

**From:** s22  
**To:** s22  
**Cc:** s22; s22; s22; s22  
**Subject:** RE: Sunscreen ingredients [SEC=OFFICIAL]  
**Date:** Wednesday, 24 July 2024 2:27:23 PM  
**Attachments:** [image001.png](#)  
[ATT00001.png](#)  
[ATT00002.png](#)  
[ATT00003.png](#)  
[ATT00004.png](#)  
[ATT00005.jpg](#)

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Many thanks s22 and also s22 and s22 for your time today.

s22  
s22

Cancer Council Australia  
 Eora Country  
 T: s22 | M: s22  
 Address: 320 Pitt Street, Sydney NSW 2000 Australia.  
 Website: [www.cancer.org.au](http://www.cancer.org.au)



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**From:** s22 s22@health.gov.au  
**Sent:** Wednesday, July 24, 2024 2:16 PM  
**To:** s22 s22@cancer.org.au  
**Cc:** s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22n@cancer.org.au>; s22 <s22@cancer.org.au>  
**Subject:** Sunscreen ingredients [SEC=OFFICIAL]

Some people who received this message don't often get email from s22@health.gov.au. [Learn why this is important](#)

Hi s22 and s22

As promised, here is the [Australian regulatory guidelines for sunscreens](#). Page 5-10

discusses the categorisation of therapeutic sunscreen vs exempt (do not need to be on the ARTG, but still therapeutic goods) and excluded (not therapeutic goods) sunscreen.

In addition, I mentioned there are certain sponsor certifications regarding products that sponsors must make under *the Therapeutic Goods Act 1989* (paragraph 26(1)(d) of the Act outlines the requirement for applicant certification relating to safety of the product for listed medicines).

Regarding your query about which ingredients we are reviewing (as noted on p 41 in the TGA's current [public consultation on developing an Australian Sunscreen Exposure Model](#))

I am happy to share with you that we are undertaking a literature review of current information relevant to the risk assessment of the following seven sunscreen active ingredients available for use in therapeutic sunscreens in Australia:

- Butyl methoxydibenzoylmethane (avobenzene)
- Ethylhexyl triazone
- Homosalate
- Octocrylene
- Octinoxate
- Oxybenzone
- Phenylbenzimidazole sulfonic acid

As I mentioned, we also intend to use the final sunscreen exposure model to establish a regulatory limit for benzophenone when present as a degradant in octocrylene containing sunscreens, following the outcome of our consultation last year in August.

Best regards,

s2

s22  
s22

**Complementary & OTC Medicines Branch**

Medicines Regulation Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 | E: s22@health.gov.au

Location: Level 1, 27 Smerger Drive, Fairbairn 2609

PO Box 100, Canberra ACT 2601, Australia

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immediately and delete all copies of this transmission."

**From:** s22  
**To:** s22  
**Subject:** FOI communication with CCA regarding 4MBC [SEC=OFFICIAL]  
**Date:** Wednesday, 16 October 2024 12:40:00 PM  
**Attachments:** [RE Meeting Request Sunscreen Ingredients - Confidential SECOFFICIAL.msg](#)  
[Sunscreen ingredients SECOFFICIAL.msg](#)  
[Sunscreen ingredients SECOFFICIAL.msg](#)  
[image001.png](#)  
[Sunscreen ingredients SECOFFICIAL.msg](#)

---

s22  
s22

**Complementary & OTC Medicines Branch**

Medicines Regulation Division | Health Products Regulation Group  
Australian Government Department of Health and Aged Care  
T: s22 | E: s22@health.gov.au  
Location: Level 1, 27 Sherger Drive, Fairbairn 2609  
PO Box 100, Canberra ACT 2601, Australia

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**From:** s22  
**To:** s22; s22; s22  
**Cc:** s22; s22  
**Subject:** RE: Meeting Request : Sunscreen Ingredients - Confidential [SEC=OFFICIAL]  
**Date:** Tuesday, 16 July 2024 9:19:00 AM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[image005.jpg](#)

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Hi All, sorry I have been unwell all week, but back now.

Happy to meet with them – I can respond directly.

s22 note we've recently requested to include 4-MBC in a future tox team review – I will advise if there are any outcomes from the meeting to be aware of regarding prioritisation with other tox work.

Speak soon,

s2

---

**From:** s22 <s22@health.gov.au>  
**Sent:** Monday, July 15, 2024 12:21 PM  
**To:** s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>  
**Cc:** s22 <s22@health.gov.au>  
**Subject:** RE: Meeting Request : Sunscreen Ingredients - Confidential [SEC=OFFICIAL]

Hi s2 and s22

I'm also not sure if I need to attend this meeting. I think s22 has my name as I met with them previously about some communication matters, but I don't think I would be able to add anything to this meeting.

Many thanks

s22

---

**From:** s22 <s22@health.gov.au>  
**Sent:** Monday, July 15, 2024 12:14 PM  
**To:** s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>  
**Cc:** s22 <s22@health.gov.au>  
**Subject:** RE: Meeting Request : Sunscreen Ingredients - Confidential [SEC=OFFICIAL]

Thanks s22

I'll let s2 and his team take the lead on this request, as they are likely to have more recent interactions with the Cancer Council.

Regards

s22

---

**From:** s22 <s22@health.gov.au>  
**Sent:** Monday, July 15, 2024 11:54 AM  
**To:** s22 <s22@health.gov.au>; s22 <s22@health.gov.au>  
**Cc:** s22 <s22@health.gov.au>  
**Subject:** FW: Meeting Request : Sunscreen Ingredients - Confidential [SEC=OFFICIAL]

Hi s22 and s2

I just received this from s22 but wonder whether it might be better for one or both of you to participate rather than me? I don't think I'd have much to contribute (and also have woeful availability!). If you're happy to be involved I can reply to s22 and include you both into the response.

Kind regards,

s22

---

**From:** s22 s22@cancer.org.au  
**Sent:** Monday, July 15, 2024 11:44 AM  
**To:** s22 s22@health.gov.au; s22  
s22@health.gov.au  
**Cc:** s22 <s22@cancer.org.au>; s22  
<s22@cancer.org.au>  
**Subject:** Meeting Request : Sunscreen Ingredients - Confidential

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Hi s22 and s22

I hope this note finds you both well.

I wondered if you would be available to meet with myself and some colleagues to discuss some queries we have around TGA's position on the sunscreen ingredients ethylhexyl triazone and 4-methylbenzylidene camphor, noting that it is different to US and UK regulators' positions.

Would you have availability after 1pm on Monday 22<sup>nd</sup> or between 12-4pm on Wednesday 24<sup>th</sup> July?

Many thanks,

s22

s22

s22

Cancer Council Australia

Eora Country

T: s22 | M: s22

Address: 320 Pitt Street, Sydney NSW 2000 Australia.

Website: [www.cancer.org.au](http://www.cancer.org.au)



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[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[image005.png](#)  
[image006.jpg](#)

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Good morning s22

My colleague s22 forwarded me your email – s22 the Sunscreen Taskforce that is leading the consultation on the Australian Sunscreen Exposure Model and would be very happy to speak with you and your colleagues.

Please let me know if this virtual meeting time works for you. My other colleague s22 who is currently s22 the Complementary Medicines Evaluation time that manages the list of permitted sunscreen ingredients, and s22 who is working with me in the taskforce may also attend if available.

Best regards,

s

s22

s22

Complementary & OTC Medicines Branch

Medicines Regulation Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 | E: s22 @health.gov.au s22 @health.gov.au>

Location: Level 1, 27 Sherger Drive, Fairbairn 2609

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Microsoft Teams Need help? <<https://aka.ms/JoinTeamsMeeting?omkt=en-US>>

Join the meeting now <[https://teams.microsoft.com/l/meetup-join/19%3ameeting\\_YzU5YzYwNDAtNWU4Yy00ODdjLWE1YmUtMjJjNWU4NjQ4YmJm%40thread.v2/0?context=%7b%22Tid%22%3a%2234a3929c-73cf-4954-abfe-147dc3517892%22%2c%22Oid%22%3a%224ba7a3eb-4399-4bf9-9d89-2b7b9e866e81%22%7d](https://teams.microsoft.com/l/meetup-join/19%3ameeting_YzU5YzYwNDAtNWU4Yy00ODdjLWE1YmUtMjJjNWU4NjQ4YmJm%40thread.v2/0?context=%7b%22Tid%22%3a%2234a3929c-73cf-4954-abfe-147dc3517892%22%2c%22Oid%22%3a%224ba7a3eb-4399-4bf9-9d89-2b7b9e866e81%22%7d)>

Meeting ID: 484 939 471 510

Passcode: WcCioP

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Dial in by phone

+61 2 8318 0010,,491670550# <tel:+61283180010,,491670550> Australia, Sydney

Find a local number <<https://dialin.teams.microsoft.com/021e9008-ebfe-4add-b865-cf7f806c0b85?id=491670550>>

Phone conference ID: 491 670 550#

Join on a video conferencing device

Tenant key: health-au@m.webex.com

Video ID: 133 589 830 7



More info <<https://www.webex.com/msteams?confid=1335898307&tenantkey=health-au&domain=m.webex.com>>

For organizers: Meeting options <[https://teams.microsoft.com/meetingOptions/?organizerId=4ba7a3eb-4399-4bf9-9d89-2b7b9e866e81&tenantId=34a3929c-73cf-4954-abfe-147dc3517892&threadId=19\\_meeting\\_YzU5YzYwNDAwNWU4Yy00ODdjLWE1YmUtMjliNWU4NjQ4YmJm@thread.v2&messageId=0&language=en-US](https://teams.microsoft.com/meetingOptions/?organizerId=4ba7a3eb-4399-4bf9-9d89-2b7b9e866e81&tenantId=34a3929c-73cf-4954-abfe-147dc3517892&threadId=19_meeting_YzU5YzYwNDAwNWU4Yy00ODdjLWE1YmUtMjliNWU4NjQ4YmJm@thread.v2&messageId=0&language=en-US)> | Reset dial-in PIN <<https://dialin.teams.microsoft.com/usp/pstnconferencing>>

Privacy and security <<https://www.health.gov.au/using-our-websites/website-privacy-policy/privacy-notice-for-ms-teams-recordings-and-transcripts>>

---

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Sent: Monday, July 15, 2024 11:44 AM  
To: s22 <s22@health.gov.au <mailto:s22@health.gov.au>>; s22 <s22@health.gov.au <mailto:s22@health.gov.au>>  
Cc: s22 <s22@cancer.org.au <mailto:s22@cancer.org.au>>; s22 <s22@cancer.org.au <mailto:s22@cancer.org.au>>  
Subject: Meeting Request : Sunscreen Ingredients - Confidential

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Hi s22 and s22

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Would you have availability after 1pm on Monday 22nd or between 12-4pm on Wednesday 24th July?

Many thanks,

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s22  
s22

Cancer Council Australia

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T: s22 | M: s22

Address: 320 Pitt Street, Sydney NSW 2000 Australia.

Website: [www.cancer.org.au](http://www.cancer.org.au) <<https://www.cancer.org.au>>

<<https://www.facebook.com/pages/Cancer-Council-Australia/79994358678>> <<https://www.instagram.com/cancercouncil/>>

<[https://www.linkedin.com/company/cancer-council-australia\\_2/](https://www.linkedin.com/company/cancer-council-australia_2/)> <<https://twitter.com/CancerCouncilOz>>

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**To:** s22 @cancer.org.au  
**Cc:** s22; s22; s22 @cancer.org.au; s22 @cancer.org.au  
**Subject:** Sunscreen ingredients [SEC=OFFICIAL]  
**Date:** Wednesday, 24 July 2024 2:16:00 PM  
**Attachments:** image001.png

---

Hi s22 and s22

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Best regards,

s22

s22  
s22

**Complementary & OTC Medicines Branch**

Medicines Regulation Division | Health Products Regulation Group  
Australian Government Department of Health and Aged Care

T: s22 E: s22 @health.gov.au

Location: Level 1, 27 Smerger Drive, Fairbairn 2609

PO Box 100, Canberra ACT 2601, Australia

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s22

---

**Subject:** FW: Australian Sunscreen Exposure Model [SEC=OFFICIAL]

**OldPM:** Australian Sunscreen Exposure Model [SEC=OFFICIAL]

---

**From:** s22

**Sent:** Monday, May 13, 2024 10:42 AM

**To:** s22@cancervic.org.au

**Cc:** s22 <s22@health.gov.au>

**Subject:** Australian Sunscreen Exposure Model [SEC=OFFICIAL]

Dear s22






Thank you again for your time on the phone this morning and for your suggestion to present to and discuss with the National Skin Cancer Committee on the work the TGA is undertaking on sunscreens.

In summary, the TGA is looking for advice to develop a sunscreen skin exposure model to help assess the safety risk of sunscreen ingredients.

We've developed some theoretical real world use scenarios that could be used to estimate potential worst-case sunscreen use (see draft below for pictorial representation). For example, the first scenario would estimate sunscreen use to hands and face twice a day for the work week for 260 days/year, while the last scenario shows full body sunscreen use (5mL/limb = 35mL whole body, for 4 applications per day, for 26 days/year during swimming season). These are not mutually exclusive scenarios and can be combined to estimate theoretical yearly sunscreen use for a person.

Please note this is still draft and under development so we would appreciate if it were not distributed outside the committee/Cancer Council Australia.

# Scenarios for use and skin surface area

<p><b>Scenario 1</b> <b>LIMITED</b> Limited sun exposure Limited sunscreen use</p>	<p><b>Scenario 2</b> <b>MODERATE</b> Frequent sun exposure Limited sunscreen use</p>	<p><b>Scenario 3</b> <b>HEAVY</b> Extended sun exposure Specific sunscreen use</p>	<p><b>Scenario 4</b> <b>INTENSIVE</b> Full day of sun exposure Specific sunscreen use</p>	<p><b>Scenario 5</b> <b>EXTREME</b> Full day of sun exposure Extensive sunscreen use</p>
				
<p>Infrequent exposure, Applying 1-2 per day 5 x 52 = 260 days/yr</p>	<p>Frequent exposure (4h/d), Applying 1-2 per day 5 x 52 = 260 days/yr</p>	<p>Extended exposure (8 h/d), Occupational/Sporting Applying 1-3 per day 5 x 52 = 260 days/yr</p>	<p>Long day in the sun (beach) SUN SMART Specific &amp; regular application Applying 1-4 per day Swim season. 26 days/yr</p>	<p>Day at the beach Minimal clothing Applying 1-4 per day Swim season. 26 days/yr</p>
<p>General street/work attire. Long-sleeved/legged clothing, covered footwear</p>	<p>General street/work/sport attire. Short-sleeved/legged clothing, no hat, covered footwear</p>	<p>Occupational/sporting clothing, hat, long-sleeved shirt and pants, covered footwear.</p>	<p>Swimmers, board shorts, long-sleeved rash top, hat, no footwear.</p>	<p>Minimal clothing Swimming briefs or bikini only</p>

Please let me know if the following times are suitable for a virtual meeting. I think 1 hour will be sufficient:

Day	Time	Yes/No
-----	------	--------

Wednesday 15 May	9-5	
Thursday 16 May	9-5	
Friday 17 May	(Anytime except 12:30-2:30pm)	

I apologise for the tight timeframes. We are planning to undertake a public consultation next month and would value the Cancer Council's views before we go public.

On a separate note, this is the link to the latest from the TGA's compliance team on [Listed aerosol sunscreen products](#).

I look forward to hearing from you.

Best regards,

s22

s22

### Complementary & OTC Medicines Branch

Medicines Regulation Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 | E: s22 [@health.gov.au](mailto:s22@health.gov.au)

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**From:** [Complementary Medicines](#)  
**To:** s22  
**Subject:** FW: Cancer Council Australia submission to TGA consultation on changes to the permissible ingredients determination [SEC=OFFICIAL]  
**Date:** Thursday, 14 September 2023 4:59:58 PM  
**Attachments:** [ATT00001.jpg](#)  
[2023-09-14 TGA Changes to permissible low risk ingredients - CCA letter.pdf](#)

---

**From:** s22 <s22@cancer.org.au>  
**Sent:** Thursday, 14 September 2023 3:52 PM  
**To:** Complementary Medicines <complementary.medicines@health.gov.au>  
**Subject:** Cancer Council Australia submission to TGA consultation on changes to the permissible ingredients determination

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

To Whom it May Concern,

On behalf of s22 of Cancer Council Australia, please see attached a letter to the TGA in response to the open consultation on proposed changes to the permissible ingredients determination - low-negligible risk, pertaining to safe levels of benzophenone.

Cancer Council welcome the opportunity to discuss the consultation outcomes further with the TGA.

If you can please acknowledge receipt of this letter as part of the consultation process that would be appreciated.

Kind regards

s22

s22 | s22  
Cancer Council Australia  
Eora Country  
Level 14, 477 Pitt Street  
T: s22 | M: s22  
Address: 320 Pitt Street, Sydney NSW 2000 Australia.  
Website: [www.cancer.org.au](http://www.cancer.org.au)



Please note my workdays are Monday - Thursday.



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14 September 2023

Complementary Medicines Evaluation Section  
Therapeutic Goods Administration  
Department of Health and Aged Care  
By email: [listed.medicines@health.gov.au](mailto:listed.medicines@health.gov.au)

**CONSULTATION: 2023 – 2024 Proposed changes to the Permissible Ingredients Determination –  
Low-negligible risk: 3. Safe levels of benzophenone**

Thank you for the opportunity to comment on the Therapeutic Goods Administration (TGA) consultation on proposed changes to the requirements of ingredients used in listed (low-risk medicines); specifically, Item 3: 'Safe levels of benzophenone'.

Cancer Council Australia wishes to thank the TGA for referencing Cancer Council recommendations for sunscreen application in contributing to the development of the safe Permitted Daily Exposure (PDE) concentration calculation of benzophenone.

Cancer Council would like to formally note that we do not recommend sunscreen as the only method of protection against UV, even if the UV is 3 or above every day of the year. We strongly encourage Australians to use the five forms of sun protection, being:

- slipping on sun protective clothing
- slopping on SPF30 or above broad-spectrum water-resistant sunscreen
- slapping on a broad brim hat
- seeking shade when possible, and
- sliding on sunglasses.

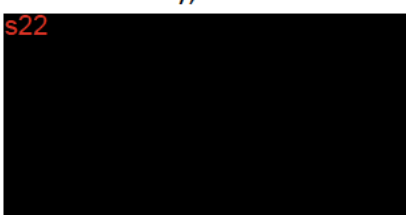
The use of the calculation of 35ml of sunscreen applied to the skin 4 times (140ml) a day (as per the consultation document pg.24) is not an accurate reflection on the full breadth of our above recommended sunscreen application and sun protection measures, as it suggests that sunscreen is the only form of skin protection, and that 140ml of sunscreen would be used every day.

We support the efforts to raise quality, safety and efficacy concerns for the use of products containing octocrylene and benzophenone and note that sunscreen is not the only listed medicine that may contain benzophenone. We are concerned that as presented, the proposed changes could increase the risk of harmful exposure to UV due to a reduction in consumer confidence in, and decreased use of, sunscreen.

Cancer Council would welcome the opportunity to continue to work with the TGA to ensure all Australians maintain confidence in sunscreen and continue to regularly use all five forms of sun protection.

Yours sincerely,

s22





# Note for file

## Purpose

This form should be:

- used to record details of meetings (where there are no formal minutes), discussions, telephone conversations, or other events that may be part of a decision making process; and
- completed electronically and saved to the relevant file in TRIM.

<b>Date and time</b>	1 April 2020
<b>Type of event</b> (e.g. meeting/ telephone conversation)	Background research
<b>Topic</b>	Background search on potential safety issues associated with sunscreen application on broken skin

## Participants

(for internal participants include name and position, for external participants include name, position organisation and contact details)

Name	Details
s22	s22, Listing Compliance Section
s22	s22, Listing Compliance Section

## Background

The ARGS states, 'the information on the label of a sunscreen must include the required warning statements as included in the RASML. The labels of both primary and secondary therapeutic sunscreens should include warning statements to the effect that the product should be kept out of the eyes and *should not be used on broken, damaged or diseased skin*'. However, it does not appear that this warning statement is a requirement in the legislation (sources checked: RASML, 26BB, Advertising Code, Sunscreen Standard). This prompted a background search for evidence to suggest that application of sunscreen to broken/damaged/diseased skin is a safety concern.

I performed the following searches in Ovid/Medline using the following terms:

- Sunscreen or sunscreens agents AND broken skin or diseased skin or damaged skin AND acute phase reaction or reaction or hypersensitivity or allergy or urticarial or dermatitis or skin reaction or anaphylaxis --> no relevant results
- Sunscreen or sunscreens agents AND broken skin or diseased skin or damaged skin AND absorption or subcutaneous absorption or skin absorption or systemic circulation or bloodstream or blood circulation --> two potentially relevant results
  - o Safety evaluation of sunscreen formulations containing titanium dioxide and zinc oxide nanoparticles in UVB sunburned skin: an in vitro and in vivo study (Monteiro-Riviere et al 2011): concluded that UVB-damaged skin slightly enhanced TiO<sub>2</sub> NP or ZnO penetration in sunscreen formulations but no transdermal absorption was detected.
  - o Study on penetration of titanium dioxide (TiO<sub>2</sub>) nanoparticles into intact and damaged skin in vitro (Senzui et al 2010): concluded that no penetration of TiO<sub>2</sub> was observed in intact or stripped skin and did not penetrate into dermis or viable epidermis
  - o Focus on skin as a possible port of entry for solid nanoparticles and the toxicological impact (Smijts et al 2010): note that only the abstract was available for this review paper. It states 'NP interactions with epidermal and dermal cells may cause cytotoxicity and undesired immune responses, especially in damaged skin', however it does not elaborate further.

Issues and  
investigation

#	Searches	Results
1	sunscreen.mp. or Sunscreening Agents/	70
2	Acute-Phase Reaction/ or reaction.mp.	13589
3	broken skin.mp.	
4	allergy.mp. or Hypersensitivity/	1064
5	Dermatitis, Phototoxic/ or Dermatitis, Allergic Contact/ or Dermatitis, Contact/ or Dermatitis, Photoallergic/ or dermatitis.mp.	901
6	Urticaria/ or urticaria.mp.	183
7	Anaphylaxis/ or anaphylaxis.mp.	299
8	damaged skin.mp.	11
9	skin reaction.mp.	38
10	diseased skin.mp. or Skin Diseases/	587
11	2 or 4 or 5 or 6 or 7	15522
12	3 or 8 or 10	588
13	1 and 11 and 12	

#	Searches	Results
1	sunscreen.mp. or Sunscreening Agents/	7018
2	broken skin.mp.	84
3	damaged skin.mp.	1156
4	diseased skin.mp. or Skin Diseases/	58708
5	2 or 3 or 4	59870
6	absorption.mp. or Subcutaneous Absorption/ or Skin Absorption/ or Absorption/	313734
7	systemic circulation.mp.	8000
8	bloodstream.mp.	21644
9	Blood Circulation/ or circulation.mp.	310485
10	6 or 7 or 8 or 9	639609
11	1 and 5 and 10	16

Uptodate:

### Inorganic (mineral) filters

The available evidence suggests that most sunscreens have an excellent safety profile and are without significant systemic absorption. However, the integration

of titanium dioxide and zinc oxide nanoparticles into sunscreens has raised questions regarding their potential percutaneous penetration and toxicity. Although some in vitro studies indicated that nanoparticles of titanium dioxide may induce the generation of reactive oxygen species with or without UV irradiation, several in vivo and in vitro studies have provided evidence that nanoparticulate titanium dioxide and zinc oxide applied to intact skin do not penetrate beyond the stratum corneum or at most show an insignificant dermal penetration... An in vivo study of zinc oxide penetration and cellular metabolic changes found that **zinc oxide nanoparticles did not penetrate into the epidermis of either intact skin or skin with impaired barrier** after a six-hour application with or without occlusion.

#### **Organic (chemical) filters**

Information on systemic absorption of organic sunscreen ingredients is limited... The US FDA sponsored an open-label, randomized, four-group, parallel study to determine the systemic exposure of active ingredients (avobenzone, oxybenzone, octocrylene, and ecamsule)...the authors concluded that while these findings support the need for further studies to determine the clinical significance of systemic exposure to sunscreens, they do not suggest that individuals should refrain from using sunscreen.

#### **Irritant and allergic reactions**

Adverse reactions from sunscreen ingredients have been reported and include allergic and irritant contact dermatitis, phototoxic and photoallergic reactions, contact urticaria, and rare anaphylactic reactions. Oxybenzone, the most widely used UVA filter worldwide, is the most frequent cause of sunscreen-induced photoallergic contact dermatitis. However, **the estimated rate of contact sensitization to oxybenzone-containing products is <0.1 percent**. In a study of approximately 24,000 patients patch tested by the North American Contact Dermatitis Group between 2001 and 2010, only 0.9 percent were sensitized to sunscreens. The top three allergens in sunscreens were benzophenone-3, DL-alpha-tocopherol, and fragrances.

#### **Decisions**

Overall, there is a lack of evidence to suggest that the application of sunscreen to broken, damaged or diseased skin poses a safety concern. Furthermore, as the warning statement does not appear to be a requirement in the legislation, it would be difficult to argue that a lack of warning statement is a breach.

As such, I recommend not pursuing the lack of warning statement regarding use in broken/damaged/diseased skin in the Proposal to Cancel notice.

#### **Author details** (include contact details and date note prepared)

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Note prepared on 1 April 2020