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

Pre-meeting Brief on Agenda Papers

Joint Advisory Committee on Chemicals and Medicines Scheduling (Joint ACMS-ACCS) #41

17 SEPTEMBER 2025

Item	Substance	Issues
2.3	**Homosalate** (Delegate initiated)	**Proposal** • The Delegate has initiated a proposal to create a new CAUTION (Schedule 5) entry for homosalate with certain exemptions based on concentration, use and applications site and age. The proposal is based on the TGA's Safety Review of Seven Active Sunscreen Ingredients (TGA Safety Review) and an evaluation on homosalate published by the Australian Industrial Chemicals Introduction Scheme (AICIS) in December 2024. • Three options for creating a new schedule 5 entry for homosalate have been proposed with certain exemptions as listed below. o Option 1 exempts all therapeutic sunscreens and cosmetic preparations containing up to 0.28% homosalate o Option 2 exempts therapeutic sunscreens and cosmetic preparations that are for face and hand applications when containing up to 0.68% and 4.35% holomosalate, respectively. o Option 3 exempts therapeutic sunscreens and cosmetic preparations for face and hand applications in adults when containing up to 2.7% holomosalate. **Delegate's reasons for the proposed changes** • Homosalate is extensively used as a UV filter in therapeutic and cosmetic sunscreen products to enhance SPF and broad-spectrum protection. It is also used in lip balms, face creams, and fragrances, with annual usage exceeding 169 tonnes. Most Australian sunscreens contain homosalate and/or octocrylene. • Homosalate penetrates skin and is systemically absorbed, with detection in plasma and breast milk. Animal studies suggest potential effects on kidneys (with a LOAEL of 60 mg/kg bw/day and an adjusted NOAEL of 10 mg/kg bw/day), fertility, and development. Its metabolite, salicylic acid, is linked to developmental toxicity. • Homosalate interacts with hormone receptors, indicating possible endocrine disruption at low potency.

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Australian Sunscreen Exposure Model (ASEM) estimated a concentration of 0.28% to maintain a MoS of 100 for long-term daily use, and an acceptable SED at 0.1 mg/kg bw/day.
For international jurisdictions,

US FDA: Approved up to 15% in OTC sunscreen drug products; not classified as GRASE due to insufficient safety data.
EU: From 1 Jan 2025, restricted to maximum at 7.34% in face products; not allowed in spray products; regulated as a cosmetic, not a therapeutic good.
New Zealand, Japan and ASEAN Cosmetic Directive Annex VII: Permitted in cosmetics up to 10%.

<u>Background and challenges of implementation</u>

Homosalate is not currently scheduled and has not been previously considered for scheduling.
Homosalate, present at 4-15% in sunscreens and up to 10% in cosmetics, poses potential systemic and genotoxic risks requiring careful regulation.
Australia’s high skin cancer rates drive daily sunscreen use, but regulatory changes may reduce confidence and usage.
Inclusion of homolsate in Schedule 5 would effectively ban its use in sunscreens, likely reducing consumer confidence. Industry indicated it would not market products requiring a “CAUTION” label.
Proposed scheduling may increase costs, reduce availability of therapeutic sunscreens, and erode consumer trust.

<u>Consultation</u>

A total of 39 submissions were received as below
<table>
<tr><th></th><th>supported</th><th>partially supported</th><th>opposed</th></tr>
<tr><td>Option 1</td><td>20 (17)</td><td>2(2)</td><td>15(15)</td></tr>
<tr><td>Option 2</td><td>2(2)</td><td>2(2)</td><td>19(19)</td></tr>
<tr><td>Option 3</td><td>1(1)</td><td>1(1)</td><td>21(21)</td></tr>
<tr><td colspan="4">(): provided written justification</td></tr>
</table>
The main points in general support of restricting use of homosalate are:

homosalate provides only UVB protection, not UVA, offering negligible benefit while posing endocrine, fertility, and developmental risks.
metabolites are mutagenic.

These stakeholders proposed a 0.28% limit for all sunscreens, safer zinc oxide based products, clearer labelling, removing therapeutic/non-therapeutic distinctions and alignment with international restrictions.

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</table>

Item	Substance	Issues

		• Submissions in general opposition of restricting use of homosalate stated:
		  ○ including homosalate in Schedule 5 would effectively ban its use in sunscreens, likely reducing consumer confidence.
		  ○ TGA's risk assessment is overly conservative, relying on limited data and unrealistic assumptions (e.g., 9 L annual use vs 100 mL actual, 2 mg/cm² vs 0.4-1.0 mg/cm², daily use vs 38% real usage).
		  ○ PBPK modelling and real-world usage data support up to 15% homlsalate content in sunscreens.
		  ○ regulatory misalignment and reformulation costs will lead to reduced product availability and potential harm from decreased sunscreen use.
		• Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ACEPT) opposed Options 2 and 3 as:
		  ○ consumers are unlikely to follow age or application site restrictions, even with clear labelling.
		  ○ enforcement of site-specific and age-related use limitations is impractical, especially at point of sale.
		• CHP Australia proposed alternative approaches via:
		  ○ removing the therapeutic entry for sunscreens from the Poisons Standard.
		  ○ regulating sunscreen ingredients under the Permissible Ingredients Determination.
		Delegate questions
		1. Are the data presented in TGA's Safety Review and AICIS Evaluation Statement on homosalate sufficient for the proposed management of risks through scheduling for therapeutic sunscreens and cosmetic preparations?
		2. Considering the intended use in sunscreen products, should scheduling of homosalate be differentiated based on site of application, and/or age of the consumer?
		3. If scheduling is appropriate, what are the concentration limits that should apply to therapeutic and cosmetic products?
		4. Is the Permissible Ingredients Determination a more appropriate instrument to regulate the amount of homosalate present in therapeutic sunscreens?

2.4	**Oxybenzone** (Delegate initiated)	**Proposal** • The Delegate has initiated a proposal to create a new CAUTION (Schedule 5) entry for oxybenzone with certain exemptions based on concentration, use and applications site and age. The proposal is based on based on the TGA Safety Review. • Three options for creating a new schedule 5 entry for oxybenzone have been proposed with certain exemptions as listed below.

Item	Substance	Issues
		○ Option 1 exempts all therapeutic sunscreens and cosmetic preparations containing up to 1% oxybenzone ○ Option 2 exempts therapeutic sunscreens and cosmetic preparations that are for face and hand applications when containing up to 2.5% and 6.0% oxybenzone, respectively. ○ Option 3 exempts therapeutic sunscreens and cosmetic preparations for face and hand applications in adults when containing up to 9.8% oxybenzone. **Delegate's reasons for the proposed changes** • Oxybenzone functions as a UVB absorber in sunscreens and cosmetics, contributing to high SPF and broad-spectrum protection. • Oxybenzone is rapidly absorbed and detected in plasma and breast milk. Animal studies showed reproductive, developmental, and endocrine effects, with some evidence of carcinogenicity and genotoxicity. Long-term human risk remains uncertain. • Systematic review of 29 studies found no adverse effects on fertility or foetal growth, but some uncertainty remains for thyroid hormones, testosterone, and kidney function. • ASEM set an acceptable SED at 6.66 mg/kg bw/day and MoS of 100 at 1% concentration for long-term daily use. • Low acute toxicity; not an irritant or sensitiser; not phototoxic, though photoallergenic reactions have been reported. • In Australia, oxybenzone is permitted in sunscreens up to 10%; most therapeutic products contain 1-6%. • For international jurisdictions: ○ US: FDA permits oxybenzone up to 6% in sunscreens; also approved as a pesticide by US EPA. ○ EU: Limits oxybenzone to 6% for face, hand, and lip products; 2.2% for whole-body and spray products; 0.5% for other cosmetics. Classified as hazardous to health and environment by ECHA, requiring warning labels. ○ Canada: Health Canada restricts oxybenzone in non-prescription sunscreens to less than 6%; 14 approved products listed. ○ Japan: Allows up to 5% in cosmetics, with no upper limit for rinse-off products not used on mucosa. **Background and challenges of implementation** • Oxybenzone is not currently scheduled and has not been previously considered for scheduling. • Inclusion of oxybenzone in Schedule 5 would effectively ban its use in sunscreens, likely reducing consumer confidence. • Industry noted fewer products contain oxybenzone than homosalate and indicated it would not market products requiring a "CAUTION" label. • Proposed scheduling may increase costs, reduce availability of therapeutic sunscreens, and erode consumer trust. Submissions

<table>
<tr><th>Item</th><th>Substance</th><th>Issues</th></tr>
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warned of unintended consequences, including reduced sunscreen use and increased skin cancer risk in Australia.

<u>Consultation</u>

• A total of 37 submissions were received as below.

<table>
<tr><th></th><th>supported</th><th>partially supported</th><th>opposed</th></tr>
<tr><td>Option 1</td><td>18 (14)</td><td>2(2)</td><td>13(13)</td></tr>
<tr><td>Option 2</td><td>4(2)</td><td>3(3)</td><td>15(15)</td></tr>
<tr><td>Option 3</td><td>2(2)</td><td>3(3)</td><td>16(16)</td></tr>
<tr><td colspan="4">(): provided written justification</td></tr>
</table>
• The main points in general support of restricting use of oxybenzone are as below:
o Oxybenzone provides UVB but no UVA protection; plasma levels after typical use exceed FDA's 0.5 ng/mL threshold, making risks outweigh benefits.
o 1.0% limit is justified due to endocrine, fertility, and developmental risks; availability of safer alternatives exist and international restrictions.
o There are concerns about foetal harm, risks to pregnant and breastfeeding women, and a need for clearer labelling and education.

• Submissions in general opposition of restricting use of oxybenzone stated
o Inclusion of oxybenzone in Schedule 5 would effectively ban its use in sunscreens, likely reducing consumer confidence.
o TGA's risk assessment is overly conservative, relying on limited data and unrealistic assumptions.
o 3.1% oxybenzone is safe for toddlers using realistic industry data (Accord Australasia).
o Regulation should align with EU standards exempting from Schedule 5: face, hand, and lip products containing up to 6% oxybenzone; whole-body products containing up to 2.2% oxybenzone, and sprays.
o At least 37 products would require reformulation, imposing cost and time burdens likely passed to consumers, reducing sunscreen access and potentially causing more harm than benefit.

<u>Delegate questions</u>

1. Are the data presented in TGA's Safety Review on oxybenzone sufficient for the proposed management of risks through scheduling for cosmetic and therapeutic sunscreens?

2. Considering the intended use in sunscreen products, should scheduling of oxybenzone be differentiated based on site of application, and/or age of the consumer?
</td></tr>
</table>

Item	Substance	Issues
		3. If scheduling is appropriate, what are the concentration limits that should apply to therapeutic and cosmetic products? 4. Is the Permissible Ingredients Determination a more appropriate instrument to regulate the amount of oxybenzone present in therapeutic sunscreens?
2.6	**Benzophenone** (Delegate initiated)	**Proposal** • The Delegate has initiated a proposal to create a new CAUTION (Schedule 5) entry for benzophenone to mitigate potential public health risks arising from its presence in sunscreen products. The proposal is based on the TGA's Safety Review of Benzophenone and an evaluation on benzophenone published by the AICIS. • Additionally, a safety direction (Use only in well-ventilated area) for air care product is also included as part of the proposal. **Delegate's reasons for the proposed changes** • Benzophenone is present in sunscreens as an impurity and degradation product of octocrylene, accumulating as products age. It is also classified by the IARC as possibly carcinogenic to humans (Group 2B). • TGA safety review sets a maximum allowable concentration of 0.0383% (383 ppm) in therapeutic sunscreens. • AICIS identified potential long-term systemic health risks from benzophenone exposure and recommended concentration limits, noting that 0.3% in air care products may reach EFSA's tolerable daily intake. • Benzophenone is used in cosmetics, coatings, cleaning agents, air care products, inks, and food flavouring. Concentrations range from 0.015% in creams to 10% in fragrances, 4.8-5.2% in inks, <0.2% in paints, and up to 3.27 ppm in frozen dairy. It was found in 17 sunscreens (up to 227.9 ppm), increasing to 461.4 ppm after stability testing. • Toxicologically, it has low acute toxicity, may cause mild irritation, is not sensitising or genotoxic, and shows no specific reproductive toxicity. • For international jurisdictions: o EU and New Zealand prohibit benzophenone as an ingredient in cosmetics; trace levels only permitted as impurity or degradation product. o US FDA prohibits benzophenone in food and food-contact rubber; California lists it under Proposition 65, requiring warnings for intentional exposure unless proven safe. o ASEAN: Benzophenone is referenced in the octocrylene listing, requiring its presence as an impurity or degradation product to be maintained at trace levels only.

<table>
<tr><th>Item</th><th>Substance</th><th>Issues</th></tr>
<tr><td></td><td></td><td>
<u>Background and challenges of implementation</u>

Benzophenone is not specifically scheduled in the current Poisons Standard.
The proposed concentration limits may require reformulation of 667 ARTG-listed products, imposing substantial cost and time burdens on industry.
Compliance challenges are expected due to lack of TGA guidance and recognised testing standards, potentially disrupting consumer access and increasing costs.
Personal care products may require re-labelling with ‘CAUTION’ statements. Though associated costs are minimal, industry indicated it would not market products requiring a “CAUTION” label
Proposed scheduling may increase costs, reduce availability of therapeutic sunscreens, and erode consumer trust. Submissions warned of unintended consequences, including reduced sunscreen use and increased skin cancer risk in Australia.

<u>Consultation process</u>

Overall, 34 submissions were received.

<table>
<tr><th></th><th>supported</th><th>partially supported</th><th>opposed</th></tr>
<tr><td>Proposal</td><td>9 (7)</td><td>1(1)</td><td>24(23)</td></tr>
<tr><td colspan="4">(): provided written justification</td></tr>
</table>

The main points in support:

Australasian College of Dermatologists advocated for a new Schedule 5 entry to restore public confidence in sunscreen products.
Pharmacologists and toxicologists acknowledged low dermal risk when used as directed but noted potential oral exposure via lip balms and children’s sunscreens.
Limiting benzophenone content was justified as a harm minimisation strategy.
Pharmacy Guild supported the proposal, citing potential risks from high-volume use despite low inherent toxicity.
Manufacturers/suppliers of zinc-based sunscreens are generally opposed to the use of any organic UV filters.

The main point in partially support:

s.22 recommended benzophenone be kept at trace levels to align with UK and EU standards.

The main points in opposition are:

Benzophenone has documented hormone-disrupting and mutagenic effects and is banned in UK cosmetics.

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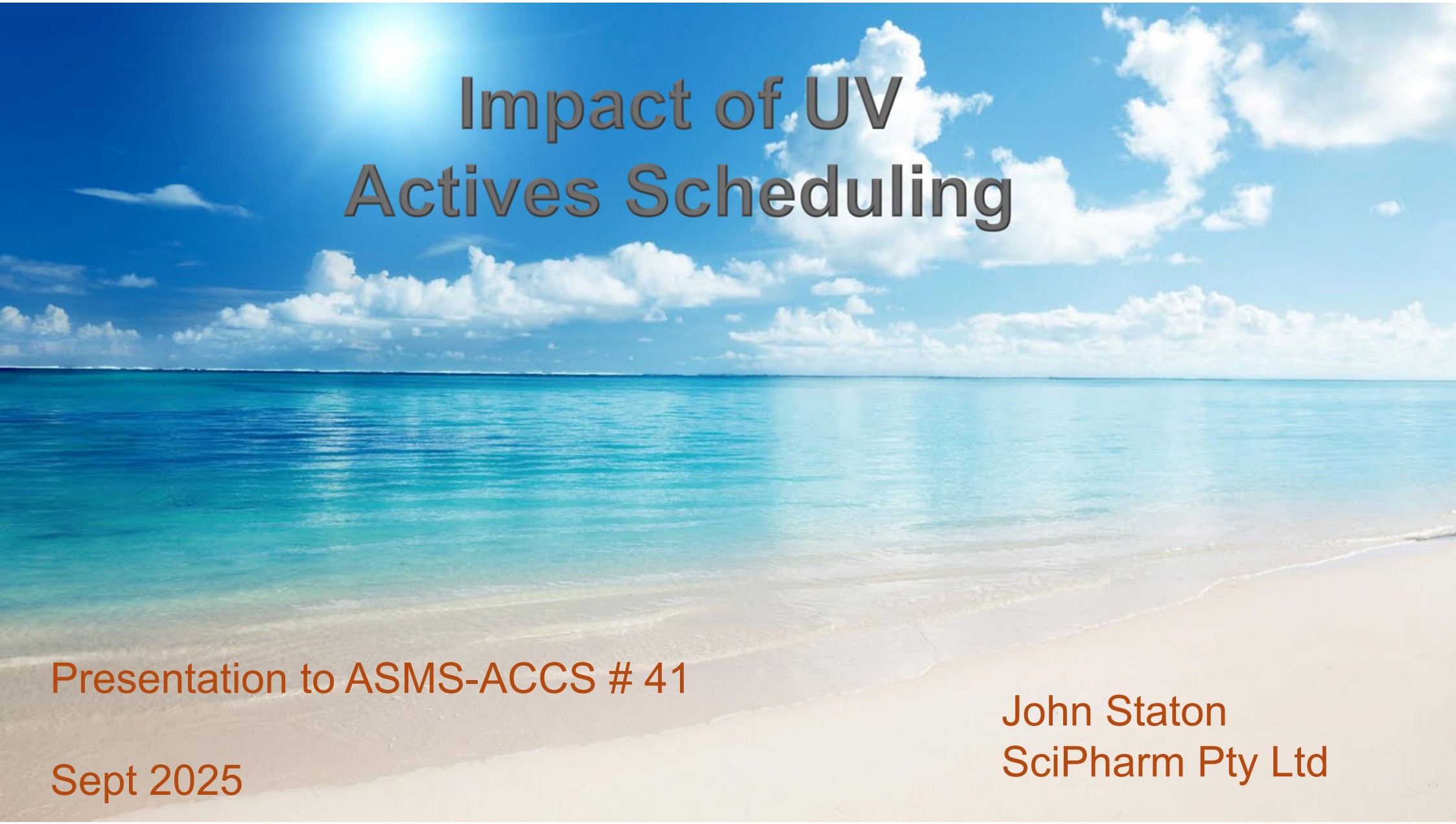
</table>

Item	Substance	Issues
		○ The proposed cut-off of 383 ppm is close to tumour-inducing dose in animals (312 ppm) and should be zero (non-detectable) or at least provide a margin of safety of 100 (13-50 ppm depending on use). ○ Evidence of risk in TGA's Safety Review is weak, limited, and equivocal. NOAEL used to derive limits was based on oral carcinogenicity studies. ○ IARC found no evidence of carcinogenicity via dermal exposure. ○ The proposed limit of 0.0383% for sunscreens is ambiguous. Real-world scenarios suggest more appropriate limits to be 7,200 ppm (ASEM) or 720 ppm (TDI for toddlers). ○ Lack of guidance on cosmetic sunscreen regulation or data requirements for compliance testing (e.g. accelerated stability or end-of-shelf-life testing). ○ Absence of internationally recognised testing methods leading to post-market issues. ○ US Pharmacopeia permits 0.5% impurity (500 ppm benzophenone) at 10% octocrylene concentration. Manufacturers may be unable to reject raw materials that meet pharmacopeial standards. • They proposed the below alternative options: ○ Apply the ALARA principle (As Low As Reasonably Achievable), consistent with international best practice. ○ Use the Permissible Ingredients Determination to regulate benzophenone levels in therapeutic goods. ○ Set a 500 ppm limit for benzophenone in sunscreen preparations at manufacture, aligning with US Pharmacopeia standards. **Delegate questions** 1. Are the data presented in TGA's Safety Review and AICIS Evaluation Statement on benzophenone sufficient for the proposed management of risks through scheduling for: a. cosmetic and therapeutic sunscreens b. use as a fragrance in cosmetic and therapeutic products c. use in air care products 2. Should limits on unavoidable hazard impurities/degradants managed through individual substance entries in the Poisons Standard? 3. If the Committee agrees that there should be limits on benzophenone in products, what should the limits be? a. As proposed - sunscreens (0.0388%) and air care products (0.3%), or b. 500 ppm (in alignment with the US Pharmacopeia), or c. at trace amounts as unavoidable impurities (ALARA principle)? 4. Is the Permissible Ingredients Determination a more appropriate instrument to regulate the amount of benzophenone present in therapeutic sunscreens?

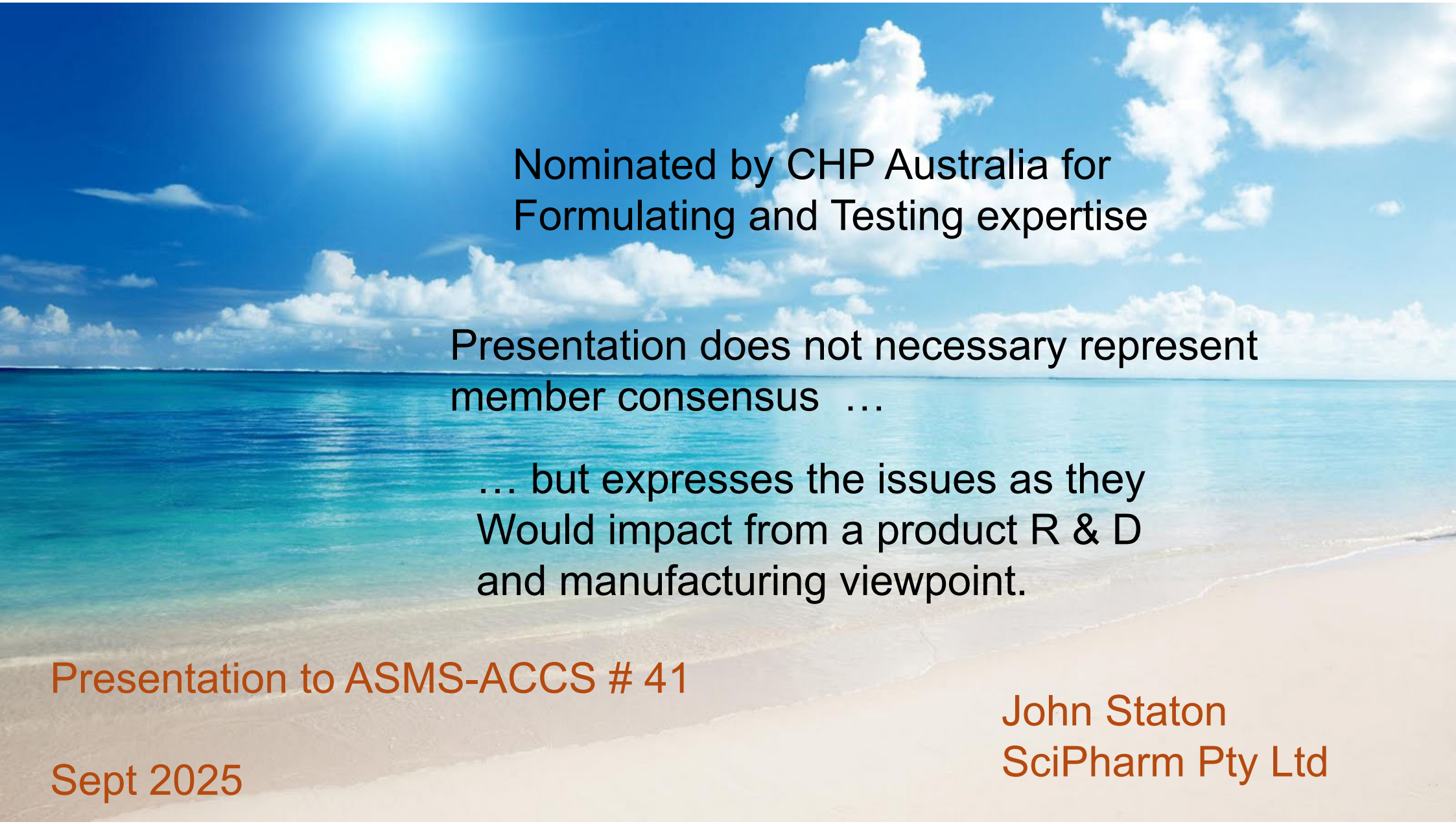


Impact of UV Actives Scheduling

Presentation to ASMS-ACCS # 41

Sept 2025

John Staton
SciPharm Pty Ltd



Nominated by CHP Australia for
Formulating and Testing expertise

Presentation does not necessary represent member consensus …

… but expresses the issues as they Would impact from a product R & D and manufacturing viewpoint.

Presentation to ASMS-ACCS # 41

Sept 2025

John Staton
SciPharm Pty Ltd

R & D Time Line

TOTAL 24 to 30 Months

PLUS 2 to 3 SEASONS for Flow Through ex Retail !

3 months

3 months

1 month

3 months

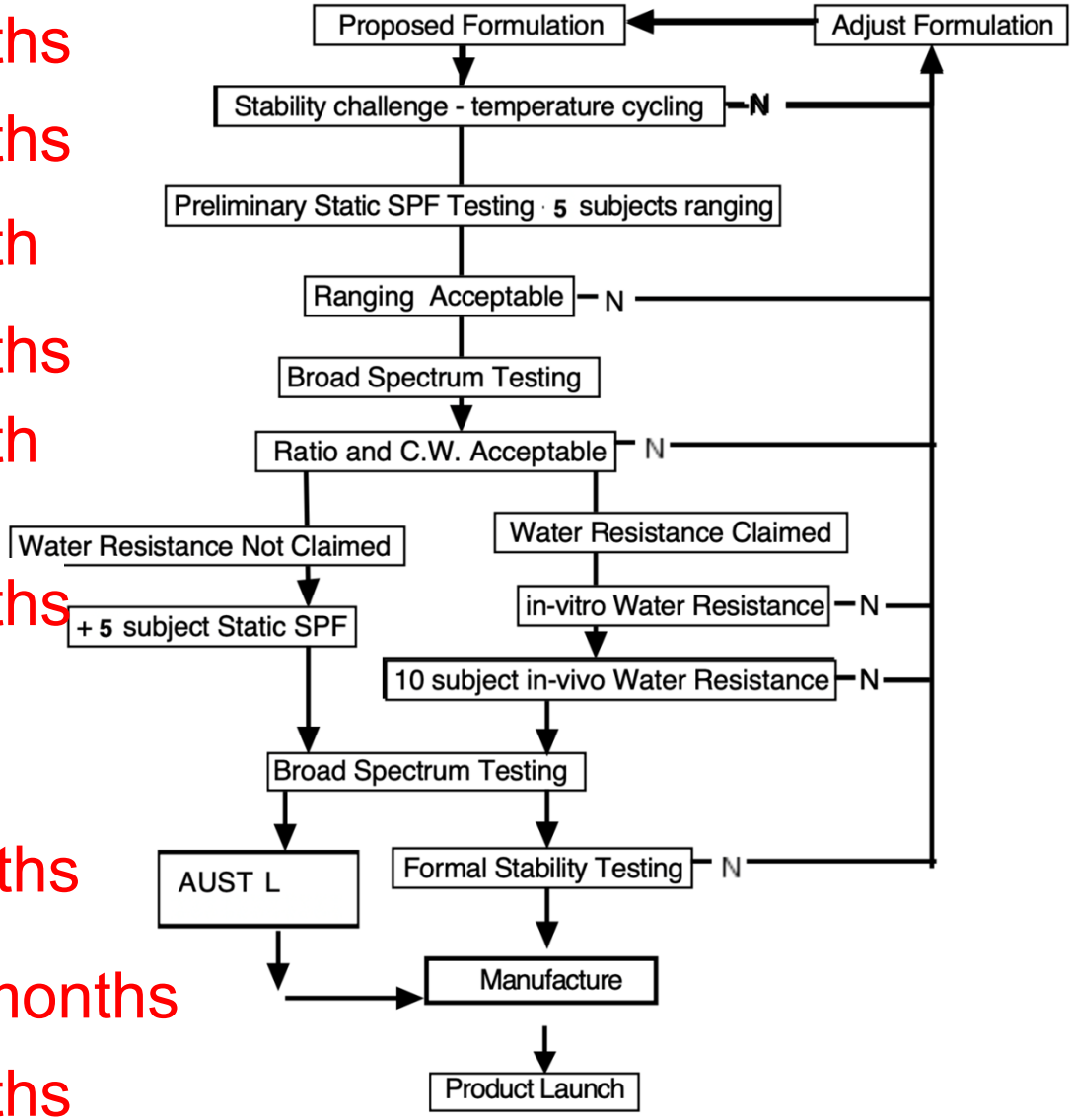
1 month

2 months

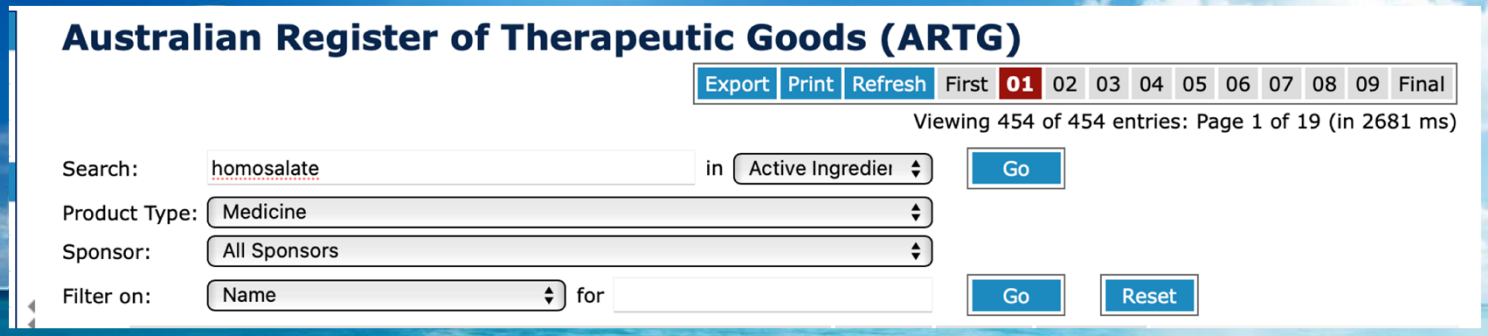
9 months

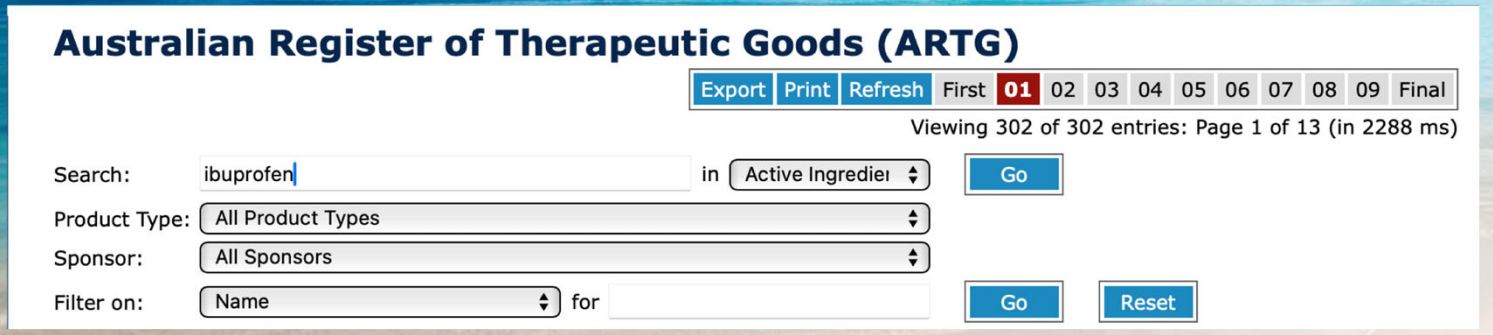
3 – 6 months

3 months



HOMOSALATE

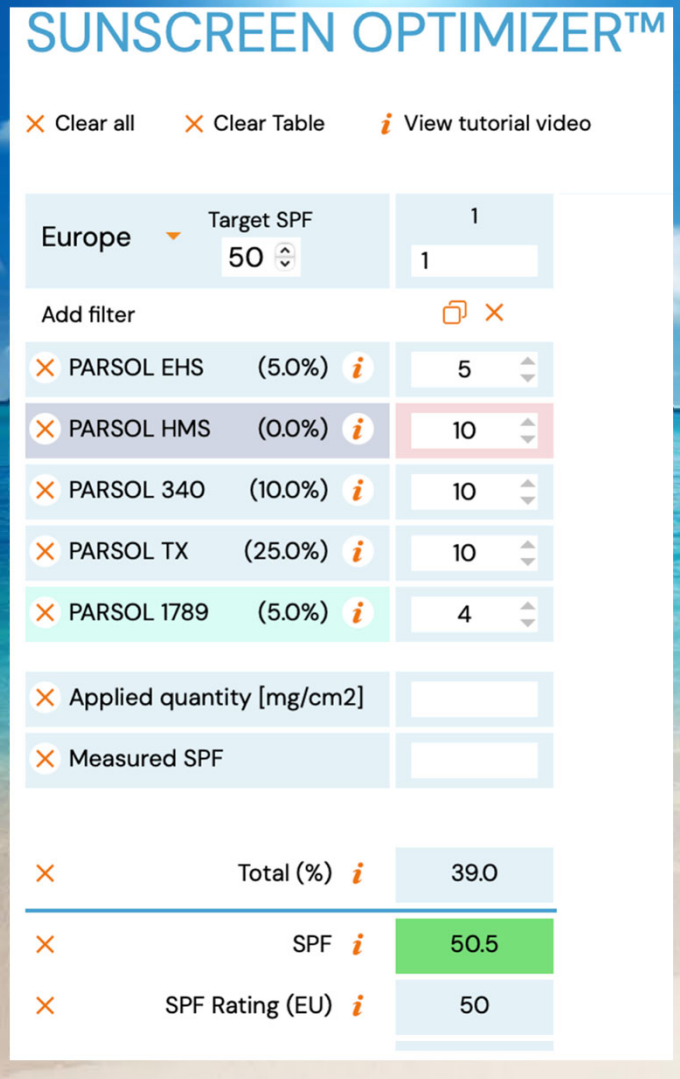




Homosalate
= 454 AUSTL
Plus
Secondary Sunscreens

Ibuprofen = 302 AUSTL

Contribution



Formulations provide efficacy !

High SPF sunscreens require the inclusion of multiple actives to cover the amplitude and breadth of the protection for both SPF and UVA “Broad Spectrum”

4 or more distinct APIs are needed

AS/NZS 2604 SPF testing is Clinical and Not Q.A.

It's R & D

ISO 24444 – Static test: $5,000
ISO 24444- Water Resistance $9,000
ISO 24443- Broad Spectrum $1,000

Performed **prior** to finalization of product development process

Contribution

SUNSCREEN OPTIMIZER™

Clear all | Clear Table | View tutorial video

Europe	Target SPF 50	1	2
		1	
Add filter			
PARSOL EHS	(5.0%)	5	5
PARSOL HMS	(0.0%)	10	
PARSOL 340	(10.0%)	10	10
PARSOL TX	(25.0%)	10	10
PARSOL 1789	(5.0%)	4	4
Applied quantity [mg/cm2]			
Measured SPF			
Total (%)		39.0	29.0
SPF		50.5	44.4
SPF Rating (EU)		50	30

Models with and without Homosalate

HMS = Homosalate

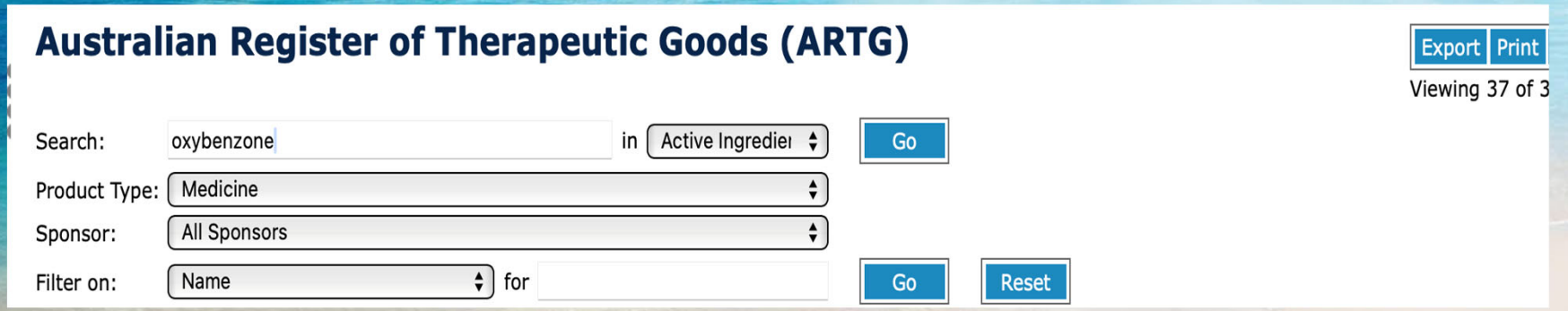
SPF reduced below SPF 50 Target…

… but impact much greater reduction to SPF 30 label claim!

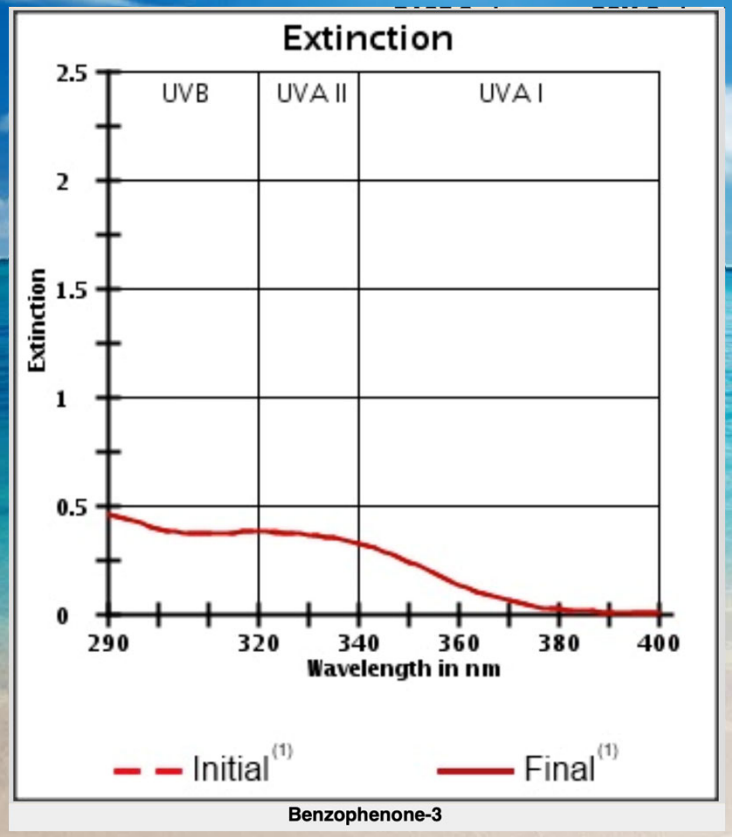
OXYBENZONE

Lower usage in Australian Sunscreens

37 in AUSTL Primary Sunscreens



OXYBENZONE



Benzophenone-3

Not a particularly strong UVB absorber !

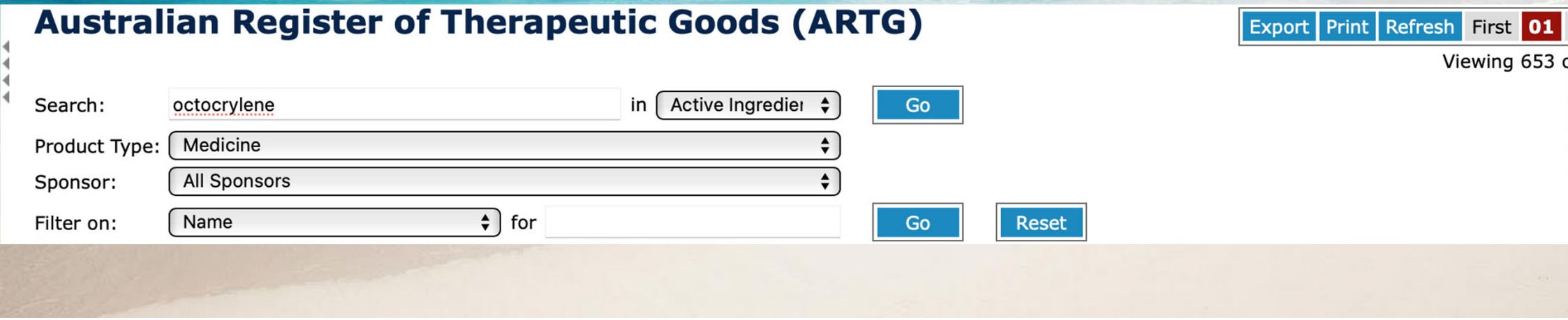
Never formulated with it!

BENZOPHENONE = OCTOCRYLENE

… is about Octocrylene

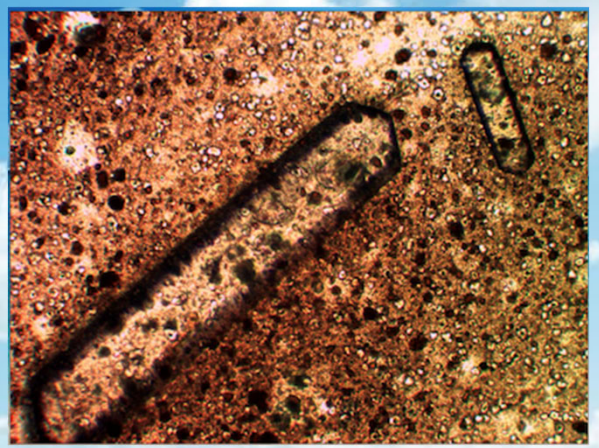
653
AUSTL's !

Most ubiquitous UVB absorber in use



OCTOCRYLENE

The most commonly used Stabiliser for Avobenzone



Avobenzone Crystals

Also Solvent for Avobenzone !

NOTE 1: These actives only absorb UV when in solution

NOTE 2: If substituted by a fatty ester solvent then impacts on product elegance

OCTOCRYLENE

… also is a solvent for other Solid UV Actives

CHALLENGE 1: Solvent Ratio is 1:1

CHALLENGE 2: These actives only absorb UV when in solution

CHALLENGE 3: If substituted by a fatty ester solvent then impacts on product elegance as solvent is Additive on top of substituted active!

OCTOCRYLENE

Contaminant versus Degradadant?

- benzophenone is limited to a maximum concentration of 383 ppm as a potential degradant in therapeutic sunscreen containing octocrylene.

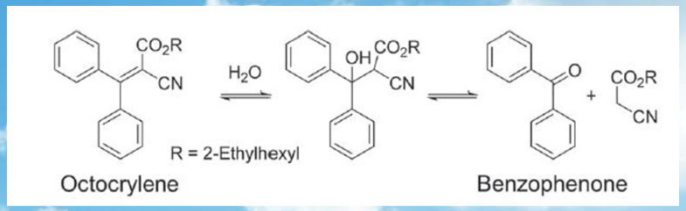
OCTOCRYLENE

API Supplier Specification

- As of **January 1, 2022,** [redacted] will offer only one grade of [redacted], with maximum benzophenone trace levels of 100 ppm, under the existing product code [redacted]
- Consequently, [redacted] will discontinue product code [redacted] on **March 31, 2022.**

At 10%w/w API contributes max 10 ppm

OCTOCRYLENE



The conditions under which octocrylene is more likely to degrade into benzophenone are not fully resolved and full product life stability studies would be required.

This applies for each individual formulation !

Possibility 1. is that MANY water containing sunscreens may need complete reformulating

Possibility 2. is that SHELF LIFE of some products may have to be reduced – from 3 to 2 years perhaps

Risk – Benefit?

API Cost Consideration – more efficient actives

Homosalate – $10 per Kg **= $1per Litre (10%)**
Ethylhexyl triazone - $100 per Kg. = **plus $5/Litre (5%)**
Tris-Biphenyl triazone $282 per Kg = **plus $27/Litre (10%)**

MAJOR cost impact on
large packs such as for Schools
and Industrial Occ Health use

Total Impact of Reg Change

Industry needs a minimum of 3 Years to complete a phase out

If review of safety is API by API then Process needs to be repeated in its entirety!


SUMMARY
To smoothly enact any regulatory changes
Industry requires a significant amount of time
In order to ensure minimal wastage and disruption

SUMMARY

If this is a consideration of
Risk – Benefit then please keep in mind that…

World Health Organization

… WHO has just recently added sunscreens to
Their list of essential medicines for CHILDREN

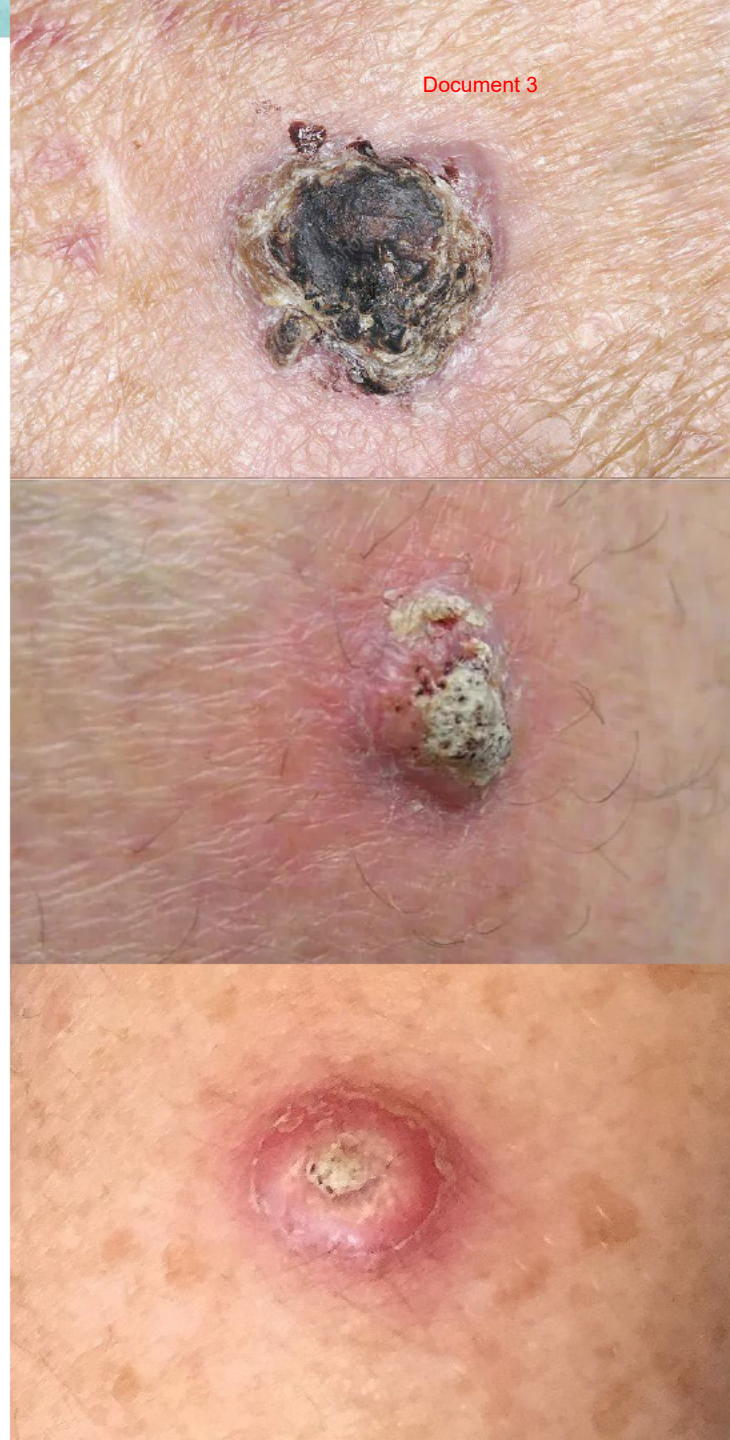
Homosalate and oxybenzone Scheduling- **Impacts on Industry**

accord
hygiene, personal care & specialty products industry

Critical public health products

- 2 out of 3 Australians will be diagnosed with some form of skin cancer during their lifetime.
- Skin cancer poses a substantial burden in Australia, with an **estimated A$1.7 billion annual cost** to the health system.

s.47



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Conservative calculations

TGA ASEM modelling considered weekday and weekend exposure as well as weather elements such as rain and low UV. The assumption is that sunscreen is used for 240 weekdays and 26 weekend days.

TOTAL = 266 days

The **TGA safety review** assumed sunscreen was used everyday in the calculations used to make the scheduling proposals.

TOTAL = 365 days

s.47

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Q&A

Benzophenone Scheduling- **Impacts on Industry**

accord
hygiene, personal care & specialty products industry

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Q&A

From: s.22 [redacted]
To: [redacted]
Cc: Medicines Scheduling; [redacted] ; Medicines Scheduling
Subject: Accord presentation in November scheduling meetings
Date: Tuesday, 4 November 2025 3:18:10 PM
Attachments: image001.png
image002.png

Dear [redacted]
Thanks for your email and continued interest in regulatory matters.
The Committee appreciated your presentation in September but there was a consensus that the points raised were substantially covered by Accord's submission on the proposals. The suppliers, manufacturers and industry associations also raised issues similar to Accord's through their submissions. The Committee Chairs have decided to not proceed with external presentations for the November meeting.
Kind regards
[redacted].

From: [redacted]
Sent: Monday, 3 November 2025 12:59 PM
To: [redacted]
Cc: Medicines Scheduling ; [redacted]
Subject: RE: Thank you [SEC=OFFICIAL]

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.

Hi [redacted],
I hope you have been well.
I just wanted to check in on the schedule for the ACCS/ACMS meeting on 13 November and when we would be presenting on the benzophenone proposal. Currently, both [redacted] and I are free all day, but it would be good to get a time in the calendar.
Feel free to give me a call if you would like to discuss.
Kind regards,
Rianna

s.22 [redacted]
Accord Australasia Limited
PO Box 290 BROADWAY NSW 2007
Email: [redacted]
www.accord.asn.au

From: [redacted]@Health.gov.au>
Sent: Monday, 22 September 2025 8:00 PM
To: [redacted]@accord.asn.au>; [redacted]@accord.asn.au>
Cc: Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: Thank you [SEC=OFFICIAL]

OFFICIAL

Dear [redacted]
Thank you for your presentation on sunscreen formulations on Wednesday, and apologies for the delay. Hopefully, the delay did not cause too much inconvenience for you. As you are aware, due to the time constrains, the Committee has decided to defer the discussion on benzophenone to their next meeting in November 2025.
As discussed, we have shared your presentation with the Committee in confidence. Please note that the material you provided may fall under the scope of FOI. Should committee documents be the subject of an FOI application, you would be consulted on the potential disclosure of any information due to it containing personal and/or sensitive information.
Warn regards

s.22 [redacted]
[redacted] – Scheduling and Chemicals Policy Section
Regulatory Engagement Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
E: medicines.scheduling@health.gov.au
www.tga.gov.au

OFFICIAL

From: s.22
To:
Cc: Scheduling Secretariat
Subject: RE: Update on sunscreen [SEC=OFFICIAL]
Date: Tuesday, 7 October 2025 3:57:32 PM

OFFICIAL

Hi s.2

Thanks for your comments.

The Committee has asked us to do the additional work (review the PBK modelling, Symrise study and SCCS and SAG-CS findings) and report back in November for further discussion. The time frame in my earlier email is developed in consultation with Tox and COMB. We are also undertaking some research into the EU market, homosalate in sunscreens in Australia, and its alternatives. The alternative options will be informed by the review and/or findings.

The agenda/options/ decisions (if any) will depend on what can come up with. It may very well be requiring further work. Will call you shortly.

Regards

OFFICIAL

From: s.22
Sent: Tuesday, 7 October 2025 3:38 PM
To:
Cc: Scheduling Secretariat
Subject: RE: Update on sunscreen [SEC=OFFICIAL]

Hi ,

I think we need to view the issue through a public health lens, given the weak safety signal coupled with how common homosalate is as an ingredient. What are the alternative options and how do they compare? What is the likely net harm? Can this be pulled together in the required time?

I think further examination of the European experience would also be worthwhile.

I think the options for the committee need a significant re-work.

I think there's no rush on this decision.

From: s.22 @Health.gov.au>
Sent: Tuesday, 7 October 2025 3:19 PM
To: @health.gov.au>
Cc: Scheduling Secretariat <Scheduling.Secretariat@health.gov.au>
Subject: Update on sunscreen [SEC=OFFICIAL]

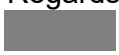
OFFICIAL

Hi

You may have seen the draft agendas for the November meetings already. Sunscreen substances are being discussed on 13 Nov at the Joint ACMS-ACCS meeting. I just discussed with Tox and COMB, the need for reviewing the PBK modelling and the differences between SCCS and SAG-CS in determining the safe level for homosalate based on the same study (provided by Symrise). Given that we need to send the agenda papers by 31 October, the time frame is:

- **14 Oct**: we reconvene to discuss Tox/COMB review of the Symrise study, PBK Modelling and SCCS and SAG-CS calculations
- **17 Oct**: Tox and COMB provide written comments and/or input for the agenda paper
- **24 Oct**: First draft of the agenda papers ready for your and James' review
- **31 Oct**: Agenda papers go out.

I will arrange the meeting for next week (14 Oct) and will invite you.
Regards



From: s.22 [redacted]
To: [redacted]
Cc: [redacted]
Subject: FW: Research on sunscreens [SEC=OFFICIAL]
Date: Thursday, 16 October 2025 12:15:14 PM
Attachments: Sunscreen Formulation After EU Restrictions on Homosalate.docx
Re For review and agreement - Action items from Joint ACMS-ACCS on suns... (35.6 KB).msg

---

Hi [redacted]
Below is [redacted]'s finding (Thanks [redacted]). Further below are some links that provided.
And attached is the action items from Sept meetings.
[redacted]

From: [redacted]
Sent: Tuesday, 14 October 2025 4:38 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Research on sunscreens [SEC=OFFICIAL]

OFFICIAL

Hi [redacted],
I done some digging and found information related to those three dot points. It's a bit difficult, as there isn't much direct evidence on how the substitutes for homosalate perform when it is absent. However, I did come across some papers discussing newer generations of UV filters, which are considered superior to traditional filters like homosalate. With the recent restrictions, it seems the industry may be shifting away from homosalate altogether regardless.
Happy to discuss further!
Happy to discuss!
[redacted]

OFFICIAL

From: s.22 [redacted]@Health.gov.au>
Sent: Thursday, 9 October 2025 10:20 AM
To: [redacted]@Health.gov.au>
Cc: [redacted]@Health.gov.au>
Subject: Research on sunscreens [SEC=OFFICIAL]

OFFICIAL

Hi [redacted]
As discussed, if you can undertake some research on the first three dot points and summarise your findings (limit to 1 page per dot point to start with). I have been looking into this as well and have added some links as starting point.

- The Committee also requested that the Scheduling Secretariat obtain additional information, if possible, on the following:
    - the current availability and SPF rating of new sunscreen products in the EU that do not contain homosalate, following the restrictions on 1 July 2025

      https://webgate.ec.europa.eu/cpnp/faq?search=sunscreen&page=1

https://www.ewg.org/sunscreen/about-the-sunscreens/?limit_to_ewgv=1

https://cosmileeurope.eu/inci/

- the ingredients being used to substitute homosalate in sunscreens and their efficacy

  https://pubs.rsc.org/en/content/articlelanding/2024/ra/d3ra08178h

  https://onlinelibrary.wiley.com/doi/10.1111/phpp.70026

  https://www.intechopen.com/chapters/1213210

  https://www.sciencedirect.com/science/article/pii/S1773224723005725#abs0010

- the effect of homosalate concentration on the SPF rating of a sunscreen product

  https://www.ingentaconnect.com/content/govi/pharmaz/2007/00000062/00000006/art00011?crawler=true&mimetype=application/pdf

  https://spflist.com/conventional-sunscreens/homosalate#:~:text=UV%20Absorption%20Spectrum,are%20needed%20for%20adequate%20protection.

- ~~consumer adherence to labelling instructions for products intended for different age groups or application to different body parts.~~

If you can provide a summary by Tuesday next week that will be great.

Cheers

s.22 [redacted]
Scheduling and Chemical Policy Section
Regulatory Engagement Branch
T: 02 [redacted]

Sunscreen Formulation After EU Restrictions on Homosalate

Availability and SPF Rating of Sunscreens Without Homosalate in the EU (Post-July 2025)

Following the EU's regulatory update effective 1 July 2025, homosalate is now restricted to a maximum concentration of 7.34% and only permitted in face products. As a result, manufacturers have begun reformulating sunscreen products using alternative UV filters, many of which are listed under Annex VI of Regulation (EC) No 1223/2009.

While no products are currently marketed as specifically compliant with the new restriction, several popular sunscreens available in the UK already exclude homosalate from their ingredient lists. The table below highlights examples of homosalate-free sunscreens from well-known brands that still offer high SPF ratings of 50+, demonstrating that effective sun protection is achievable without homosalate.

Product Name	UV Filters (as approved in Annex VI)	SPF Rating	Official Website
Eucerin Sun Face Oil Control Gel-Cream SPF 50+	• Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine • Diethylamino Hydroxybenzoyl Hexyl Benzoate • Ethylhexyl Triazone • Butyl Methoxydibenzoylmethane • Phenylbenzimidazole Sulfonic Acid	50+	Sun Gel-Cream Oil Control SPF 50+ | sunscreen for oily, acne-prone skin | Eucerin
Laroche-Posay Anthelios UVMune 400 Invisible Fluid Spf50+ Sun Cream For Sensitive Skin 50ml	• Ethylhexyl Salicylate • Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine • Ethylhexyl Triazone • Butyl Methoxydibenzoylmethane • Diethylamino Hydroxybenzoyl Hexyl Benzoate • Drometrizole Trisiloxane • Terephthalylidene Dicamphor Sulfonic Acid • Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate (Mexoryl 400)	50+	Anthelios Ultra-Light Invisible Fluid SPF50+ | La Roche-Posay
Avene SPF 50+ Cream	• Diethylamino Hydroxybenzoyl Hexyl Benzoate • Ethylhexyl Triazone • Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine (TriAsorB)	50+	SPF 50+ Cream | Eau Thermale Avène
Altruist Face Fluid SPF 50	• Diethylhexyl Butamido Triazone • Diethylamino Hydroxybenzoyl Hexyl Benzoate • Ethylhexyl Salicylate • Phenylbenzimidazole Sulfonic Acid • Titanium Dioxide • Ethylhexyl Triazone	50+	FACE FLUID SPF50 50ml – Altruist. Dermatologist Sunscreen

Ingredients Substituting Homosalate and Their Efficacy

Traditionally, homosalate has been widely used in sunscreen formulations for its ability to absorb UVB rays and help dissolve other UV filters. However, with the emergence of new technologies, the sunscreen industry has shifted its approach, adopting newer-generation UV filters that offer enhanced photostability and broader spectral coverage.

According to a review published in *Photodermatology, Photoimmunology & Photomedicine*, recent advancements in sunscreen technologies have enabled formulators to achieve improved efficacy in UV protection. This has been accomplished by incorporating newer-generation UV filters such as **Mexoryl 400** (MCE or Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate) and **TriAsorB** (BPT or Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine) into modern formulations.

Supporting this, a study published in *Health Science Reports* demonstrated that a sunscreen containing **Mexoryl 400** significantly improved skin barrier function, increased hydration, and reduced melanin content over four weeks, with no adverse effects reported. Melanin acts as a natural defence against UV radiation by absorbing and neutralising harmful rays, thereby reducing the risk of DNA damage and skin cancer, according to an article in *Photochemistry and Photobiology*.

Another peer-reviewed article in *Photochemical & Photobiological Sciences* assessed the photo-protective efficacy of **TriAsorB** across the UV and visible light spectrum. The study found that **TriAsorB** effectively absorbs UVB, UVA (including long UVA), and high-energy visible (HEV) blue light.

Additionally, the *UL Prospector 2025 Sunscreen Trends & Formulation Playbook* (a resource outlining ingredient innovations and regulatory strategies for personal care products) indicates that the EU sunscreen industry may be reformulating with alternative UVB filters such as **Diethylhexyl Butamido Triazone** (**DBT/DEBT)**. These are often used in combination with UVA filters like **Mexoryl 400** and **TriAsorB** to ensure broad-spectrum protection.

DSM-Firmenich, a global science-based company specialising in health, nutrition, and beauty, also notes that to substitute homosalate in sunscreen formulations, manufacturers can use a combination of alternative UVB filters that provide similar protection and solubilising properties. Common substitutes include **PARSOL® EHT (Ethylhexyl Triazone), PARSOL® HS (Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine)**, and **PARSOL® EHS (Ethylhexyl Salicylate),** which help maintain SPF performance and formulation stability.

While **Mexoryl 400** and **TriAsorB** have been extensively studied for their advanced UV protection, no published studies explicitly reference the absence or replacement of homosalate in their formulations. Instead, the focus remains on the individual efficacy, photostability, and safety of these newer-generation filters.

However, the fact that many of the sunscreen products mentioned in the table above contain next-generation UV filters like **Mexoryl 400 (MCE), TriAsorB (BPT), Ethylhexyl Triazone, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, and Ethylhexyl Salicylate**, while omitting homosalate, suggests a clear shift in the industry. Brands are increasingly moving toward more advanced, photostable filters that offer broad-spectrum protection without relying on older ingredients like homosalate. This shift still allows them to maintain high SPF ratings (50+) while meeting EU regulatory standards.

The effect of homosalate concentration on the SPF rating of a sunscreen product

Homosalate has long been used in sunscreen formulations due to its ability to absorb UVB radiation and act as a solvent for other active ingredients. However, its efficacy as a standalone UVB filter is limited. According to FDA, a standard sunscreen preparation containing 8% homosalate yields an SPF rating of approximately 4.47 ± 1.279, which is considered low and insufficient for high-protection products. As a result, formulators often use homosalate in higher concentrations or combine it with other UV filters to achieve more effective sun protection.

DSM's Sunscreen Optimizer is a tool that helps sunscreen developers figure out how different UV filters will perform. It lets formulators combine different filters to predict SPF levels, check broad-spectrum coverage, and even consider how eco-friendly the formula might be.

From: Marion Healy
To: s.22 [redacted]
Cc: Scheduling Secretariat
Subject: Re: For review and agreement - Action items from Joint ACMS-ACCS on sunscreen substances [SEC=OFFICIAL]
Date: Friday, 10 October 2025 8:33:14 AM
Attachments: image001.png

Thankyou for the updated summary.

Re a solution for cosmetics, grateful if, as you suggest, the secretariat considers reverse scheduling and/ or other options.

Marion

From: [redacted]@Health.gov.au>
Sent: Friday, October 3, 2025 5:04:20 PM
To: [redacted]
Cc: Scheduling Secretariat <Scheduling.Secretariat@health.gov.au>
Subject: RE: For review and agreement - Action items from Joint ACMS-ACCS on sunscreen substances [SEC=OFFICIAL]

OFFICIAL

Dear Marion and Bridin

Thank you for your review. I have amended the Actions items following Marion's suggestions i.e. added a new item for secretariat to follow and deleted the text on ' and/or cosmetics' in relation to applicability PID (under oxybenzone). The revised actions items are:

Homosalate:
The Joint Committee decided to defer providing recommendations or advice on the scheduling proposal for homosalate, pending further discussion at the next meeting. The Joint Committee requested that the Scheduling Secretariat provide further information on the following matters, to inform further discussion:

- An appraisal of the full combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (Dettwiler, 2013; confidential) that was submitted by the manufacturer during the consultation period. The committee seeks additional information on the conclusions regarding kidney injury observed in male rats and the conduct of the study.
- An analysis of the different conclusions reached by the EU Scientific Committee on Consumer Safety (SCCS) and UK Scientific Advisory Group on Chemical Safety of Non-food and Non-medicinal Consumer Products (SAG-CS) which were based on the same study (Dettwiler, 2013; confidential).
    - The SCCS established an adjusted NOAEL of 10 mg/kg bw/day while SAG-CS established a NOAEL of 120 mg/kg bw/day.

SAG-CS adopted a physiologically-based kinetics (PBK) modelling to predict internal concentrations of homosalate after repeated oral and topical application in its Opinion on Homosalate use in Cosmetic Products. Using the PBK modelling and a higher NOAEL, SAG-CS concluded that homosalate is safe at a maximum concentration of 10% in sunscreen products.

- The Committee also requested that the Scheduling Secretariat obtain additional information, if possible, on the following:
    - the current availability and SPF rating of new sunscreen products in the EU that do not contain homosalate, following the restrictions on 1 July 2025
    - the ingredients being used to substitute homosalate in sunscreens and their efficacy
    - the effect of homosalate concentration on the SPF rating of a sunscreen product
    - consumer adherence to labelling instructions for products intended for different age groups or application to different body parts.

Oxybenzone:

The Committee considered the toxicity data for oxybenzone to be sufficiently robust and the impact of any scheduling restrictions to be far less than homosalate. The Committee also considered the Permissible Ingredient Determination to be a viable alternative to scheduling to impose any restriction on oxybenzone in therapeutic sunscreens and/or cosmetics. However, the Committee reserved their recommendations and advice on the scheduling proposal pending further discussion on homosalate.

Regarding regulation of these substances in cosmetics, Scheduling is the regulatory lever we have. So, a meeting with AICIS may not be that productive. Noting industry is very averse to applying CAUTION heading to any cosmetics – they consider it as an effective ban – we can think of reverse scheduling. We can propose this for Committee discussion through the agenda papers. Let us know how you would prefer to progress.

Have a nice long weekend.

Regards
[redacted]

OFFICIAL

From: s.22 [redacted]
Sent: Friday, 3 October 2025 12:15 PM
To: [redacted]@Health.gov.au>; 'Bridin Murnion [redacted]
Cc: Scheduling Secretariat <Scheduling.Secretariat@health.gov.au>
Subject: RE: For review and agreement - Action items from Joint ACMS-ACCS on sunscreen substances [SEC=OFFICIAL]

OFFICIAL

Hi [redacted]

Thank you for the summary.

For both substances, there was a question around whether or not there is information on consumer behaviour and if consumers differentiate between different products based on the labelling, eg labelling for different age groups, application to different parts of the body.

For oxybenzone, the second sentence appears to imply that the Permissible Ingredients List could be used for cosmetics. Grateful if you can confirm that this is correct. I had understood that it does not cover these types of products.

I think it would be also useful for Bridin. TGA, AICIS and myself to have a discussion ahead on the November meeting to discuss risk management options for both therapeutic sunscreens and cosmetics. The joint committee was generally concerned about using schedule 5 of the Poison Standard because of the required 'Caution' labelling. For therapeutic sunscreens, the Permissible Ingredients List may well continue to be an appropriate risk management tool. As per my question above, I am unsure that this tool can be used for cosmetics. If it can't be used for cosmetics, it would be helpful to be aware of the alternative tools so we have some suggested ways forward.

Marion

OFFICIAL

From: [redacted]@Health.gov.au>
Sent: Friday, 3 October 2025 9:15 AM
To: [redacted]
Cc: Scheduling Secretariat <Scheduling.Secretariat@health.gov.au>
Subject: For review and agreement - Action items from Joint ACMS-ACCS on sunscreen substances [SEC=OFFICIAL]
Importance: High

OFFICIAL

Good morning, Marion and Bridin

I have summarised the action items from the Joint ACMS-ACCS meeting on the scheduling of sunscreen substances. Could you please review the action items (below)

and indicate your agreement? This will allow us to progress the work while we draft the Minutes.

ACTION ITEMS:

Homosalate:
The Joint Committee decided to defer providing recommendations or advice on the scheduling proposal for homosalate, pending further discussion at the next meeting. The Joint Committee requested that the Scheduling Secretariat provide further information on the following matters, to inform further discussion:

- An appraisal of the full combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (Dettwiler, 2013; confidential) that was submitted by the manufacturer during the consultation period. The committee seeks additional information on the conclusions regarding kidney injury observed in male rats and the conduct of the study.
- An analysis of the different conclusions reached by the EU Scientific Committee on Consumer Safety (SCCS) and UK Scientific Advisory Group on Chemical Safety of Non-food and Non-medicinal Consumer Products (SAG-CS) which were based on the same study (Dettwiler, 2013; confidential).
    - The SCCS established an adjusted NOAEL of 10 mg/kg bw/day while SAG-CS established a NOAEL of 120 mg/kg bw/day.
    - SAG-CS adopted a physiologically-based kinetics (PBK) modelling to predict internal concentrations of homosalate after repeated oral and topical application in its Opinion on Homosalate use in Cosmetic Products. Using the PBK modelling and a higher NOAEL, SAG-CS concluded that homosalate is safe at a maximum concentration of 10% in sunscreen products.
- The Committee also requested that the Scheduling Secretariat obtain additional information, if possible, on the following:
    - the current availability and SPF rating of new sunscreen products in the EU that do not contain homosalate, following the restrictions on 1 July 2025
    - the ingredients being used to substitute homosalate in sunscreens and their efficacy
    - the effect of homosalate concentration on the SPF rating of a sunscreen product.

Oxybenzone:

The Committee considered the toxicity data for oxybenzone to be sufficiently robust and the impact of any scheduling restrictions to be far less than homosalate. The Committee also considered the Permissible Ingredient Determination to be a viable alternative to scheduling to impose any restriction on oxybenzone in therapeutic sunscreens and/or cosmetics. However, the Committee reserved their recommendations and advice on the scheduling proposal pending further discussion on homosalate.

Kind regards

s.22 .

[redacted] Scheduling and Chemicals Policy Section
Regulatory Engagement Branch
Therapeutic Goods Administration
Department of Health, Diability and Ageing
PO Box 100
Woden ACT 2606
E: medicines.scheduling@health.gov.au
www.tga.gov.au

From: s.22
To:
Cc: Scheduling Secretariat;
Subject: Toxicological advice for homosalate [SEC=OFFICIAL]
Date: Monday, 20 October 2025 3:56:42 PM
Attachments: image001.png
image002.png
image004.png

OFFICIAL

Hi s.22 ,

Our toxicological advice for homosalate has been finalised and can be found here D25-4618675.

Please let me know if you wish to discuss anything further or if further information is required.

Kind regards,

s.22
Toxicology Section
Scientific Evaluation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
T: 02 | E:

This email comes to you from Ngunnawal Country

Location: Fairbairn ACT
PO Box 100, Canberra ACT 2601, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

OFFICIAL

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

NONCLINICAL ADVICE FOR HOMOSALATE

Since the publication of the Safety Review of Seven Active Sunscreen Ingredients[1] by the TGA, further information has become available to the TGA regarding the repeat dose toxicity of homosalate.

The TGA has received the full study report for the 'Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test' (Study 2012068 / D54938). This study is evaluated in full in Appendix 1.

Additionally, the TGA has considered a published physiologically-based pharmacokinetics (PBPK) model for use in the risk assessment for homosalate. This is discussed below.

1. REVIEW OF THE 'COMBINED REPEATED DOSE TOXICITY STUDY WITH THE REPRODUCTION / DEVELOPMENTAL TOXICITY SCREENING TEST'

1.1. ASSESSMENT AND DISCUSSION

General comments

The combined repeated dose toxicity study with the reproduction / developmental toxicity screening test was performed in general accordance with:

- OECD guideline 422 (OECD guideline for testing of chemicals 422, "Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in the Rat", adopted by the Council on 22nd March 1996).
- "Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test" Health Effects Test Guideline OPPTS 870.3650 Guideline from the Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency, July 2000.

Rats were treated with homosalate at doses of 0, 60, 120 or 750 mg/kg/day. Males were treated for 67 days prior to pairing. Males were sacrificed after pairing. Females were treated for 14 days prior to pairing, through the pairing and gestation periods until the F1 generation reached day 3 *post-partum*.

A significant study deviation was that animals were exposed to constant lighting throughout the study (the automatic light cycle of 12 h on / 12 h off was not functional within a block of rooms).

Systemic toxicity

In adult animals, mortality occurred in two females at the highest dose, one found dead and one euthanised due to severe body weight loss (17%). Clinical signs of toxicity at high doses included salivation at ≥300 mg/kg/day, and decreased food consumption and body weight gain at 750 mg/kg/day.

[1] Safety review of seven active sunscreen ingredients | Therapeutic Goods Administration (TGA)

The main targets for homosalate systemic toxicity in this study were the kidney (males), liver, thymus, thyroid gland and male reproductive organs.

Kidney

Kidney histopathology revealed minimal to moderate intra-epithelial hyaline droplets in males at all dose levels, with an increase in incidence and severity observed at ≥300 mg/kg/day. These findings were associated with a statistically significant increase in kidney weight in males at all dose levels. Isolated incidences of basophilic tubules, single cell death, and granular casts were observed in males. While these findings did not show a dose-relationship, they are likely related to the formation of hyaline droplets in these animals.

In females, histopathological findings of basophilic tubules, dilated cortical tubules, diffused fat vacuolation of tubular epithelium, cortico-medullary mineral deposits and single cell death were observed in one or two animals at the high dose only. Increased kidney weight was observed at doses of ≥300 mg/kg/day (without statistical significance). Intra-epithelial hyaline droplets were not observed in females at any dose level.

Findings of intra-epithelial hyaline droplets in males were interpreted by the study author as hyaline droplet nephropathy, a condition known to occur in male rats, due to alpha-2u-globulin accumulation. Analysis of alpha-2u-globulin was not conducted in the original study report. Alpha-2u-globulin-induced nephropathy occurs in male rats via a well know mechanism of action following exposure to some chemicals. Studies have demonstrated that alpha-2u-globulin-induced nephropathy is specific to male rats and is not observed in female rats, mice, NBR male rats or humans (Borghoff *et al*., 1990; US EPA, 1991; Swenberg *et al.,* 1993; IARC, 1999; Goyak *et al.,* 2022).

To investigate the nature of the kidney lesions observed in males, AnaPath Services GmbH conducted a re-evaluation of paraffin-embedded kidney sections[2] using immunohistochemistry to search for the presence of alpha 2u-globulin (re-evaluation cited by the SCCS 2021; data not available to the TGA). According to the SCCS, the analysis confirmed minor increases in alpha 2u-globulin staining in males, primarily at doses of ≥120 mg/kg/day, with one case of single cell necrosis associated with hyaline inclusions. Alpha 2u-globulin staining was also observed one female sample tested at 750 mg/kg/day at levels comparable to treated males (and higher than male positive controls), despite females typically expressing lower levels of alpha 2u-globulin due to estrogen regulation.

The SCCS reports that:

- In males, "at 120 mg/kg, the mean value of alpha 2u-globulin was higher than in controls. However, at 300 and 750 mg/kg, the differences of mean values were not higher compared to controls. The differences were not statistically significant between test item-treated groups and controls."
- "…differences in alpha 2u-globulin levels were not statistically significant between treated males and controls."
- "… staining for alpha 2u-globulin was also observed in females (at 750 mg/kg comparable to males exposed the same way and higher when compared to male positive control), where much lower amounts of alpha-2- microglobulin would be expected."

The re-evaluation of the data by AnaPath Services GmbH led SCCS to conclude the following:

- "the SCCS cannot support the conclusion that observed kidney toxicity was dependent on alpha 2u-globulin mediated mechanism, which is not relevant to humans", and that

[2] AnaPath Services GmbH (2021): Re-Evaluation of Rat Organs from the Harlan Study D54938 by Immunohistochemical Analysis (alpha 2u-globulin). AnaPath Study Number: 13152.

- "human relevance of the kidney findings cannot be ruled out due to inconclusive results from immunohistochemical reanalysis of kidneys".

The TGA considers that despite the lack of statistical significance, the presence of alpha 2u-globulin observed in all males exhibiting intraepithelial hyaline droplets, supports its potential role in the formation of these droplets in male rat kidneys. In addition, the presence of alpha 2u-globulin in one female at 750 mg/kg/day in the absence of associated histopathology (hyaline droplets) does not intrinsically suggest that the findings in male rats are unrelated to alpha 2u-globulin or relevant to humans.

Regarding the consistent association between hyaline droplets containing alpha 2u-globulin and production of certain lesions in the male rat kidney, the U.S. EPA (1991) has stated that 'The histopathological sequence in the male rat consists of the following: an excessive accumulation of **hyaline droplets** containing alpha 2u-globulin in renal proximal tubules; subsequent cytotoxicity and **single-cell necrosis** of the tubule epithelium; sustained **regenerative tubule cell proliferation**, providing exposure continues; development of intralumenal **granular casts** from sloughed cell debris associated with tubule dilation, and papillary mineralization; foci of tubule hyperplasia in the convoluted proximal tubules; and finally, renal tubule tumours.' Indeed, apart from the increased incidence of intraepithelial **hyaline droplets** in the kidneys, other renal findings in males treated with homosalate included varying and low incidences of foci of **basophilic (regenerating) tubules**, **single-cell death** and **granular casts.**

Furthermore, historical data (from 13-week studies in Wistar Hannover Rats; available from the website of the contract research organization **Inotiv**)[3] show that among 79 studies of 13-week duration that investigated hyaline droplets in the kidneys (see table in the Appendix), these droplets were observed in male rats in 53 studies (67% of the studies), with within-study incidences ranging from 7% to 100%. Across all 79 studies, an average of 52% of male rats exhibited hyaline droplets in the kidneys. In contrast, hyaline droplets in female rat kidneys were reported in only 1 of the 79 studies, with an incidence of 20% in females compared to 100% in males in that same study.

Overall, these findings support the conclusion that the presence of intraepithelial hyaline droplets in the kidneys of male rats is a species and sex specific effect and is not relevant to humans.

Liver

Centrilobular hepatocyte hypertrophy and statistically significant increases in liver weight were observed in both sexes at doses of ≥300 mg/kg/day. Hepatocyte hypertrophy is commonly associated with microsomal enzyme induction secondary to exposure to certain xenobiotics and in the absence of other evidence of liver toxicity is considered to be an adaptive, non-adverse, treatment-related response (Hall *et al.,* 2012).

Thymus

Decreased cortical lymphocytes and associated decreases in thymus weight were observed in both sexes at 750 mg/kg/day. In the absence of any effects in other lymphatic tissues, this finding was considered to be a stress related response[4].

Thyroid gland

[3] Historical Control Data on Histological Findings in 13-Weeks Studies in RccHanTM: WIST, Wistar Hannover Rats, available from the website of the contract research organization (CRO) **Inotiv**, hosts extensive historical control data on RccHan®:WIST rats, compiled from 13-week Bioassays performed at Harlan Laboratories Ltd. Itingen/Switzerland (https://www.inotiv.com/hubfs/resources/data-sheets/hcd_tabellen_13weeks_main_kopiervorlage.pdf)
[4] Thymus - Apoptosis, Lymphocyte - Nonneoplastic Lesion Atlas

Diffuse hypertrophy of the thyroid follicular epithelium was observed in animals from all groups including controls, however an increase in the incidence and severity of this finding was observed at the 750 mg/kg/day in both sexes. This finding is likely to be secondary to hepatocellular microsomal enzyme induction and is often seen concomitantly in rats with hepatocellular hypertrophy[5].

Male reproductive organs

A mild reduction in secretions in the prostate and seminal vesicle occurred at 750 mg/kg/day. Reduced organ weights were observed at doses of ≥300 mg/kg/day. An increased incidence of intra-tubular degenerate spermatozoa was also observed at 750 mg/kg/day. These findings correlate with finding of abnormal sperm and decreased normal complete sperm and sperm motility (see *Reproductive toxicity* below) indicating possible effects on male fertility.

The study authors derived a NOAEL of 300 mg/kg/day for general toxicity based on mortality in high-dose females and decreased food consumption. **A NOAEL of 120 mg/kg/day is considered to be more reflective of the available data**, since there were treatment-related histopathological findings in the liver of both sexes as well as effects on male reproductive organs at doses of ≥300 mg/kg/day.

Reproductive toxicity:

Fertility and developmental toxicity of homosalate was also examined in this study, however the study was significantly compromised by the constant lighting condition. Fertility indices were reduced at all doses, although not in a dose-dependent manner, with pregnancies recorded as 8/10 in control, 4/10 at 60 mg/kg, 5/10 at 120 mg/kg, 7/10 at 300 mg/kg, and 3/10 at 750 mg/kg. At the highest dose, females had fewer corpora lutea and higher post-implantation loss, with only one live pup observed at the first litter check. At 300 mg/kg, increased post-implantation loss was noted, although litter size remained unaffected. In males, sperm count was not affected at any dose, but at 750 mg/kg, there was a reduction in normal complete sperm and sperm motility, along with increased abnormalities. No effects on sperm morphology or motility were observed at doses ≤300 mg/kg. These findings coincided with reduced weight of the prostate and seminal vesicles. Post-natal loss occurred across all groups, including controls, and no treatment-related effects were observed in pups regarding body weight, sex ratio, or macroscopic examination. Embryofetal development was not examined.

Although no effects on reproductive parameters were observed at doses ≤ 120 mg/kg bw/day, due to the low number of pregnancies and the confounding effect of constant lighting, a NOAEL for reproductive or developmental toxicity could not be reliably established.

Conclusions on the NOAEL for risk assessment:

Based on the information available, a NOAEL of 120 mg/kg/day for general toxicity is established, based on histopathological changes on the liver and thymus of both sexes and in the male reproductive organs at doses of ≥300 mg/kg/day. histopathological findings of minimal to moderate intra-epithelial hyaline droplets in the kidneys of treated male rats are a species and sex specific effect.

A NOAEL for reproductive or developmental toxicity could not be reliably established.

[5] Thyroid Gland, Follicular Cell - Hypertrophy - Nonneoplastic Lesion Atlas

2. PBPK MODELLING OF HOMOSALATE

A PBPK model has been developed (Najjar *et al.* 2021) to predict human internal exposure (C_{max} and AUC) of homosalate after repeated oral and topical application.

In the study described by Najjar *et al.* (2021), based on *in vivo* studies performed in rats (Kim *et al.*, 2014), an *in vivo* rat PBPK model was calibrated for the intravenous (IV) route and C_{max}. Data from the IV route in rats was extrapolated to the oral route in order to calculate the C_{max} and AUC that would result from an oral dose of 120 mg/kg bw/d. The rat PBPK model was then extrapolated to a human PBPK model which was refined by results from clinical trials in humans reported in Matta *et al.* (2020).

The SCCS notes the following:

> "*the rat PBPK model for the i.v. route has been calibrated but not validated by independent data. The rat PBPK model for the oral route has neither been calibrated nor validated. Therefore, it is not possible to assess the reliability of this model to derive an internal PoD from an external oral dose. In consequence, the subsequent step (i.e. animal to human extrapolation) is not feasible.*
>
> *According to the WHO guidance on PBPK (WHO 2010), the level of confidence of the rat PBPK model can be considered as low, especially regarding the reliability and performance.*"

In contrast to the opinion of the SCCS, the Scientific advisory group on chemical safety on non-food and non-medicinal consumer products (SAG-CS), noted in their opinion published in 2025 that the PBPK model described by Najjar *et al.* (2021) was "adequately representative of the actual exposures likely to be reached following use of homosalate-containing cosmetic products and was robust and predictive". Following an independent review of the model, the SAG-CS considered the model valid noting the following:

> *"the prediction of the mean plasma C_{max} and the 95% confidence interval values after a single application of 163 µg/cm²/day (assuming both 2% and 2.48% dermal penetration) were within the range reported in a human clinical trial by Matta et al. 2020)".*

As a result, the SAG-CS reduced the usual 100-fold uncertainty factor used in the safety assessment of cosmetics to 25, due to the removal of uncertainty when using the PBPK model.

In consideration of the points raised by the SCCS regarding the validation of the PBPK model and in the absence of further expert advice, the TGA concurs with the opinion of the SCCS, that the level of confidence for the rat PBPK model can be considered as low, especially regarding the reliability and performance.

3. EXPOSURE ASSESSMENT AND MARGIN OF SAFETY FOR HOMOSALATE

Standard parameters for the estimation of the systemic exposure dose for homosalate are shown below:

Parameter	Value
NOAEL (adjusted for bioavailability[6])	60 mg/kg bw/day
Dermal absorption (DAp)	5.3%

[6] In the absence of further information, a default value for oral bioavailability of 50% was used.

Parameter	Value
Highest concentration permitted to be used in Australian sunscreen products (C)	15%

The estimated homosalate SED and MoS using the Australian Sunscreen Exposure Model (ASEM) method 1 (%) is shown below:

$$SED = ASEM_{(\text{method 1})} \times DA_p \times C$$
$$= 673\ mg/kg\ bw/day \times 5.3\ \% \times 15\ \% = 5.35\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{60\ mg/kg\ bw/d}{5.35\ mg/kg\ bw/d} = \mathbf{11.2}$$

DA_p: Dermal Absorption, C: Concentration

See ASEM Method 1 for parameters.

Therefore, for a general sunscreen product, the acceptable concentration of homosalate would be 1.68%, based on the MoS calculation below:

$$SED = ASEM_{(\text{method 1})} \times DA_p \times C$$
$$= 673\ mg/kg\ bw/day \times 5.3\ \% \times 1.68\ \% = 0.599\ mg/kg\ bw/day$$

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)} = \frac{60\ mg/kg\ bw/d}{0.599\ mg/kg\ bw/d} = \mathbf{100}$$

DA_p: Dermal Absorption, C: Concentration

Further consideration for homosalate

If the use of a sunscreen product containing homosalate is applied to specific parts of the body e.g. face, the MoS may increase. However, as shown in the two tables below for application of a homosalate-containing sunscreen product, by the whole family, twice a day for 240 days per year and 365 days per year, respectively, the various estimates are still less than satisfactory, i.e. a MoS less than 100.

Annual use considered for 240 days/years based upon Scenario 1 of the ASEM.

Scenario*	Skin Surface Area (cm^2)	Body weight (kg)	Reapplications (no. per day)	Annual use (days/year)	SED (mg/kg bw/d)	MoS
Face only (Toddlers)	500	13	2	240	0.8	75
Face + Hands (Toddlers)	900	13	2	240	1.4	41

Scenario*	Skin Surface Area (cm^2)	Body weight (kg)	Reapplications (no. per day)	Annual use (days/year)	SED (mg/kg bw/d)	MoS
Adult Face only	675	107	2	240	0.1	455
Adult Face + Hands	1875	107	2	240	0.4	164

*95th percentile for SSA body parts and total body weight (For Adult: average of male and female adult values combined).

Annual use considered for 365 days/years if sunscreen product containing homosalate is used every day.

Scenario*	Skin Surface Area (cm^2)	Body weight (kg)	Reapplications (no. per day)	Annual use (days/year)	SED (mg/kg bw/d)	MoS
Face only (Toddlers)	500	13	2	365	1.2	49
Face + Hands (Toddlers)	900	13	2	365	2.2	27
Adult Face only	675	107	2	365	0.2	299
Adult Face + Hands	1875	107	2	365	0.6	108

*95th percentile for SSA body parts and total body weight (For Adult: average of male and female adult values combined).

For these homosalate-containing sunscreen products to reach a satisfactory MoS (≥100) based on specific part of the body and for use by whole family vs adult only, the concentration of homosalate would need to be reduced as shown in the table below for different periods of use (240 & 365 days/year).

The concentration of homosalate that is low-risk in sunscreen products, if applied to specific areas of the body are shown in the table below:

Scenario*	Concentration (%) 240 d/yr	Concentration (%) 365 d/yr
Toddler Face only	11.2	7.3
Toddler Face + Hands	6.2	4.1

*95th percentile for SSA body parts and total body weight (For Adult: average of male and female adult values combined).

Recommendation

A MoS less than 100 was calculated using the ASEM. As a result, homosalate is not deemed to present a low risk to human health and safety when used at the highest maximum permitted concentration of 15% in therapeutic sunscreens.

To mitigate the risk from chronic exposure to homosalate in therapeutic sunscreens, it is recommended that homosalate is listed in the Poisons Standard. To manage the potential risks associated with homosalate it is recommended that the entry restrict the use of homosalate in therapeutic sunscreens, giving consideration to the following:

OPTION 1

Homosalate can be deemed low-risk and appropriate for use in general therapeutic sunscreens for daily use at a concentration up to 1.68%.

OPTION 2

Specific use sunscreens are likely to be used differently by consumers, such as daily application year-round, compared with the use pattern for general sunscreens which are applied to larger parts of the body. Calculations for 240 days/year (based on ASEM scenario 1 for indoor workers) and 365 days/year exposure assumptions have been provided above.

Homosalate can be deemed low-risk and appropriate for use in specific therapeutic sunscreens for daily use when used by adults only;

Or

Homosalate can be deemed low-risk and appropriate for use in general therapeutic sunscreens for daily use by the whole family when:

- Limited to face-only or face and hand application, not to the whole body; and
- At a reduced maximum concentration (between 4.1% and 11.2% of the product), depending on the types of products that are currently marketed and their directions for use.

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APPENDIX 1 — EVALUATION OF NONCLINICAL DATA

COMBINED REPEATED DOSE/REPRODUCTIVE/ DEVELOPMENTAL TOXICITY SCREENING STUDY

Study 2012068 / D54938
Harlan Laboratories Ltd. Füllinsdorf, Switzerland
7 June 2013
GLP

Rat (Han Wistar); *n* = 10/sex/dose
Males were treated for 67 days prior to pairing. Males were sacrificed after pairing. Females were treated for 14 days prior to pairing, through the pairing and gestation periods until the F1 generation reached day 3 *post-partum*. Dams and pups were sacrificed 4 days *post-partum*.
Dose: 0, 60, 120, 750 mg/kg/day PO
Vehicle: corn oil

Maternal/paternal animals

Mortality:

- 1 female found dead during the pre-pairing period on day 6, one female euthanised on day 7 during the pre-pairing period due to poor condition (17% weight loss, uncoordinated movements, hunched posture, weakened condition, decreased activity, ruffled fur).

Clinical signs:

- salivation at ≥300 mg/kg/day considered to be related to the administration procedure

Body weight gain:

- reduced bodyweight gain during pre-pairing period at 750 mg/kg/day (males: by 3% *cf.* 9% in controls; females: bodyweight loss of 4% *cf.* 5% gain for controls). Bodyweight findings correlated with decreased food consumption at this dose.
- No treatment-related effects at doses ≤300 mg/kg/day

Functional observational battery/locomotion: no treatment-related findings

Haematology: no treatment-related effects

Serum chemistry:

- increased albumin: at ≥300 mg/kg/day in males (by 6-11%)
- decreased globulin: at 750 mg/kg/day in males (by 13%)
- increased albumin/ globulin ratio: at 750 mg/kg/day in males (by 24%)

Urinalysis: not examined

Organ weights: see table 1 below

Gross pathology: no treatment-related findings

Histopathology: see table 1 below

Toxicokinetics: not performed

Reproductive parameters

Male fertility: changes in sperm morphology and ↓ sperm motility (sperm counts normal) correlating with ↓ weights of prostate and seminal vesicles at 750 mg/kg/day

Parturition: see table 2 below

Litter values: see table 2 below

Pup external examination: no treatment-related findings. Pup examinations did not include visceral or skeletal examinations

Pup development:

- Lower body weight in one pup at 750 mg/kg/day (Day 1 postpartum)
- No effects up to 300 mg/kg/day (up to Day 4 postpartum)

Table 1: Organ weights and histopathology findings

Dose (mg/kg/day)	Males					Females giving birth				
	0	60	120	300	750	0	60	120	300	750
Organ weight (as % of body weight)										
Brain	0.45	0.45	0.47	0.48	0.52* (↑16%)	0.69	0.73	0.69	0.67	0.66
Heart	0.23	0.24	0.24	0.24	0.25	0.33	0.32	0.33	0.32	0.29
Liver	2.93	2.98	3.04	3.36* (↑15%)	4.05* (↑38%)	3.49	3.29	3.90	4.12* (↑18%)	4.87* (↑40%)
Thymus	0.078	0.083	0.076	0.071	0.049* (↓37%)	0.089	0.074	0.083	0.071 (↓20%)	0.037 (↓58%)
Kidneys	0.49	0.57* (↑16%)	0.56 (↑14%)	0.58* (↑18%)	0.60* (↑22%)	0.59	0.61	0.63	0.64 (↑8%)	0.73 (↑24%)
Adrenal glands	0.013	0.012	0.014	0.013	0.014	0.032	0.037	0.037	0.031	0.025
Spleen	0.2	0.21	0.21	0.2	0.2	0.25	0.30*	0.31*	0.27	0.24
Testis (left)	0.46	0.49	0.52* (↑13%)	0.52* (↑13%)	0.53* (↑15%)	NA	NA	NA	NA	NA
Uterus/duct	NA	NA	NA	NA	NA	0.478	0.524	0.565	0.470	0.380
Prostate/seminal vesicles	0.509	0.513	0.503	0.496	0.420	NA	NA	NA	NA	NA
Organ weight (as % of brain weight)										
Kidneys	110.0	125.5*	119.66	121.66	116.33	84.33	84.89	90.87	96.18* (↑14%)	110.5* (↑31%)
Prostate/seminal vesicles	116.7	112.3	115.6	112.9	87.3* (↓25%)	NA	NA	NA	NA	NA
Histopathology (*incidence*)										
Kidney (*number examined*)	5	5	5	5	5	5	-	-	5	7
Kidney: intraepithelial hyaline droplets										
— minimal	0	1	0	0	0	0	-	-	0	0
— mild	0	0	0	0	1	0	-	-	0	0
— moderate	0	1	3	5	4	0	-	-	0	0
— Total	0	2	3	5	5	0	-	-	0	0
Kidney: focus(i) of basophilic (regenerating) tubules										
— minimal	1	2	1	2	0	0	-	-	0	0
— mild	0	1	0	0	0	0	-	-	0	0
— moderate	0	0	0	0	0	0	-	-	0	1
— Total	1	3	1	2	0	0	-	-	0	1
Kidney: dilated cortical tubules										
— mild	0	0	0	0	0	0	-	-	0	1
Kidney: diffused fat vacuolation of tubular epithelium										
— mild	0	0	0	0	0	0	-	-	0	1
Kidney: unilateral hydronephrosis										
— minimal	0	0	0	0	0	0	-	-	0	1
Kidney: cortico-medullary mineral deposits										
— minimal	0	0	0	0	0	0	-	-	0	2
Kidney: single cell death										
— minimal	0	1	0	0	0	0	-	-	0	0
— mild	0	1	1	0	0	0	-	-	0	1
— Total	0	2	1	0	0	0	-	-	0	1
Kidney: granular cast(s)										
— mild	0	1	0	0	0	0	-	-	0	0

Dose (mg/kg/day)	Males					Females giving birth				
	0	60	120	300	750	0	60	120	300	750
Liver (number examined)	5	5	5	5	5	6	9	9	5	7
Liver: centrilobular hypertrophy										
— minimal	0	0	1	5	2	0	0	0	4	6
— mild	0	0	0	0	3	0	0	0	0	0
— Total	0	0	1	5	5	0	0	0	4	6
Thymus (number examined)	5	5	5	5	5	5	9	9	5	7
Thymus: decreased cortical lymphocytes										
— minimal	0	1	0	4	2	1	1	3	1	1
— mild	0	0	0	0	2	3	0	0	4	3
— moderate	0	0	0	0	0	0	0	0	0	3
— Total	0	1	0	4	4	4	1	3	5	7
Thyroid glands (number examined)	5	5	5	5	5	5	9	9	5	7
Thyroid: diffuse hypertrophy of the follicular epithelium										
— minimal	2	2	2	2	4	0	2	2	4	2
— mild	0	0	0	0	0	1	1	0	0	4
— Total	2	2	2	2	4	1	3	2	4	6
Epididymides (number examined)	10	6	5	8	10	NA	NA	NA	NA	NA
Epididymides: intra-tubular degenerate spermatozoa										
— minimal	0	0	0	1	3	NA	NA	NA	NA	NA
— moderate	0	1	0	0	0	NA	NA	NA	NA	NA
— Total	0	1	0	1	3	NA	NA	NA	NA	NA
Prostate gland (number examined)	10	6	5	7	10	NA	NA	NA	NA	NA
Prostate gland: reduced secretion										
— mild	0	0	0	0	1	NA	NA	NA	NA	NA
Seminal vesicles (number examined)	10	6	5	7	10	NA	NA	NA	NA	NA
Seminal vesicles: reduced secretion										
— mild	0	0	0	0	1	NA	NA	NA	NA	NA

- = not examined; NA = not applicable;

Table 2. Reproductive findings and litter values:

Finding	Dose (mg/kg/day)				
	0	**60**	**120**	**300**	**750**
Pregnant females^ (/10)	8	4	5	7	3
Percentage mating	100	100	100	100	87.5
Fertility index	80	40	50	70	37.5
Conception rate	80	40	50	70	42.9
Gestation index	87.5	100	100	100	33.3
Litters evaluated	**8**	**4**	**5**	**7**	**1**
Duration of gestation	21.5	21.3	21.4	21.5	22
Corpora lutea (total)	108	55	80	97	10
Mean corpora lutea/dam	13.5	13.8	16	13.9	9 (*n*=3)
Total implantations	85	52	63	88	8
Post implantation loss					
% of implantations	8.2	9.6	4.8	20.5	87.5
Litters affected (#)	4	3	3	6	1
Total (#)	7	5	3	18*	7*
Dead pups at first litter check	2	0	0	1	-
Living pups at first litter check	78	47	60	70	1
% Males/females	38/62	49/51	42/58	44/56	100/0*
Postnatal loss days 0 - 4 p.p.					
% of living pups	2.6	0	1.7	1.4	100
Litters affected	2/8	0/4	1/5	1/7	1/1*
Living pups on day 4 p.p. (total)	76	47	59	69	0
(Living pups/litter)	9.5	11.8	11.8	9.9	0
Birth index	91.8	90.4	95.2	79.5*	12.5*
Viability index	97.4	100	98.3	98.6	0*

^ = decreased fertility was considered to be due to a disturbance of the light / dark cycle during the conduct of this study and not test item-related; * = statistically significant difference from control; - not applicable

NOAEL (general toxicity): **120 mg/kg/day** based on histopathological findings in the liver and effects on the male reproductive organs at 300 mg/kg/day; the study authors had concluded the NOAEL was 300 mg/kg/day based on adverse effects on food consumption and bodyweights in both sexes and mortality in females at 750 mg/kg/day.

NOAEL (reproductive performance): not established due to the low number of pregnant females at doses of 60 and 120 mg/kg/day. Post-implantation loss was increased at 300 mg/kg/day, and no indication of any effect on reproduction was observed at ≤120 mg/kg/day).

NOAEL (developmental toxicity): not established (limited examinations)

HISTORICAL DATA FOR HYALINE DROPLETS IN THE KIDNEYS OF WISTAR RATS

Historical control data on RccHan®:WIST rats for the presence of hyaline droplets in the kidney, compiled from 13-week Bioassays performed at Harlan Laboratories Ltd. Itingen/Switzerland, available from the website of the contract research organization **Inotiv** (https://www.inotiv.com/hubfs/resources/data-sheets/hcd_tabellen_13weeks_main_kopiervorlage.pdf) are shown below:

Historical data for the presence of hyaline droplets in the kidney of male rats

Study number	Male rats displaying hyaline droplets in the kidney (%)									
Studies 1-10	100	20	100	-	20	40	*NM*	45	-	93
Studies 11-20	-	-	100	22	85	-	90	85	7	90
Studies 21-30	90	-	67	-	90	100	100	25	100	-
Studies 31-40	-	100	90	100	100*F	100	70	-	70	-
Studies 41-50	-	100	30	-	8	8	-	80	-	-
Studies 51-60	100	-	90	-	100	-	60	-	80	100
Studies 61-70	-	-	-	100	-	100	-	90	100	-
Studies 71-80	60	80	80	100	100	85	90	100	90	70

– = incidence was 0; *F = in Study 35, an incidence of 20% was found for females; NM: not measured

From: s.22
Cc: ; Scheduling Secretariat;
Subject: CMES input to scheduling agenda paper - sunscreen ingredients scheduling [SEC=OFFICIAL]
Date: Monday, 20 October 2025 10:51:30 AM
Attachments: image001.png
CMES - INPUT FOR SUNSCREEN INGREDEINTS SCHEDULING - October 2025.docx

OFFICIAL

Hi ,

As requested at our last meeting, here is CMES' input to the scheduling agenda paper pertaining to the ASEM and its consideration during the public consultation.

I've attached a word document, but it can also be found at D25-4616748.

Please don't hesitate to reach out should you need more information or need to chat further.

Kind regards,

s.22
Complementary Medicines Evaluation Section
Complementary and OTC Medicines Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
T: 02 5132 3124 | E: sharon.pok@health.gov.au
Location: Fairbairn, Gulgana Level 1 South East
PO Box 100, Woden ACT 2606, Australia

Gulgana First Aid Officer: On-site Tuesdays and Thursdays

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

OFFICIAL

INPUT FOR SUNSCREEN INGREDEINTS SCHEDULING

The Australian Sunscreen Exposure Model (ASEM) was the preferred option based on the outcome of the public consultation TGA undertook in 2024, receiving broad support over other options. While most respondents endorsed the ASEM, some industry stakeholders suggested technical adjustments to improve flexibility and reduce complexity in exposure calculations. Some of the aspects that were considered prior to adoption of the ASEM have been briefly noted below.

- **Importance of consistency of regulatory assessments and outcomes**

Respondents stressed the need for consistent safety data inputs across global regulators. The ASEM's alignment with the Scientific Committee on Consumer Safety (SCCS) inputs supports international harmonisation. The ASEM's Margin of Safety (MOS) calculations were seen as reliable, unlike SCCS's variability from dermal absorption data, reinforcing its regulatory consistency and support for innovation.

- **Flexibility of risk assessments using the ASEM**

Industry feedback highlighted the need for the ASEM to support product-specific scenarios like facial sunscreens. The TGA agreed and committed to developing standardised exposure assumptions and guidance for niche products. Unlike legislated models, the ASEM is included in regulatory guidelines and can evolve to accommodate emerging use cases, offering greater flexibility than SCCS.

- **Sunscreen application rate of 2 mg/cm² used in the ASEM**

Most respondents agreed with the 2 mg/cm² application rate used in the ASEM, which aligns with SPF labelling requirements. While some argued this rate exceeds typical consumer behaviour, the TGA defended its use to ensure safety under high-use conditions and reflect Australian-specific practices.

- **Exposure-related assumptions and safety considerations**

The ASEM adopts an annual average exposure model to reflect realistic sunscreen use across seasons and activities. While designed for long-term risk assessment, it also accounts for acute toxicity via maximum daily doses. The TGA supports this approach, citing variability in usage patterns and the need for practical exposure estimates.

High-exposure scenarios such as beach lifestyles and sports are already captured within the ASEM's upper-bound estimates, ensuring safety even under extended use. Concerns about toddler application frequency were addressed using empirical data from early childhood centres, with conservative assumptions applied to safeguard diverse practices.

Seasonal variation, particularly in northern Australia, was considered but found to have minimal impact on overall exposure calculations.

- **Barriers to trade**

Concerns were raised about trade barriers due to Australia-specific assessments. The TGA emphasised the need for tailored evaluations given Australia's high UV exposure and skin cancer rates, ensuring safe ingredient use without compromising availability.

- **Clarity on preferred method used when dermal absorption is reported as both % and µg/cm²**

Respondents sought clarity on which dermal absorption method the ASEM prefers. The TGA explained that both methods yield consistent risk outcomes when applied correctly, and the choice depends on data quality and study conditions.

For more details about the considerations of these aspects, please refer to:
https://consultations.tga.gov.au/tga/proposed-model-for-assessing-sunscreen-ingredients/

From: HENDERSON, Nick
To: CLARKE, Avinash; s.22
Cc: [redacted] VUCKOVIC, George; [redacted]
Subject: RE: MO URGENT MEETING REQUEST: Australian Sunscreen Council (ASC) - MB25-002661 - MIR to follow [SEC=OFFICIAL]
Date: Thursday, 6 November 2025 12:16:54 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png
image008.png
image009.png

OFFICIAL

Thanks Avi, it would be great to clarify all the below in response back to ASC as they have not provided the context as per below and also in the now requested MIR. Given the direction from MO to meet with ASC we'll need to setup this meeting over the next fortnight.

I suggest Tony and I don't attend the meeting, but happy to get your thoughts?

Nick

OFFICIAL

From: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>
Sent: Wednesday, 5 November 2025 4:06 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s.22 [redacted]
Cc: [redacted] VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; [redacted]
Subject: RE: MO URGENT MEETING REQUEST: Australian Sunscreen Council (ASC) - MB25-002661 - MIR to follow [SEC=OFFICIAL]

OFFICIAL

Hi Nick and s.22 ,

Please see further background on s.22 , Homosalate s.22 below.

Thanks to [redacted] for pulling together.

A

s.22

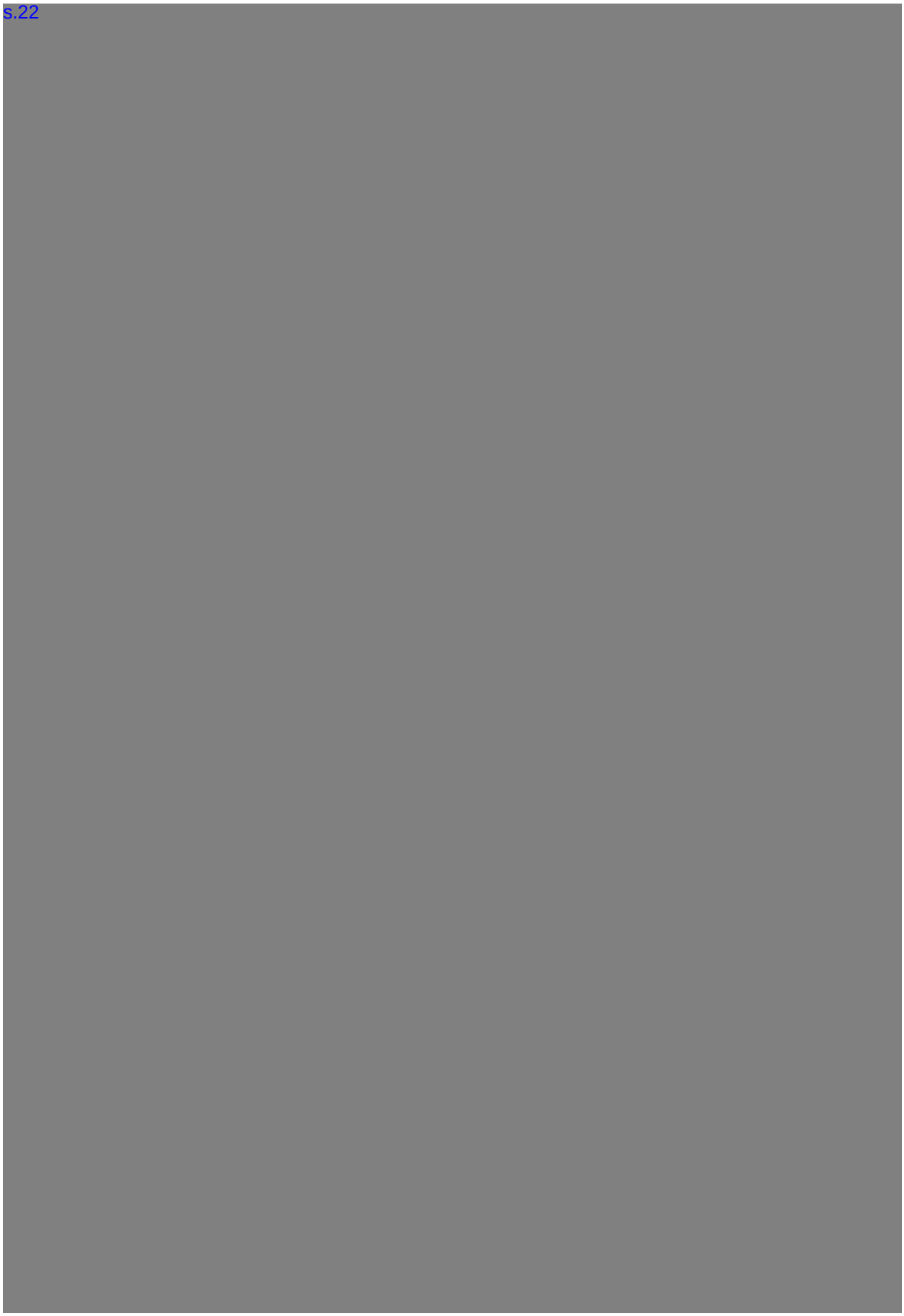
[redacted]

Homosalate as a permissible sunscreen ingredient

- Due to insufficient data to support positive GRASE determination of homosalate, FDA has proposed the ingredient as Category III: Not GRASE because additional data needed in 2020. Since then, the FDA had undertaken public consultation to request for further information about homosalate and other ingredients. To date, an update on the assessment of homosalate has not been published by the FDA.
- The safety review and the scheduling proposals for homosalate and 2 other ingredients were published in July 2025.
- The scheduling proposals were discussed at the joint meeting of the Advisory Committees on Chemicals and Medicines Scheduling on 17 September 2025.

- The Committees sought further information from the TGA on these proposals, which will be discussed by the Committees on 13 November 2025.

s.22



s.22 [redacted]

Avinash Clarke
[redacted]

OFFICIAL

From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Wednesday, 5 November 2025 2:07 PM
To: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; [redacted]
s.22 [redacted]
Cc: [redacted]
Subject: RE: MO URGENT MEETING REQUEST: Australian Sunscreen Council (ASC) - MB25-002661 - MIR to follow [SEC=OFFICIAL]

OFFICIAL

Great thank you, Tony is keen to get more info

OFFICIAL

From: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>
Sent: Wednesday, 5 November 2025 2:05 PM

To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; [redacted] s.22 [redacted]; HPRG Parliamentary <HPRG.Parliamentary@Health.gov.au>
Cc: [redacted]
Subject: Re: MO URGENT MEETING REQUEST: Australian Sunscreen Council (ASC) - MB25-002661 - MIR to follow [SEC=OFFICIAL]

OFFICIAL

Yes - it is permissible ingredient related. Just getting a little more background from the team - will send through this arvo.

A

Sent from Workspace ONE Boxer

OFFICIAL

On 5 November 2025 at 1:58:25 pm AEDT, HENDERSON, Nick <Nick.Henderson@health.gov.au> wrote:

> OFFICIAL
>
> Hi [redacted]
>
> I'll talk to the CO MB team as this may be a permissible Ingredients issue.
>
> Nick
>
> ---
>
> OFFICIAL
>
> **From:** s.22 [redacted] @health.gov.au>
> **Sent:** Wednesday, 5 November 2025 12:39 PM
> **To:** [redacted]; CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
> **Cc:** [redacted]

s.22 [redacted]

Subject: RE: MO URGENT MEETING REQUEST: Australian Sunscreen Council (ASC) - MB25-002661 - MIR to follow [SEC=OFFICIAL]

OFFICIAL

Hi all,

I've just had a chat to Tony about this and the request related to homosalate and ingredient scheduling, not the SPF issues.

This will need to go to RPSD please.

Cheers,

[redacted]

Products Regulation Group
Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
☎: 02 [redacted]

This email comes to you from Ngunnawal Country
Location: 27 Scherger Drive Fairbairn, Level 2

I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.

The Department of Health, Disability and Ageing acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

HEALTH PRIDE NETWORK Ally

OFFICIAL

From: [redacted]@Health.gov.au>
Sent: Wednesday, 5 November 2025 11:33 AM

To: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>

Cc: s.22 [redacted]

Subject: MO URGENT MEETING REQUEST: Australian Sunscreen Council (ASC) - MB25-002661 - MIR to follow [SEC=OFFICIAL]

OFFICIAL

Good morning Avi and Nick,

Cc Dep Sec office for awareness.

The Minister Office have requested relevant people within the TGA to meet with the Australian Sunscreen Council (ASC) regarding recent ministerial decisions and regulatory inconsistencies within Australia's sunscreen framework. Please find further details in the attached letter and below.

The MO has also requested a MIR to follow this meeting outlining background and summary, due by Friday 21 November. This will be assigned to you shortly in PDMS.

Warm regards,

[redacted]
Ministerial Correspondence | Ministerial Submissions | Ministerial Briefs | QTBs
Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government Department of Health, Disability and Ageing
T: 02 6289 3194 | 0473 527 028 | E: HPRG.Parliamentary@health.gov.au
Location: Fairbairn Office
PO Box 100, Woden ACT 2606, Australia
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Regulatory Engagement Service Gateway

Direct access to our services and resources.

OFFICIAL

OFFICIAL

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Wednesday, 5 November 2025 10:56 AM
To: MPS <MPS@health.gov.au>
Subject: FW: For action: FW: Urgent Request for Meeting – Sunscreen Ingredient Safety and Regulatory Inconsistencies [SEC=OFFICIAL]

Hi team,

Request for the department to please meet with the below organisation, with an MIR to follow outlining background and summary.

Due to MO Friday 21 November – have tried to allow sufficient time for meeting to occur. For MRD please.

Thanks

Office of the Hon Mark Butler MP
Minister for Health and Ageing
Minister for Disability and the National Disability Insurance Scheme
Minister.Butler.DLO@health.gov.au | Minister.Butler.DLO@protected.health.gov.au
Suite MG.51 | PO Box 6022, Parliament House, Canberra ACT 2600

From: Minister Butler <Minister.Butler@Health.gov.au>
Sent: Tuesday, 4 November 2025 1:59 PM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: Minister.Butler.Meetings <Minister.Butler.Meetings@Health.gov.au>
Subject: For action: FW: Urgent Request for Meeting – Sunscreen Ingredient Safety and Regulatory Inconsistencies [SEC=OFFICIAL]

OFFICIAL

For consideration – urgent stakeholder meeting request

Office of the Hon Mark Butler MP
Minister for Health and Ageing
Minister for Disability and the National Disability Insurance Scheme
E: Minister.Butler@health.gov.au
PO Box 6022
Parliament House, Canberra ACT 2600
The Department of Health, Disability and Ageing acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

OFFICIAL

From: s.22 [redacted] @australiansunscreencouncil.org>
Sent: Tuesday, 4 November 2025 1:46 PM
To: Minister Butler <Minister.Butler@Health.gov.au>
Subject: Urgent Request for Meeting – Sunscreen Ingredient Safety and Regulatory Inconsistencies

To: The Hon. Mark Butler MP, Minister for Health and Aged Care

Dear Minister Butler,

Please find attached a formal letter on behalf of the **Australian Sunscreen Council (ASC)** requesting an urgent meeting regarding **recent ministerial decisions** and regulatory inconsistencies within Australia's sunscreen framework.

As outlined in the letter, the ASC and **Danger Sun Overhead (DSO)**—a concerned industry participant and Australia's largest sun safety educator in the construction sector, having trained more than **85,000 outdoor workers**—are deeply concerned about recent decisions that appear to contradict both international standards and prior determinations of the Therapeutic Goods Administration (TGA).

We would appreciate the opportunity to meet with you in Canberra at your earliest convenience to discuss these matters and support the Government's efforts to restore public confidence in the safety and regulation of Australian sunscreens.

Please don't hesitate to contact me directly should your office require any further information or wish to coordinate a suitable meeting time.

Kind regards,

s.22

Australian Sunscreen Council

www.australiansunscreencouncil.org

[SEC=OFFICIAL]

Microsoft teams chats

Chat 1

s.22

[redacted]

[redacted] 17/09/2025 12:33 pm

Robyn has also sent through a number of papers related to the kidney findings and the tox section can review these and consider the choice of NOAEL used in the risk assessment

[redacted] 7/09/2025 12:34 pm

Not just around the technical kidney matters but also the broader benefit risk approach.

Friday, 3 October 2025

3/10/2025 9:56 am

FYI, [redacted] who presented on sunscreen formulation at the Joint meeting was also interviewed by [redacted] made points that differences in SPF are not that critical except possibly for high sun exposure scenarios and people should keep using the same. https://app.mediaportal.com/isentia/#/playnow/v2?

Chat 2

s.22 [redacted]

Thursday, 13 November 2025

[redacted] 13/11/2025 10:43 am Edited

There is quite a gap between 1.68 and 15. The hands and face products for adults only are a very niche segment of the market.

The effect of this would be to effectively make 1.68 the cut-off (for most products) for a cheap, effective substance with a weak safety signal, when we don't really have the evidence over what it would be replaced with and the impact on cost...

I'm comfortable with different recommendations for children/toddlers - makes it more complex but something we should unpack.

13/11/2025 10:47 am

Cosmetic products with tints and foundations are easy to restrict to adults.

As people aren't going to normally apply these products to children.

[redacted] 13/11/2025 10:49 am

My comments apply to therapeutic sunscreens

[redacted] 13/11/2025 11:11 am

I think the importance of the transition period and how to optimally manage thisis a key point.

s.22 [redacted]

Chat 3

Wednesday, 17 September 2025

17/09/2025 11:37 am

Was PBPK/PKB modelling considered? Could we do it?

[redacted] 17/09/2025 11:39 am

It was not considered because thee report was not available. We relied on the work of the SCCS. Could we do it - don't know. I have never used it when we actually had data.

17/09/2025 11:39 am Edited

Did you have the s.22 homosalate study beforehand? They submitted it as part of the consultation.

[redacted] 17/09/2025 11:39 am

Not that I was aware.

My recollection was that we only had the SCCS reports - not the actual study reports.

17/09/2025 11:42 am

well we have it now - light reading at 940 pages [redacted]

Chat 4

[redacted] 15/09/2025 9:39 am

FYI G/TBT/N/AUS/183 The active TBT notification regarding the proposed amendments to the Poisons Standard, specifically in relation to the substances homosalate, oxybenzone, and benzophenone.

👍 3

Chat 5

Thursday, 30 October 2025

[redacted] 30/10/2025 4:28 pm

> [redacted] 30/10/2025 4:13 pm
>
> Option 4/5: A decision on scheduling be deferred pending further analysis around public health issues, including impact on .... (alternative products available and their risk profiles; supply lines, price and lead times required for any change; impact on SPF and sunscreen usage patterns). The related issues/policy landscape are too complex to decide at present, and the relative weakness of the safety signal does not warrant an expedited decision.

> [redacted] 30/10/2025 4:18 pm
>
> Points for paper: Around 50% sunscreens contain H, unclear what it would be replaced with and the risk benefit profile of alternative substances. Also unclear the impact on supply, price, usability, SPF which can also affect benefit risk. Impact of changes in Europe will be better known in 6-12 months.

s.22 [redacted]

[redacted] 30/10/2025 5:50 pm

Homosalate has been amended. New text are in track changes.

Chat 6


20/10/2025 12:15 pm
I haven't found any literature that discusses homosalate use as a solubilser in sunscreen or cosmetics. There is information that support it is lipophilic and a strong grease dissolver and may prevent water solubility of other substances. Given that Accord and industry haven't really discussed this as a factor, at least not one worth bringing up in their submissions, I think we focus on the UVB properties as the core reason for its use.
20/10/2025 12:21 pm
Salicylates were the first UVR filters used in sunscreen preparations. They are ortho-disubstituted compounds, which allows the formation of internal hydrogen bonds and thus decreases the ability of electrons to interact with other ingredi□ents or solvent or biological substrates. Although they are relatively weak UVR absorbers, they have excellent safety records and, because they are easily incorporated into cosmetic formulations, some are used to solubilize other usually insoluble cosmetic ingredients, such as benzophenones. Of the salicy□lates on the market today, homosalate and ethylhexyl salicylate are the most widely used in sunscreen preparations
I did find this in one of WHO publication "Chemical and Physical Characteristics of Sunscreen Constituents" It doesnt mention homosalate directly. But you're right, there are not many article i can find looking at this... maybe we can just leave it out since we dont find anything in the literature
https://publications.iarc.who.int/_publications/media/download/3885/328e5bf71433b98b966e9d4773a30ae...
20/10/2025 12:24 pm Edited
I found a US-based cosmetic ingredient search engine that mentions its 'excellent dissolving properties for solid sunscreens'

Chat 7

22/09/2025 12:58 pm

Hi team, [redacted] has enquired about 5/6 agvet products that [redacted] mentioned at the meeting last week. Anyone has any notes on that? I can respond to [redacted]

[redacted] 22/09/2025 1:05 pm Edited

Hi [redacted], in my memory, [[redacted] from APVMA mentioned that For the Committee's awareness, there are altogether 8 insect repellent and sunscreen combination products registered by the APVMA. Oxybenzone is also included in 7 of them and one contains benzophenone. Earlier discussed homosalate is not included in APVMA registered products.] However, my memory of numbers listed above might be wrong. The detailed info of products might be best to check through APVMA PubCRIS or Permits database.