The ASEM formula is a way to calculate and therefore estimate how much sunscreen is used daily. It is based on data for skin surface area, age, and body weight for the Australian population. The formula calculates the daily sunscreen exposure by considering how many times it is applied a day, number of days of the year it is applied, and the skin surface area of each body part it is applied to.

$$ASEM\ (method\ 1) = \frac{Appl\ Rate \times SSA \times AF \times Duration}{Bw_t \times AT}$$

$$ASEM\ (method\ 2) = \frac{SSA \times AF \times Duration}{Bw_t \times AT}$$

where:

Parameter	Description	Explanation
ASEM	Estimated daily sunscreen exposure (mg/kg bw/d) or (cm^2/kg bw/day)	The ASEM formula provides the amount of sunscreen applied to the skin per day relative to body weight (kg). The amount is expressed in units of either mass (mg) or surface area (cm^2), depending on how the data for dermal absorption of an ingredient is reported.
Appl Rate	Application rate of product mg/cm^2	For a sunscreen product to reach the labelled sun protection factor (SPF), it must be applied in quantities similar to those used in SPF testing. This application rate of 2 mg/cm^2 is specified in the Sunscreen Standard. **NOTE:** Appl rate is not required for Method 2 calculations because it is accounted for as part of the dermal absorption study protocol.
SSA	Surface area of skin sunscreen applied to (cm^2) per application	The skin surface area exposed to sunscreen (per application) is predicted based on the practices outlined in the ASEM scenarios (**Table 3**) for different population groups and activities e.g. an

Parameter	Description	Explanation
Bw_t	Body weight linked to SSA (kg)	individual working outdoors may be wearing a hat, shorts. half-sleeved shirt and footwear, and therefore the exposed skin where sunscreen is applied would include the face, neck, hands, forearms, and lower legs. The scenarios account for parts of Australia with warmer climates where less clothing may be worn year-round. The Australian Exposure Factor Guidance publication (enHealth) (DOHAC 2012) provides the most up-to-date information that can assist with assessing the human health risks from environmental hazards. It contains information on skin surface area (for different body parts) and body weight for adults and children. The data underlying this information is reliant on overseas data derived from either empirical data (actual measurements of skin areas) or algorithms that have extrapolated from weight and height measurements to generate skin (body) surface area values. The data utilised for the ASEM is based on enHealth (DOHAC 2012) data in: • Table 3.2.3 and 3.2.5 for skin surface area of body parts for adults, adolescents and children • Table 2.2.1 and E2 for body weights for adults (≥18 years), adolescents and children enHealth reports both mean and 95th percentile value for SSA and BW (DOHAC 2012). The TGA has referred to the 95th percentile SSA and BW data for the ASEM calculations.
AF	Application Frequency (applications/day)	Application frequency is expressed as the number of sunscreen applications per day. This can range from 2 – 3 applications per day for the different exposure scenarios outlined in ASEM Scenarios.
Duration	Annual Use (days)	Duration is expressed as the number of days in a year sunscreen application/exposure is expected to occur. The ASEM scenarios for the use of sunscreens in Australia provides information on the duration anticipated by different population groups.
AT	Averaging time (365 days)	An average daily dose based on exposure over a 1-year period (i.e. 365) is being calculated.

All the variables in the ASEM formula (SSA, BW, Age, AF and Duration) can change based on how the sunscreen is used and who it is used by. The respective input values for these variables are described in the ASEM scenarios below.

ASEM Scenarios

It is clear that the use of a single maximum daily-use scenario, i.e. a full day at the beach with multiple reapplications of sunscreen (that would amount to ~140 mL application daily), is not useful for determining the safety of sunscreen ingredients for the Australian population as a whole. Hence 6 sunscreen use scenarios have been developed to account for the Australian context, the most current Australian research, and national guidelines and policies, with consideration given to:

- The frequency of sunscreen application in both occupational and recreational contexts.
- How sunscreen may be used by different age groups.
- The environment (sun exposure) that an individual may be in.
- Clothing that an individual is likely to be wearing in that environment.
- The total skin surface area for exposed skin where sunscreen is likely to be used.
- The number of days sunscreen is applied in a year, factoring in variables such as weather conditions, and different use based on weekday vs weekend activity.

Table 3 describes the 6 ASEM scenarios.

How do the ASEM scenarios estimate days sunscreen is applied in a year?

The ASEM scenarios (**Table 3**) consider sunscreen exposure across weekdays and weekends to account for the highest-use case across a year, which is divided by 365 to give the average daily sunscreen exposure. The use of sunscreen is required when exposed to the sun year-round for parts of Australia where the UV index consistently exceeds 3, such as Darwin, Brisbane, and Perth etc. as discussed under 'Current evidence-based sunscreen use guidelines' above.

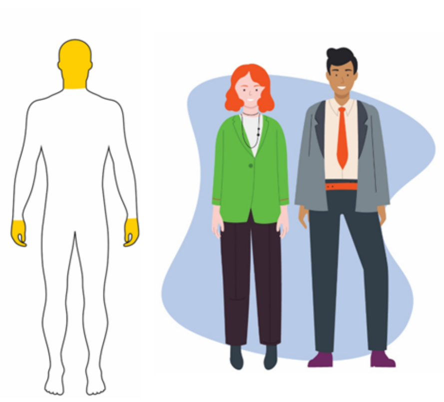
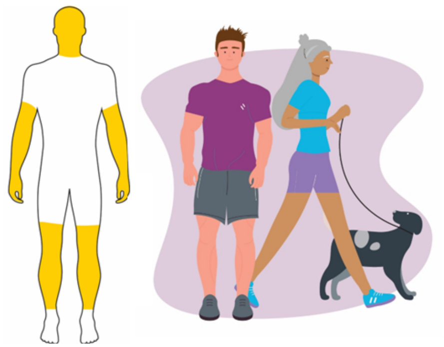
Weekday exposure is estimated based on a 5-day work week (i.e. 5 x 52 = 260 weeks annually), then adjusted for days of heavy rainfall (>10 mm). It is acknowledged that low rainfall days (rainfall ≥1 mm) with a UV index ≥3 may still necessitate sunscreen use (e.g. partly cloudy days, rainfall only for small period or in evening) as sun damage is also possible on cloudy days, since UV radiation can penetrate some clouds, and may even be more intense due to reflection off the clouds (Cancer Council Australia 2024c). Additionally, people are likely to be indoors on heavy rainfall days (rainfall ≥10 mm), thereby negating the use of sunscreens on such days. Average heavy rainfall days were calculated using BOM climate data (BOM 2024e) for rainfall for the past 3 years (2021-2023) for locations across Australia (see **Table 2**). The average weekly total heavy rainfall days was assumed to be 20 days (i.e. 5/7 x 29). Hence the total weekdays of exposure were calculated as **240 days** (260 – 20). This has been used for the assumed highest-use plausible duration of sunscreen use during weekdays in scenarios 1 to 4.

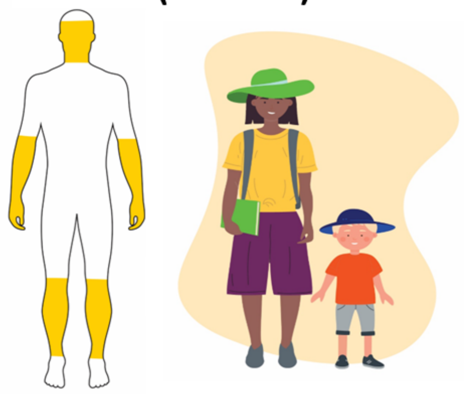
Table 2: Average heavy rainfall days for Australia (2021-2023)

Location		Rainfall ≥ 10mm days		
Station	**City**	**2021**	**2022**	**2023**
94029	Hobart	17	20	13
86232	Melbourne	23	21	13
23034	Adelaide	11	8	13
9021	Perth	27	26	18
14015	Darwin	50	58	43
40913	Brisbane	42	45	22
66006	Sydney	42	77	32
70351	Canberra	28	30	25
3-year average		**29**		

Weekend exposure is estimated for recreational activities that involve extended sun exposure, such as beach outings or outdoor activities such as water sports and fishing. This exposure is calculated for one day each weekend over a 6-month period from October to April, which is conducive to these activities due to warmer weather. The calculation does not deduct the average annual heavy rainfall days for weekends (2/7 x 29 days = 9 days) because the estimated exposure already accounts for only 25% of all weekend days annually, and 50% of all weekend days from October to April. It is assumed that the remaining 50-75% of weekend days would cover non-exposure days, including those with weather not suitable for prolonged outdoor activities. Therefore, the exposure duration for scenarios 5 and 6 is set at **26 days**, representing one day of sunscreen exposure for each of the 26 weekends in the 6-month warmer weather period.

Table 3: Six ASEM scenarios

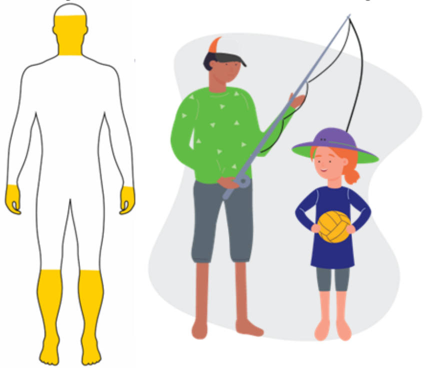
Scenario Yellow areas represent sunscreen applied to skin		Parts of body applied	AF (applications per day)	Duration (days per year)	Description
Scenario 1 **INDOOR WORKER (Adults)** 	Infrequent sun exposure. Limited sunscreen use. Office, retail, hospitality, health worker, vehicle operator	Head (including face and neck), hands	Up to 2	240	This scenario accounts for daily sunscreen application practice for adults undertaking indoor work during the **weekdays**. This population is likely to wear formal or semi-formal clothing that fully covers the torso, arms, legs, and footwear. It presumes that sunscreen is applied once in the morning and once again during morning tea, lunch, or afternoon. This is supported by the 'Current evidence-based sunscreen use guidelines' discussed above. Also see Whiteman et al. (2019).
Scenario 2 **NON-OCCUPATIONAL DAILY (Adults)** 	Regular sun exposure. Limited sunscreen use. Daily exercise, dog walking, gardening, and other recreation	Head (including face and neck), hands, ¾ arms, ¾ legs	Up to 2	240	This scenario accounts for daily sunscreen application for adults (including active retirees) undertaking outdoor recreational activities during **weekdays**. This population, particularly in warmer regions of Northern Australia, are likely to wear sport/casual clothing that may cover approximately ¼ of the arms and legs, torso and footwear. It presumes that sunscreen is applied once in the morning/start of the activity and once again halfway into the activity. This is supported by the 'Current evidence-based sunscreen use guidelines' discussed above. Also see ASSC (2023) and Whiteman et al. (2019).

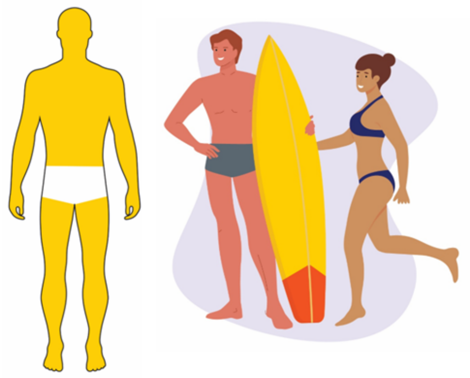
<table>
<tr><th colspan="2">Scenario
Yellow areas represent sunscreen applied to skin</th><th>Parts of body applied</th><th>AF (applications per day)</th><th>Duration (days per year)</th><th>Description</th></tr>
<tr><td rowspan="2">Scenario 3
CHILDCARE / SCHOOL
(Children)
</td><td>Frequent sun exposure. Regular sunscreen use.</td><td rowspan="2">Face, neck, hands, ½ arms, ½ legs</td><td rowspan="2">Up to 3 (Childcare)
Up to 2 (School)</td><td rowspan="2">240</td><td rowspan="2">This scenario accounts for daily sunscreen application for children (above one year of age) attending sun smart childcare services (and schools) during the weekdays.

This population, particularly in warmer parts of Australia, are likely to wear hats and clothing that covers the torso, ½ arms and legs, and footwear. Sunscreen is applied frequently as a policy/practice in the majority of the early childhood centres but sun protection behaviours tend to reduce in older children and therefore sunscreen has been assumed to be applied up to two applications per day in older children.

This is supported by the evidence under the heading 'Sunscreen use in children' discussed above, in particular see Cancer Council SA (2018).

The estimation of sunscreen exposure for childcares is based on toddlers aged above 12 months instead of 6 to 12 months, as children normally learn to walk on their own between 12-15 months of age (DOHAC 2023; ACECQA 2024) and are more likely to be exposed to the sun (and consequently sunscreens) in a childcare setting relative to a 6-12-month-old child. Moreover, as discussed under the heading 'Sunscreen for infants (birth to 12 months)', infants under 12 months are not recommend to be exposed to the sun, and children under 6 months are not recommended to use sunscreen.</td></tr>
<tr><td>Childcare (1-2 years old) and school children (under 18)</td></tr>
</table>

Scenario Yellow areas represent sunscreen applied to skin		Parts of body applied	AF (applications per day)	Duration (days per year)	Description
Scenario 4 **OUTDOOR WORKER (Adults)** 	Frequent sun exposure. Regular sunscreen use. Agricultural worker, grounds keeper, landscaper, tradesperson, surf lifeguard	Face, neck, hands, ½ arms, ½ legs	Up to 3	240	This scenario accounts for daily sunscreen application practice for adults engaging in outdoor work (as their main occupation) during **weekdays**. This population, particularly in warmer regions of Australia, are likely to wear specific workwear including a hat, clothing that fully covers the torso, ½ arms and legs, and footwear. Sunscreen is applied once in the morning, during lunch/midday and in the afternoon as this would include professions that are expected to spend long periods of time during the day (~6 hours) during peak UV periods. This is supported by the evidence under 'Sunscreen use by outdoor workers' discussed above.
Scenario 5 **SUN SMART CLOTHING (Adults and Children)** 	Prolonged sun exposure. Extensive sunscreen use. Full day in the sun (beach or other activities)	Face, neck, hands, ½ legs, feet	Up to 3	26	This scenario accounts for daily sunscreen application for sun-smart adults and children, undertaking outdoor recreational activities that lead to prolonged sun exposure on **weekends**. This population is likely to wear hats and clothing such as a long sleeve shirt/rashie, shorts/boardies that cover ½ legs. Sunscreen is applied once in the morning/start of the activity and twice again during the day, particularly due to swimming, sweating or towel drying that may remove the product. This is supported by the evidence under 'Sunscreen use by the general population' and 'Current evidence-based sunscreen use guidelines' discussed above.

Scenario  Yellow areas represent sunscreen applied to skin		**Parts of body applied**	**AF (applications per day)**	**Duration (days per year)**	**Description**
Scenario 6 **MINIMAL BEACH WEAR** **(Adults and Adolescents)** 	Prolonged sun exposure. Extensive sunscreen use.	Full body	Up to 3	26	This scenario accounts for sunscreen application for adults and adolescents spending full day at the beach leading to prolonged sun exposure on **weekends**. This population is likely to wear minimal swimwear. It presumes that sunscreen is applied once in the morning and twice again during the day, particularly due to swimming, sweating or towel drying that may remove the product. This is supported by the 'Current evidence-based sunscreen use guidelines' discussed above for sunscreen application if the full body is exposed to the sun. This scenario does not include children, as they are typically supervised by parents and expected to wear sun-smart attire, including hats and protective clothing, as outlined in scenario 5.
	Full day at the beach				

Calculations for establishing the highest estimated daily sunscreen exposure

The TGA has calculated the sunscreen exposure for each ASEM scenario and combined the weekday and weekend scenarios to provide a yearly realistic exposure. These yearly exposure scenarios are:

- For adults: Scenarios 4 + 6.
- For secondary school children: Scenarios 3 + 6.
- For other children, including toddlers, pre-school, and primary school children: Scenarios 3 + 5.

To derive the estimated daily sunscreen exposure, the output was divided by 365 days.

Scenarios 3 and 5 for toddlers aged 1-2 years old provided the highest estimated daily sunscreen exposure per kg/bw due to:

- their high skin surface area to body weight ratio, and
- high estimated sunscreen exposure based on the scenarios.

All the calculations for the estimated daily sunscreen exposure for each age group and scenario, and the combinations of the above scenarios (including how Australian skin surface area and body weight data have been used) are provided in the **ASEM Calculations Microsoft Excel file** (see tab '2. ASEM calculations' in Attachment 5). The calculations for Scenario 3 and 5 for toddlers aged 1-2 years are provided below:

Estimated daily sunscreen exposure for Method 1 (%)
Scenario 3 = 607 mg/kg bw/day
Scenario 5 = 66 mg/kg bw/day

Highest estimated daily sunscreen exposure Method 1 (%)
Scenario 3 + Scenario 5 = 607 + 66 = **673 mg/kg bw/day**

Estimated daily sunscreen exposure for Method 2 (μg/cm2)
Scenario 3 = 303 cm^2/kg bw/day
Scenario 5 = 33 cm^2/kg bw/day

Highest estimated daily sunscreen exposure for Method 2 (μg/cm2)
Scenario 3 + Scenarios 5 = 303 + 33 = **336 cm^2/kg bw/day**

Because the ASEM formula calculates the highest estimated **sunscreen exposure as a proportion of kg body weight per day**, risk assessments using the SED and MoS calculations can be conducted using this value to account for any body weight (i.e. accounting for adults or children). This approach ensures that our risk assessment comprehensively cover the highest exposure for all Australians and ensure ingredients are safe to be used by everyone, no matter their age, weight, or outdoor activity.

Reasons for Option 1

- The ASEM has been specifically developed for the Australian context, which has the highest incidence of skin cancer globally and a culture that enjoys outdoor activities. Consequently, Australians are advised to use sunscreen and other sun protection measures more diligently and regularly than in other countries with different circumstances. Moreover, the assessment of all therapeutic goods, including sunscreens, should be based on the amount they are used according to their directions to be effective. Therefore, the ASEM provides a model that accounts for these factors and ensures safety when used correctly. This approach bolsters confidence in sunscreen regulation and allows Australians to trust in using sunscreen as a daily UV radiation protective measure for the entire family.

- The ASEM is grounded in current Australian evidence-based sunscreen use guidelines and research. It models sunscreen exposure based on how sunscreens are directed to be used to achieve effective UV protection. The ASEM models exposure of a sunscreen application thickness of 2 mg/cm^2 to attain the labelled SPF, and while this thickness may not be commonly applied by many Australians, it is supported by studies indicating that some participants do apply sunscreen at the correct thickness or even more. This is particularly significant for therapeutic sunscreens in Australia, which are allowed to claim they may assist in preventing some skin cancers, a claim not permitted for sunscreens in Europe where they are considered cosmetics. Use of the ASEM ensures that sunscreens are safe for use according to their instructions, supporting the claims of effectiveness and promoting regular, liberal application as a preventative measure against skin cancer.

- The ASEM's reliance on current Australian guidelines means the model takes into account future expected sunscreen use, aligning with efforts to promote the correct application of sunscreen.

- Unlike the SCCS model, which uses for example, a single maximum daily use scenario (18 g/day) based on research from countries that are likely to have a very different context for sunscreen use than Australia, or a maximum full day at the beach daily use scenario (that would amount to ~140 mL application daily), the ASEM employs realistic highest-use Australian scenarios to model the diversity of regular daily use for adults and children. The ASEM caters to the safety of all Australians, especially frequent sunscreen users, while avoiding unnecessarily restricting effective sunscreen ingredients from the Australian market and guaranteeing assessments are fit for purpose.

- Recognising that systemic exposure to a sunscreen ingredient depends on the amount of skin it covers, and that individuals experience varying levels of exposure based on body weight, the ASEM employs skin surface area and body weights representative of the Australian population across all age groups. It places particular emphasis on safeguarding young children, who have the highest skin surface area relative to body weight, thereby affirming the safety of sunscreen use for the entire family in daily life, whether it be for work, school, or leisure activities.

- The ASEM offers a simpler calculation to determine sunscreen exposure for regulatory purposes. This reduces the complexity of application dossiers that would simply be able to provide the absorption data and simple calculation, rather than discussing suitability in the Australian context or account for different age groups.

- A standardised method for evaluating sunscreen ingredients reduces discrepancies in risk assessments. This uniform approach guarantees that ingredients are approved based on the same criteria, reducing and overcoming varied outcomes due to different types of data presented, such as those limitations observed with the SCCS method 1 and method 2 calculations (see Attachment 3 and Attachment 4). It levels the playing field for new ingredient applicants, providing regulatory consistency and certainty for ingredient evaluations, which facilitates the development and introduction of novel ingredients to the Australian market.

- Evaluations are less likely to be contested, saving time and resources for all stakeholders involved in application decisions. This streamlined process reduces potential delays in introducing new sunscreen ingredients and alleviates the regulatory burden of the processes due to unnecessary contention.

Reasons against Option 1

- This approach provides estimations of sunscreen use based on Australian evidence-based recommendations and limited research. However, it is important to note that actual comprehensive Australian sunscreen use data, combined with these recommendations, would provide a more robust model for estimating highest-use exposure in the Australian context. While gathering such extensive data that would be statistically representative of all Australians poses challenges, the ASEM scenarios and variables are derived from the best available information to date.
- The formal adoption of ASEM would not align with international jurisdictions that use the SCCS estimation of sunscreen use for risk assessments. This could lead to discrepancies where certain sunscreen ingredients are permitted overseas but restricted or limited to lower or higher maximum concentrations in therapeutic sunscreens in Australia. While the TGA recognises the SCCS as a Comparable Overseas Body (COB) where evaluation reports can be used for abridged evaluations, the Guidance on using evaluation reports from COBs clarifies that that use of a product or substance in the Australian context may differ from international use. The guidance further clarifies that the TGA retains the final regulatory decision to ensure safety, quality, and efficacy in accordance with the Australian regulatory framework.

Consultation questions on Option 1

These questions can be answered in the TGA consultation hub.

Questions for all stakeholders:

1. **Should the TGA implement Option 1, by using the highest estimated daily sunscreen exposure for Australians (i.e. 673 mg/kg bw/day and 336 cm^2/kg bw/day) in ingredient risk assessments?**

   Please describe why / why not?

2. **Do you agree with the calculations and assumptions for the ASEM formula, ASEM scenarios, and how the highest estimated daily sunscreen exposure has been derived?**

3. **Do you have any additional data, information or comments that may assist in refining Option 1?**

Option 2: SCCS sunscreen exposure model

This option considers formally adopting the Scientific Committee on Consumer Safety (SCCS) sunscreen exposure model, as outlined in the SCCS guidance for testing cosmetic ingredients 12th revision (SCCS 2023). This model is recognised in certain international regions where sunscreens are regulated as cosmetics such as Europe and has been used in previous TGA assessments and submitted by sunscreen ingredient applicants.

This option is being considered for its international application in Europe. However, the TGA seeks to ensure that any model adopted is reflective of Australian sunscreen use and provides a realistic and safe framework for evaluating sunscreen ingredients.

We invite stakeholders to provide their perspectives on the SCCS model's suitability for the Australian context, including any proposed modifications to the model that would make it a better alternative than the other options.

How does it work?

The SCCS uses two different estimated daily sunscreen exposure values to calculate SED and, consequently, the MoS. For detailed explanations of the equation used by the SCCS, please refer to Attachment 2. Different sunscreen exposure values and methods are used depending on the way the data for dermal absorption of a sunscreen ingredient is reported:

Method 1

If the dermal absorption is based on the percentage dermally absorbed (%), the SCCS recommends a default daily sunscreen usage of 18 g/day. The SCCS calculations of **18 g/day** are **not based on a 2 mg/cm^2 application thickness** required to achieve the claimed sunscreen SPF rating, but data about habits and practices derived from surveys and research from non-Australian countries.

Method 2

If the dermal absorption is based on the absolute amount bioavailable (μg/cm^2), the SCCS recommends the skin surface area (SSA) expected to be applied with sunscreen is **17,500 cm^2** (1.75 m^2) and frequency of application is **2 applications/day**. This is equivalent to SSA of 3.5 m^2/day.

The SCCS estimated daily sunscreen exposures are summarised below:

How dermal absorption data is reported	Estimated daily sunscreen exposure	Estimated daily exposure per unit body weight*
Method 1 (%)	18 g/day (i.e. 9 g of sunscreen applied twice daily)	300 mg/kg bw/day
Method 2 (μg/cm^2)	35,000 cm^2/day (i.e. 2x whole body applications daily)	583 cm^2/kg bw/day

* Estimated daily exposure per unit body weight is calculated by dividing estimated daily sunscreen exposure by the SCCS default human body weight of 60 kg.

The TGA notes that depending on the data available, these 2 methods result in substantial differences in the MoS calculation for the same ingredient. This means in some cases the SCCS calculations result in less or more conservative calculations for the MoS than the ASEM (Option 1).

Real world and hypothetical examples of the SED and MoS calculations using the ASEM highest estimated daily sunscreen exposure (Option 1) and SCCS (Option 2) methodology are provided in Attachment 3 and Attachment 4.

Background for the estimated daily sunscreen exposure values used by SCCS

For method 1, the SCCS model uses an estimated daily sunscreen exposure of 18 g per day, a figure derived from studies outside Australia, such as Biesterbos et al. 2013, in the Netherlands (SCCS 2021). This figure is further supported by research from Gomez-Berrada et al. (2017 and 2018) (encompassing 75 studies in adults and children across Mauritius, Spain, France and Italy (p. 98, SCCS 2023).

For method 2, the SCCS model assumes sunscreen is applied twice a day to the whole adult body.

The SCCS does not consider the recommended sunscreen application thickness (2 mg/cm^2) required to achieve the labelled SPF ratings for neither of these two methods.

How does the SCCS model consider exposure in children?

The default body weight used by the SCCS is 60 kg, and the SCCS sunscreen exposure model does not differentiate different age groups. However, the SCCS guidance acknowledges that the skin surface area to body weight ratio (SSA/BW) between children and adults are different (SCCS 2023). The ratio between the SSA/BW of children and adults changes from 0- to 10 years and is 2.3 at birth, 1.8 at 6 months, 1.6 at 12 months, 1.5 at 5 years, and 1.3 at 10 years (Renwick 1998). The ratio between the SSA/BW children of 0 to 1 year of age and that of adults is at maximum 2.3. The SCCS considers that the inter-individual variation in SSA/BW is covered by the generally accepted default uncertainty factor value of 100 (10 for interspecies variations and 10 for intraspecies variations) for intact skin used in the MoS calculation. The SCCS also notes that for certain specific compounds the potential differences in metabolism between newborns/infants up to 6 months and adults could require extra consideration, however in general, the SCCS is of the opinion that there is no need for an additional uncertainty factor for children when intact skin is present (SCCNFP 2002).

Reasons for Option 2

- The SCCS model is recognised by European nations and other international regions where sunscreens are regulated as cosmetic products. Adopting the SCCS model would align regulatory risk assessments of sunscreen ingredients with these international jurisdictions.
- The SCCS model has been employed in previous TGA assessments and the current Application requirements for new substances in listed medicines (ARNS) guidance recommends using appropriate dermal exposure models from the SCCS's 11th revision guidance to calculate the maximum daily exposure for dermally applied ingredients.
- The SCCS is recognised by the TGA as a Comparable Overseas Body (COB) where evaluation reports can be used for abridged evaluations. However the Guidance on using evaluation reports from COBs clarifies that that use of a product or substance in the Australian context may differ from international use and the TGA retains the final regulatory decision to ensure safety, quality, and efficacy in accordance with the Australian regulatory framework.
- Evaluations may be less prone to being challenged/contested, reducing time and resources expended by all stakeholders in debating application decisions that are not based on a consistent methodology. This reduces potential delay of the introduction of new sunscreen ingredients but and reduces burden on the regulatory process from unnecessary contention.

Reasons against Option 2

- One of the estimated daily sunscreen exposure values used by the SCCS is 18 g per day, a figure derived from studies outside Australia. Some of the supporting data for example, appears to be predominantly from Mauritius (57 studies), which, like other countries in Europe, has significantly lower skin cancer incidence rates compared to Australia. For example, in 2022, Mauritius had a melanoma and non-melanoma skin cancer age-standard incidence rate per 100,000[10] for both sexes of 0.24 and 4.2 respectively, compared with Australia which was 37 and 140.1, the highest rates out of all countries (IARC 2024b).[11] Given Australia's high skin cancer rates and a culture that emphasises outdoor activities, the suitability of the 18 g/day exposure calculation is uncertain as Australians are encouraged to apply sunscreen more frequently, thoroughly, and diligently, as part of a broader sun protection strategy, which includes policies implemented in settings like childcare. The Australia context is likely to be very different from other countries with a lower incidence of skin cancer.

- The SCCS sunscreen exposure value of 18 grams per day is used for risk assessments but is not intended as a consumer usage recommendation (p. 98, SCCS 2023). The European Commission acknowledges that to achieve the claimed SPF protection level, sunscreen must be applied at the same density used in testing, approximately 2 mg/cm², equating to around 36 grams for an average adult's full body (European Commission 2006). Furthermore, the European Commission recommends that sunscreen products should include instructions to ensure adequate application for effective protection, along with a warning about the risks of insufficient application, such as 'Warning: reducing this quantity will significantly lower the level of protection' (European Commission 2006). While it is likely that many Australians may not apply sunscreen at the recommended thickness of 2mg/cm², it is reasonable to assume there are individuals who would to achieve the intended SPF rating, and this application rate is also shown in the limited Australian research discussed above. The assessment of therapeutic goods, including sunscreens, must be based on how much is applied to be effective as per the directions provided. However, the applicability of the SCCS model for Australians who correctly use sunscreen, or its alignment with initiatives promoting correct sunscreen application in Australia, remains to unclear.
- In Australia, therapeutic sunscreens are permitted to claim to 'assist in preventing some skin cancers' and 'reduce the risk of some skin cancers,' which is not permitted for cosmetic sunscreens in Europe. The efficacy of therapeutic goods, including sunscreens, should be evaluated based on the recommended usage to achieve their stated indications, a factor not considered in the SCCS model.
- While the ARNS refers to the SCCS 11th revision for calculating the maximum daily exposure of dermal substances, and the SCCS is included in the list of COBs, clarity is still needed on expectations for ingredient evaluations, particularly concerning the suitability of the SCCS model for the Australian context considering current Australian evidence-based sunscreen use guidelines and research discussed in this consultation for all populations, including children.
- While the SCCS method is established, it has limitations that may lead to inconsistencies in risk assessments. Depending on the available data, the SCCS exposure calculation method can yield considerable differences in the MoS calculation for the same ingredient (see calculation examples in Attachment 3 and Attachment 4). This discrepancy could result in the same ingredient being approved under one set of data but rejected if presented in a different way. Such inconsistencies raise concerns about the appropriate calculation method for regulatory approvals and the potential for regulatory uncertainty if absorption data is presented in both % and ug/cm^2 requiring expert judgement for which calculation method will be most suitable.
- Australia experiences higher UV radiation levels than any country in the European Union (WHO 2013) and has the highest incidence of skin cancer worldwide. Given the Australian outdoor lifestyle, it is reasonable to assume that Australians use, or should at least use, more sunscreen than other nations. Sunscreen in Australia play a vital role in public health and are permitted to make claims relating to preventing skin cancer and are regulated as therapeutic goods under stricter standards than in some international jurisdictions where they are classified as cosmetics. Continued reliance on a European exposure model, rather than developing a tailored Australian approach based on current evidence, could undermine

[10] The age-standardised rate is a summary measure of the rate that would have been observed if the population had a standard age structure, as age has a strong influence on cancer risk. The World Standard Population is used to calculate the incidence rate per 100,000 person-years (IARC 2024a)

[11] Data obtained from Cancer Today DATAVIZ world heatmap tool – Displaying global output for different cancer types.

confidence in sunscreen regulation and its use as a protective measure against UV radiation in Australia.

Consultation questions on Option 2

These questions can be answered in the TGA consultation hub.

Questions for all stakeholders:

4. **Should the TGA implement Option 2 by using the estimated daily sunscreen exposure used by the SCCS (i.e. 300 mg/kg bw/day and 583 cm^2/kg bw/day) in ingredient risk assessments?**

5. **If you support Option 2, please explain how the SCCS model accounts for the Australian sunscreen use context, or how the model can be modified to better reflect the Australian context.**

Option 3: *Status quo*

Noting the TGA draws upon the same risk assessment method developed by the SCCS for cosmetic ingredients to calculate the SED and MoS (see Attachment 2), this option considers maintaining the *status quo*, where the standard estimated daily sunscreen exposure value for sunscreen ingredient risk assessments in Australia are not formalised. Rather, risk assessment for sunscreen ingredients will be conducted on a case-by-case basis through a variety of risk-based methodologies that may utilise different estimates of daily sunscreen exposure. This may mean that ingredient risk assessments may be based on estimated sunscreen exposure values such as those used in either Option 1, Option 2, or other approaches based on case-by-case justifications.

Reasons for Option 3

- Applicants have greater flexibility to employ diverse scientific justifications to support evaluations of new sunscreen ingredients. This may better account for technological advancements, changes in public behaviour, and emerging scientific evidence and sunscreen use guidelines and risk assessments.

Reasons against Option 3

- Some estimated daily sunscreen exposure values proposed by applicants, and those ultimately employed may not adequately reflect the unique Australian context, such as the higher levels of UV exposure and adherence to current evidence-based guidelines for effective sun protection. The methods employed may not account for Australian practices today for the most frequent sunscreen users.
- The current approach has resulted in regulatory inconsistencies, leading to confusion and uncertainty. This is problematic given the lengthy research and development process required to bring new ingredients to market, with tests that may need to be conducted at the proposed concentration for final products. Uncertainty about the concentration that may be approved by the TGA, based on the assessment methodology, can stifle innovation and the development of new sunscreen ingredients.
- The absence of an agreed estimated daily sunscreen exposure value means there is no standardised method for evaluating sunscreen ingredients, potentially leading to discrepancies in risk assessments where some may be overly conservative, while others may not be conservative enough.
- Without a universally accepted approach, evaluations are more prone to being challenged, leading to increased time and resources expended by all stakeholders in debating application decisions. This not only delays the introduction of new sunscreen ingredients but also burdens the regulatory process with unnecessary contention.
- Applicants may be required to provide scientifically robust arguments to support their chosen approach, which may not be supported by the TGA evaluator if not well-founded. Given the complexity of assessing sunscreen exposure, this could pose significant challenges and add unnecessary regulatory costs for new ingredient applicants.

Consultation questions on Option 3

These questions can be answered in the TGA consultation hub.

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Questions for all stakeholders:

6. **Do you support Option 3?**

   Please describe why /why not?

Consultation questions on all options

These questions can be answered in the TGA consultation hub.

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General feedback:

7. Which is your preferred option?

- Option 1
- Option 2
- Option 3

8. Do you have an alternative option to propose?

What happens after the consultation outcome?

After the consultation outcome is published which will clarify which of the above options for assessing sunscreen exposure will be implemented, the TGA will utilise this option for future sunscreen ingredient risk assessments where an ingredient can be absorbed past the outer layer of skin (stratum corneum) and lead to systemic absorption.

The TGA will update the Australian Regulatory Guidelines for Sunscreens to provide comprehensive guidance for applicants seeking approval for new sunscreen ingredients as required to align with the final exposure model implemented. This will ensure a consistent and transparent process, offering regulatory certainty and a fair framework for applications, while reinforcing Australian expectations that sunscreens continue be safe to be used by everyone, no matter their age or outdoor activity.

Additionally, the TGA is undertaking a literature review of some common sunscreen active ingredients. Setting an acceptable regulatory limit for benzophenone was also deferred in December 2023 pending consideration of an appropriate sunscreen exposure model. The final sunscreen exposure model will be utilised in assessing the risk of these active ingredients and benzophenone. It is important to note that the TGA does not propose to revisit previously approved ingredients unless new safety concerns necessitate a review of the current scientific data.

The consultation paper does not propose new regulatory requirements for currently approved sunscreen ingredients, such as reduced permitted concentrations stipulated in the Therapeutic Goods (Permissible Ingredients) Determination. Any future regulatory decisions regarding specific sunscreen ingredients will be made in consultation with stakeholders, utilising the implemented option.

While the primary purpose of the consultation is to estimate daily sunscreen exposure for conducting risk assessments of sunscreen ingredients, it may also have broader future applications for ingredients in other skin products.

Attachments

Attachment 1: Sunscreen regulation in Australia

In Australia, sunscreens are regulated as either cosmetics or therapeutic goods depending on a number of factors, such as their ingredients, health claims and claimed SPF.

The objective of regulation of sunscreens in Australia is to ensure their quality, safety, and efficacy to protect consumers from the sun's harmful UV radiation and reduce the incidence and tragic outcomes of skin cancer.

Primary and secondary sunscreens

Sunscreens fall into 2 categories: 'primary' sunscreens and 'secondary' sunscreens. The Australian therapeutic goods legislation relies on the definition of primary and secondary sunscreens provided in the Australian/New Zealand Standard for sunscreens (AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification* for sunscreens) (the Sunscreen Standard) as reproduced below:

- **Primary sunscreen product**: Product that is represented as being primarily to protect the skin from UV radiation.
- **Secondary sunscreen product**: Product that is represented as having a primary function other than sun protection whilst providing some protection of the skin from UV radiation for example:
  - Skin care
    - moisturising products for face, hand and body that are secondary sunscreen products for dermal application including anti-wrinkle, anti-ageing and skin-whitening products.
    - sunbathing products that are secondary sunscreen products (e.g. oils, creams or gels) including products for tanning without sun, and "after-sun" skin care products.
  - Colour cosmetic products that are secondary sunscreen products and are either tinted base or foundation (make-up), or products intended for application to the lips (tinted or untinted).

Therapeutic sunscreens

Under the *Therapeutic Goods Act 1989* (the Act) and supporting legislation, sunscreen products that are regulated as therapeutic goods (also known as "**therapeutic sunscreens**") by the TGA include:

- **Primary sunscreens**
- **Some secondary sunscreens**: Products with a primary purpose other than sun protection, that also contain sun screening agents but are not excluded (see below) from therapeutic goods legislation e.g. sunbathing and moisturising skin care products with an SPF over 15.

Many secondary sunscreen products are not considered to be therapeutic goods and are 'excluded' from therapeutic goods legislation. These product types are outlined under the *Therapeutic Goods (Excluded Goods) Determination 2018*. These include moisturisers with an SPF less than 15 and tinted foundations with an SPF up to 50+. These products must also meet certain criteria (such as not containing ingredients included in the Poisons Standard and compliance with the Sunscreen Standard). Ingredients in sunscreen products that are not considered to be therapeutic goods, are regulated under the Australian Industrial Chemicals Introduction Scheme (AICIS).

All therapeutic sunscreens must be included in the Australian Register of Therapeutic Goods (ARTG) to be supplied, imported, or exported in Australia. Most sunscreens are eligible for **listing** in the

ARTG, in accordance with the criteria of Schedule 4, item 7 of the *Therapeutic Goods Regulations 1990*, excerpt below:

Item No.	Therapeutic goods
7	sunscreen preparations for dermal application, if: (a) the claimed sun protection factor has been established by testing according to the method described in Australian/New Zealand Standard AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as in force from time to time; and (b) the performance statements and markings on the label comply with that Standard; and (c) the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and (d) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the sunscreen preparation—none of the requirements have been contravened; and (e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and (f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened

Listed therapeutic sunscreens are not pre-market evaluated by the TGA. Instead, they are included in the ARTG under section 26A of the Act, based on a number of sponsor certifications that their therapeutic good meets all legislative requirements, for example, they can only include TGA pre-approved ingredients and indications. Listed sunscreens must also comply with the Sunscreen Standard which specifies SPF and other testing and labelling requirements. The Sunscreen Standard is adopted by the TGA and referenced in the Regulations and Excluded Goods Determination.

It is also the legal responsibility of each sponsor to ensure that their sunscreen is safe for the purposes for which it is to be used. Listed therapeutic sunscreens are also required to be manufactured under the principles of Good Manufacturing Practice, and sponsors must have an appropriate system of pharmacovigilance and report to the TGA adverse reactions experienced by users. The requirements for therapeutic sunscreens are described in the Australian Regulatory Guidance for Sunscreens (ARGS).

If a sunscreen does not meet the eligibility criteria for listing in the ARTG provided by Schedule 4 to the Regulations (e.g. it contains ingredients that are not permitted for use in listed medicines), then it is required to be included in the ARTG as a registered good and undergo a full TGA pre-market evaluation of safety, quality, and efficacy.

Many overseas jurisdictions (such as in the European Union) regulate sunscreens as cosmetics, and only permit them to make cosmetic claims. However, in Australia, therapeutic sunscreens providing SPF 30 or higher can make high-level therapeutic indications referring to the prevention of skin cancer, while cosmetic sunscreens cannot make such claims.

Attachment 2: How are ingredients in therapeutic sunscreens regulated?

Sponsors of therapeutic sunscreens can only use pre-approved low risk ingredients included in the Therapeutic Goods (Permissible Ingredients) Determination for listed medicines. Any new ingredients must be evaluated for safety and quality and assessed as being low risk by the TGA before it can be added to this list.

The safety data for new ingredients must be comprehensive, covering both short-term (acute) and long-term (chronic) effects on human health and safety from exposure to the ingredients. The Australian Regulatory Guidelines for Sunscreens (ARGS) specify that sponsors must consider the safety of the substance across different population groups, as sunscreens are used by individuals of all ages, genders, and could be used frequently (daily) for extended periods.

The ARGS also refer to the Application requirements for new substances in listed medicines (ARNS) for more detailed guidance. The ARNS provides guidance for assessing toxicological data for substances for dermal use, such as sunscreens, and references methods in the Notes of guidance for the testing of cosmetic ingredients and their risk assessment, 11th revision (SCCS 2021). It also states that substances not restricted to adult use must discuss the relevance of Margin of Safety (MoS) calculations for children, considering the difference in skin surface area to body weight ratio. Additionally, the ARNS mentions that limited safety data is required if a substance is not absorbed beyond the stratum corneum and does not react with the skin in a hazardous way.

This process allows the TGA to ascertain whether a substance presents a sufficiently low risk to be permissible for use in listed medicines.

How is risk evaluated?

When considering the risks to human health and safety from the use of substances in therapeutic goods, including sunscreens, it is essential to consider their use in the context of hazard and exposure.

The hazard of a substance is defined by its intrinsic toxicity, characterised by the dosage and its short-term or long-term adverse effects on biological systems, with a critical factor being the identification of a toxicological threshold known as the 'No Observed Adverse Effect Level' (NOAEL) where no adverse effects are observed.

Exposure is the identification and characterisation of the contact between a product or substance and the host, in this case humans. For dermally applied products, the exposure can be either local or both local and systemic.

There are 2 broad areas of risk associated with dermally applied products, including sunscreens:

(1) adverse effects at or around the site of application/administration e.g. irritation and inflammation.
(2) adverse effects related to systemic effects following distribution of substances internally via ingestion, inhalation, or penetration/absorption though the skin, eyes, and other areas of the body.

Local intolerance of a dermally applied product may be thought as time-limited and self-identifiable, i.e. a product can be removed (washed) off the skin or flushed from the eyes, (skin surface removal/sloughing) and a person could readily identify irritation to the eyes, skin, and mucosal surfaces.

On the other hand, the adverse effects of the product on the human body when distributed internally to other tissues and organs and for varying periods of time may not be immediately obvious or not become apparent for many months or years after exposure. The TGA considers the systemic exposure as a critical determinant when considering the inherent risks from contact with dermally applied products, including sunscreens. The risk is assessed using a Margin of Safety (MoS) calculation described below.

Margin of Safety

When considering the risks to human health and safety from a wide range of substances, a Margin of Safety (MoS) approach is used by many regulators. The MoS compares the expected systemic exposure dose (SED) of a substance within the human population to a toxicological threshold, known as the 'No Observed Adverse Effect Level' (NOAEL). The NOAEL is the level at which no specific adverse effects were observed in humans or animals, adjusted for body weight. Typically, the NOAEL is derived from long-term, repeat-dose toxicity studies in animals. As such, the MoS value indicates the likelihood of an adverse health effect occurring under specific exposure conditions.

To correct for the uncertainty in the data, the internationally accepted methodology utilises a correction factor of 10 to account for interspecies differences between animals and humans, and a further correction factor of 10 for intraspecies differences to account for variations in the human population. These factors are multiplied together to arrive at a value of 100. Margins of Safety below 100 are generally considered unacceptable.[12] Moreover, as the MoS increases, the potential risk decreases.

Determining the adequacy of the MoS requires expert judgment, which is typically exercised on a case-by-case basis. This judgment should account for uncertainties in the risk assessment process, such as data completeness and quality, the nature and severity of the adverse effects, and intra/inter species variability.

The following formula is used to calculate the MoS:

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)}$$

Systemic Exposure Dose

The TGA has used the following formulas to calculate systemic exposure dose (SED) of dermally applied products, including sunscreen products. These are the same calculations described by the SCCS to calculate the SED in cosmetic products.

To determine the expected SED of a sunscreen ingredient in humans, exposure models generally consider the daily the amount of sunscreen applied per kg body weight, in combination with the dermal absorption potential (in %) and concentration of the substance under consideration. This is shown in the SCCS equations for calculation of SED (SCCS 2023), as below:

Method 1

$$SED = E_{product} \times \frac{C}{100} \times \frac{DA_p}{100}$$

Where:

SED (mg/kg bw/d)	Systemic Exposure Dose
$E_{product}$ (mg/kg bw/day)	Estimated daily exposure to a sunscreen product per kg body weight, based upon the amount applied and the frequency of application (Note: for calculated relative daily exposure levels

[12] The acceptable MoS cutoff should reflect the quality of safety data available. Acceptance of lower MoS values may be deemed appropriate when the NOAEL is based upon human toxicological data. Conversely, a requirement for higher MoS values may arise such as, in instances where the duration of the toxicological study does not adequately reflect the intended duration of exposure.

	for sunscreen lotion, an amount of **18 g/day** is used by SCCS and default body weight used is **60 kg**).
C (%)	Concentration of the substance under study in the finished sunscreen product on the application site
DA_p (%)	Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions

When dermal absorption potential is expressed in μg/cm^2 (not as a %) the estimated daily exposure to a sunscreen is evaluated based on the skin surface area sunscreen is applied to per kg body weight. This is then used in combination with the dermal absorption potential of the substance under consideration to determine the SED as shown in the calculation method 2 equation:

Method 2

$$SED = \frac{DA_a \times 10^{-3} \times SSA \times f_{appl}}{bw}$$

Where:

SED (mg/kg bw/d)	Systemic Exposure Dose
DA_a (μg/cm^2)	Dermal Absorption as an absolute amount absorbed (bioavailable) per surface area applied, resulting from an assay under in-use mimicking conditions
SSA (cm^2)	Skin Surface Area expected to be treated with the finished product (According to Table 4 in SCCS Guidance, the default SSA value used by the SCCS for sunscreen lotion is **17,500 cm^2**)
f_{appl} (day^{-1})	Frequency of application of the finished product (According to Table 4 in SCCS Guidance, the default frequency for sunscreen lotion used by the SCCS is **2 applications per day**)
bw (kg bw)	human body weight (the default value used by SCCS is **60 kg**)

Factors affecting exposure

Exposure can be characterised by the site of contact e.g. dermally applied sunscreen on skin; the period of time that the contact was in place; and whether that contact was a singular event, regular exposure over a short-term, e.g. hours or days, or regular exposure over a long-term, e.g. weeks or years. Exposure also characterises the level/concentration of specific substances at the site of contact and their distribution to other areas within the human body.

All manner of substances may be absorbed by the human body after contact or application (this is known as systemic exposure). How much is absorbed into the body is dependent on a number of factors related to the human body interface and the substance itself (see **Table 4**). Any systemic exposure of a substance, and adverse effects related to systemic effects must be considered when assessing the risk, and subsequent suitability for the use of a substance in humans.

Table 4. Factors affecting the absorption and subsequent systemic distribution of dermally applied substances

Human body interface	Substance
• Route of exposure: skin, eyes, nasal, respiratory, gastrointestinal, etc. • Integrity of the interface: irritated, inflamed, abraded, etc. • pH of the interface. • Contact time with the product or substance. • Enzymatic metabolism (e.g. metabolism into smaller molecules) or clearance of the substance at the site of contact. • Movement of the substance from the site of contact e.g. washing of the skin; flushing of the eyes; aspiration by the lungs; vomiting, transit and/or enzymatic degradation in the gastrointestinal tract following ingestion.	• Molecular weight • pKa • Lipophilicity (log KOW) • Photoreactivity/stability • Co-formulation with other substances that can affect absorption e.g. solvents that alter skin permeability. • Concentration • Vapour pressure

In general, small and lipophilic substances in contrast to large and hydrophilic substances are more likely to penetrate the skin and distribute systemically around the body. While some medicines are formulated to be absorbed into the body (e.g. transdermal patches), sunscreens are not, as their primary role is to provide either a physical barrier (reflector) to UV radiation e.g. zinc oxide and titanium dioxide, or absorb the UV radiation e.g. avobenzone and octocrylene, and prevent the penetration of this radiation through to deeper layers of the skin.

Attachment 3: Real world example comparing MoS calculations using ASEM and SCCS model

The following comparison provide a “real world” examples of the Margin of Safety (MoS) calculations employing the ASEM highest estimated daily sunscreen exposure (Option 1) and SCCS model (Option 2). Octocrylene has been selected for this comparative purpose as it is a common sunscreen active ingredient and has real data that can be used for these calculations.

The values used for the calculations below have been reported in the SCCS’s opinion on octocrylene, and are utilised solely for the purpose of this demonstration. These should not be construed as reflective of the TGA’s stance on the dermal absorption rate, NOAEL, MoS, or safety of octocrylene.

Dermal absorption data of octocrylene

The following variables have been reported in the SCCS opinion on octocrylene (SCCS 2021) and will be used to demonstrate the MoS calculations for the ASEM and SCCS model:

Variable/input	Value	Comment
NOAEL	76.5 mg/kg bw/d	Based on the animal studies reviewed, 76.5 mg/kg bw/d was considered by the SCCS as the NOAEL for octocrylene.
Concentration of ingredient (C, %)	10% w/w in formulation	Concentration of ingredient used to test dermal absorption. Based on study by Fabian and Landsiedel (2020)
Application thickness	3 mg formulation/cm^2	Based on study by Fabian and Landsiedel (2020)
Dermal absorption – percentage dermally absorbed (DA_p, %)	0.33%	The dermal absorption of 0.97 µg/cm^2 used by the SCCS corresponds to 0.33% of applied dose (mean + 1SD: 0.15% + 0.18%). This value is used in the Method 1 calculation.
Dermal absorption – absolute amount bioavailable (DA_a, µg/cm^2)	0.97 µg/cm^2	A dermal absorption of 0.97 µg/cm2 (mean + 1SD: 0.45 + 0.52 µg/cm2) was considered by SCCS as a worst-case scenario and was used by the SCCS in the SED and MoS calculations. This value is used in the Method 2 calculation.

SCCS method 1 (%) MoS calculation

$$SED = E_{product} \times \frac{C}{100} \times \frac{DA_p}{100} = \frac{18000\, mg/day}{60\, kg} \times \frac{10}{100} \times \frac{0.33}{100}$$
$$= 0.099\, mg/kg\, bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{76.5\, mg/kg\, bw/d}{0.099\, mg/kg\, bw/d} = \mathbf{772}$$

$E_{product}$: Estimated daily exposure per kg body weight (18 g/day sunscreen exposure and 60 Kg body weights are default values used by SCCS), C: Concentration, DA_p: Dermal Absorption

SCCS method 2 (µg/cm²) MoS calculation

$$SED = \frac{DA_a \times 10^{-3} \times SSA \times f_{appl}}{bw} = \frac{0.97\ \mu g/cm^2 \times 10^{-3} \times 17500\ cm^2 \times 2\ /\ day}{60\ kg}$$
$$= 0.566\, mg/kg\, bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{76.5\, mg/kg\, bw/d}{0.566\, mg/kg\, bw/d} = \mathbf{135}$$

DA_a: Dermal Absorption, SSA: Skin Surface Area, f_{appl}: Applications per day, bw: Body weight (SCCS default of 60kg)

ASEM method 1 (%) MoS calculation

$$SED = ASEM_{\text{highest estimated daily sunscreen exposure}} \times DA_p \times C$$
$$= 673\ mg/kg\ bw/day \times 0.33\ \% \times 10\% = 0.222\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{76.5\, mg/kg\, bw/d}{0.222\, mg/kg\, bw/d} = \mathbf{345}$$

DA_p: Dermal Absorption, C: Concentration

ASEM method 2 (µg/cm²) MoS calculation

$$SED = ASEM_{\text{highest estimated daily sunscreen exposure}} \times DA_a$$
$$= 336\ cm^2/kg\ bw/day \times 0.97\ \mu g/cm^2$$
$$= 326\ \mu g/kg\ bw/day = 0.326\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{76.5\, mg/kg\, bw/d}{0.326\, mg/kg\, bw/d} = \mathbf{235}$$

DA_a: Dermal Absorption

Differences in MoS between SCCS and ASEM

How dermal absorption data is reported	MoS (SCCS)	MoS (ASEM)
Method 1 (%)	**772**	**345**
Method 2 (μg/cm^2)	**135**	**235**

The SCCS model shows a substantial disparity in MoS values depending on whether dermal absorption is reported in as a percentage (method 1) or in μg/cm² (method 2). The difference is greater than 5 times. This difference arises from the default values used in method 1 and method 2 calculations.

In method 2, daily sunscreen usage is determined based on body surface area and application frequency. For this calculation, the SCCS assumes that sunscreen products are applied to the entire body of an adult (17,500 cm²) twice daily. Conversely, in method 1 calculations, a fixed amount of sunscreen usage is utilised in the calculation, regardless of skin surface area or application rate. For this calculation, the SCCS assumes sunscreen products are applied at a rate of 18 grams per day.

In contrast, the ASEM shows a less pronounced increase in MoS values when dermal absorption is reported as a percentage. The difference in MoS values is approximately 1.5 times. This difference arises because the octocrylene-containing formulation that was applied to the skin in the study reported by the SCCS was at a thickness of 3 mg/cm². In contrast, the application thickness used in the ASEM exposure scenarios was 2 mg/cm². This difference in application thickness (1.5 times) led to a corresponding 1.5 times disparity in MoS values when calculating the MoS based on dermal absorption reported in μg/cm² or as a percentage. It is reasonable to predict that if the octocrylene-containing formulation was applied at a thickness of 2 mg/cm², the MoS values derived from dermal absorption reported in percentage or μg/cm² would be similar. To demonstrate this, another theoretical example has been provided where the dermal absorption study used a formulation applied to the skin at 2mg/cm^2 (see Attachment 4).

The SCCS model tends to be more conservative than the ASEM when dermal absorption is reported in μg/cm² for all population groups. However, when reported as a percentage, the SCCS model is less conservative than the ASEM.

Attachment 4: Hypothetical example comparing MoS calculations using ASEM and SCCS model

The following comparison provides hypothetical examples of the Margin of Safety (MoS) calculations employing the ASEM highest estimated daily sunscreen exposure (Option 1) and SCCS model (Option 2) when the test formulation is applied at a thickness of 2 mg/cm^2 in the dermal absorption study. This application thickness is deemed optimal for dermal absorption studies involving sunscreen active ingredients, aligning with the mandatory testing thickness for determining the Sun Protection Factor (SPF).

The dermal absorption data for a hypothetical ingredient referred to as "Ingredient A" are based on data reported in from a skin absorption study that has been rounded to the nearest whole number to simplify the calculations. The No Observed Adverse Effect Level (NOAEL) for Ingredient A is also a synthesised hypothetical value for the purposes of this demonstration.

Dermal absorption data of Ingredient A

The following variables will be used to demonstrate the MoS calculations for the ASEM and SCCS model:

Variable/input	Value	Comment
NOAEL	300 mg/kg bw/d	Hypothetical value of a NOAEL derived from animal studies.
Concentration of ingredient (C, %)	10% w/w in formulation	Concentration of ingredient used to test dermal absorption. Based on data reported in a skin absorption study.
Application thickness	2 mg/cm^2	Based on data reported in a skin absorption study.
Dermal absorption – percentage dermally absorbed (DA_p, %)	4 %	Based on data reported in a skin absorption study rounded to the nearest whole number. This value is used in the Method 1 calculation.
Dermal absorption – absolute amount bioavailable (DA_a, μg/cm^2)	8 μg/cm^2	Based on data reported in a skin absorption study rounded to the nearest whole number. This value is used in the Method 2 calculation.

SCCS method 1 (%) MoS calculation

$$SED = E_{product} \times \frac{C}{100} \times \frac{DA_p}{100} = \frac{18000\ mg/day}{60\ kg} \times \frac{10}{100} \times \frac{4}{100} = 1.200\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{300\ mg/kg\ bw/d}{1.200\ mg/kg\ bw/d} = \mathbf{250}$$

$E_{product}$: Estimated daily exposure per kg body weight (18 g/day sunscreen exposure and 60 Kg body weights are default values used by SCCS), C: Concentration, DA_p: Dermal Absorption

SCCS method 2 (µg/cm²) MoS calculation

$$SED = \frac{DA_a \times 10^{-3} \times SSA \times f_{appl}}{bw} = \frac{8\ \mu g/cm^2 \times 10^{-3} \times 17500\ cm^2 \times 2\ /\ day}{60\ kg} = 4.667\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{300\ mg/kg\ bw/d}{4.667\ mg/kg\ bw/d} = \mathbf{64}$$

DA_a: Dermal Absorption, SSA: Skin Surface Area, f_{appl}: Applications per day, bw: Body weight (SCCS default of 60kg)

ASEM method 1 (%) MoS calculation

$$SED = ASEM_{\text{highest estimated daily sunscreen exposure}} \times DA_p \times C = 673\ mg/kg\ bw/day \times 4\% \times 10\% = 2.692\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{300\ mg/kg\ bw/d}{2.692\ mg/kg\ bw/d} = \mathbf{111}$$

DA_p: Dermal Absorption, C: Concentration

ASEM method 2 (µg/cm²) MoS calculation

$$SED = ASEM_{\text{highest estimated daily sunscreen exposure}} \times DA_a = 336\ cm^2/kg\ bw/day \times 8\ \mu g/cm^2 = 2688\ \mu g/kg\ bw/day = 2.688\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{300\ mg/kg\ bw/d}{2.688\ mg/kg\ bw/d} = \mathbf{111}$$

DA_a: Dermal Absorption

Differences in MoS between SCCS and ASEM

How dermal absorption data is reported	MoS (SCCS)	MoS (ASEM)
Method 1 (%)	**250**	**111**
Method 2 (μg/cm^2)	**64**	**111**

Like the octocrylene example presented in Attachment 3, the SCCS model again shows a substantial disparity in MoS values depending on whether dermal absorption is reported as a percentage (method 1) or in μg/cm² (method 2). The MoS value is approximately 4 times higher when dermal absorption is reported as a percentage.

It is generally acknowledged that MoS values under 100 are deemed unsatisfactory from a safety standpoint.[13] In this example, the hypothetical Ingredient A would be considered safe using the SCCS calculation if dermal absorption data was reported as a %, but unsafe if reported in μg/cm². Consequently, even though both datasets originate from the same study, the SCCS approach can result in significantly different regulatory outcomes.

In comparison, the ASEM exhibits identical MoS values irrespective of whether dermal absorption is quantified in μg/cm² or as a percentage when the test formulation is applied at a thickness of 2 mg/cm² in the dermal absorption study. This can therefore yield more consistent regulatory outcomes that are less affected by the way dermal absorption data is reported.

[13] The acceptable MoS cutoff should reflect the quality of safety data available. Acceptance of lower MoS values may be deemed appropriate when the NOAEL is based upon human toxicological data. Conversely, a requirement for higher MoS values may arise, such as, in instances where the duration of the toxicological study does not adequately reflect the intended duration of exposure.

Attachment 5: ASEM Calculations Microsoft Excel file

Attachment 5 can be accessed via the TGA consultation hub.

All the calculations for the estimated daily sunscreen exposure for each age group and scenario, and the combinations of the ASEM scenarios (including how Australian skin surface area and body weight data have been used) are provided in the **ASEM Calculations Microsoft Excel file** (see tab '2. ASEM calculations').

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