From: S 22
To: LAWLER, Tony; 22
Cc: S 22
Subject: FW: ABC TV interview request (sunscreens) [SEC=OFFICIAL]
Date: Monday, 1 December 2025 2:56:43 PM
Attachments: image001.png

OFFICIAL

Hi Tony,
Please see interview request below from ABC's 730 and Background Briefing program for an interview either tomorrow, Tuesday, December 2 or Wednesday December 3 regarding sunscreens made by Veganic SKN using zinc from Advance ZincTek. The story, as suggested below will look at potential concerns about the SPF of some of their products and the way some of their zinc sunscreens are listed and advertised.
However, given estimates is on this week I will decline and ask her to provide questions if you are OK with that.
Thanks,

s 22
A/g Director I Media and Events
Corporate Communication Branch
Australian Government, Department of Health, Disability and Ageing
T: s 22 | E s 22 @health.gov.au

The Department of Health, Disability and Ageing acknowledges the Traditional Custodians of Australia and their connection to land, sea and community. We pay our respects to all Elders past and present.

OFFICIAL

From: s 22
Sent: Monday, 1 December 2025 2:36 PM
To: S 22
Cc: s 22
Subject: ABC TV interview request (sunscreens)

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 TGA media team,
I'm an ABC journalist working on a story for Background Briefing and ABC TV's 730 program, with s 22 and s 22 .
The story is looking at sunscreens made by Veganic SKN using zinc from Advance ZincTek. The story will look at potential concerns about the SPF of some of their products and the way some of their zinc sunscreens are listed and advertised.
I am writing to request an on-camera interview with the TGA about this matter tomorrow December 2 or Wednesday December 3.

If you could please respond to this request by COB today or first thing tomorrow, I'd appreciate it.
I am on s 22 if you would like to discuss.
Many thanks,
s 22

ABC

s 22
ABC News
M: s 22

We acknowledge Aboriginal and Torres Strait Islander peoples as the First Australians and Traditional Custodians of the lands where we live, learn and work.

From: 22
To: S 22 LAWLER, Tony
Cc: S 22 ; 22
Subject: RE: ABC TV interview request (sunscreens) [SEC=OFFICIAL]
Date: Monday, 1 December 2025 2:58:10 PM
Attachments: image002.png
image003.png
image004.png

OFFICIAL

Hi 22 ,

That sounds great, thanks. Can I please ask that you remember to cc 22 into all interview requests as well.

Cheers,

22 [redacted]

OFFICIAL

From: S 22
Sent: Monday, 1 December 2025 2:57 PM
To: LAWLER, Tony ; 22
Cc: S 22
Subject: FW: ABC TV interview request (sunscreens) [SEC=OFFICIAL]

s.22, Duplicate email [redacted]

From: S 22
To: S 22
Cc: S 22
Subject: MEDIA ENQUIRY - ABC News - Sunscreens - deadline 3pm Thursday [SEC=OFFICIAL]
Date: Tuesday, 2 December 2025 4:53:07 PM
Attachments: image001.png
DOC 1_ AUST L 407959 26 NOV 2025.pdf
DOC 3_ AUST L 405572 14 November 2024.pdf
DOC 5_ Report Evaluation of Sun Protection SPF Determination.pdf
DOC 4_ AUST L 407959 28 NOV 2025.pdf
DOC 6_SBO4 ZTR203.03 Sunbase SSTL Test Report ISO 24444 FDA.pdf
DOC 2_AUST L 405572 19 June 2024_2.pdf
image002.png

OFFICIAL

HI team
Please see the below enquiry from ABC News with a deadline of 3pm Thursday. This is for TV, so it might be better to address the questions in one response if possible, especially as we are unable to be too specific when it comes to individual investigations etc. Please get in touch if you have any issues.
Thanks
S 22

OFFICIAL

From: S 22
Sent: Tuesday, 2 December 2025 4:27 PM
To: S 22
Cc: S 22
Subject: Re: ABC TV interview request (sunscreens) [SEC=OFFICIAL]

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.
Dear TGA media team,
Myself and my colleagues S 22 are looking into zinc oxide from Advance ZincTek and zinc sunscreens made by Veganic SKN using Advance ZincTek zinc.

We have been provided with 2 x sets of preliminary 3 person panel SPF results which show that Natural Mineral Face Sheer Liquid Zinc Sunscreen AUSTL 4055752 may not be providing the SPF50 on its label. The indicative results are SPF 25 and SPF 18 [Doc 2 & 3].

We understand that this formula was recently cancelled from the ARTG but it is still for sale.

We have seen documentary evidence that the under performance of this product and concerns about the zinc oxide used in it were raised with the TGA in a pharmacovigilance report on 27 June 2024.

We have also been provided with 1 x set of preliminary 5 person panel SPF results showing Zinclear S01 AUSTL 407959 showing an SPF of 21 [Doc 1].

The ABC has also commissioned a 3 person panel SPF test on Zinclear S01 AUSTL 407959 which returned a result of SPF 25 [Doc 4].

The ABC understands that these results are indicative and preliminary and are not a 10 person panel.

The results in Doc 1- 4 were conducted by Eurofins Dermatest in Sydney.

The ABC has spoken to multiple SPF testing experts who say that these results are a serious red flag that the SPF of these sunscreen formulas is likely not to be anywhere near the SPF50 on the label. The SPF experts we have spoken to have examined all results attached and told us that, in their opinion, there is no scientific, statistical or valid way these results would reach SPF 50 even if testing was extended to a 10 person panel.

The ABC has established that the formula registered to Veganic SKN and using the 407959 AUSTL is now used by upwards of 30 brands, including Surf Life Saving Australia and Game Face.

The ABC asked Veganic SKN for the ISO 2444:2019 SPF results required to list these sunscreens and they provided two sets of results. One is a 10 person panel done according to the FDA method, not the method mandated by the Australian Standard [Doc 5]. One is a result by the Australian Sunscreen Safety Testing Laboratory, which is owned by Advance ZincTek and is also from May 2025, which is after both these sunscreens were listed on the ARTG [Doc 6]. Veganic SKN has not, at this point, provided us with information on which test results are for which product.

Many of these brands, including some owned by Veganic SKN, are marketing these products online using language and images that promote zinc sunscreen as a safe and natural alternative to toxic chemical sunscreens.

Questions:

1. What action did the TGA take when it was informed via a pharmacovigilance report in June 2024 of testing that suggested that sunscreens using Advance ZincTek zinc were likely not to be providing the SPF 50 on their labels?

2. The company responsible for the 2024 pharmacovigilance report has told the ABC that the TGA did not follow up with any requests for information regarding that report and was told any potential action by the TGA was confidential. They have expressed the opinion and concern that the TGA appears not to have acted in response to the concerns raised in that

report. What is the TGA's response to this allegation? What action did the TGA take in relation to this safety report?

3. Test result [Doc 2] for a sunscreen with the AUSTL 405572 was attached to that pharmacovigilance report. Did the TGA check that this sunscreen held SPF rest reports as required by the regulations to demonstrate its SPF50 label? Was the TGA satisfied with these test results?

4. Is the TGA concerned about the additional test results attached to this email for the two sunscreen formulas with an AUSTL of 405572 and 407959?

5. What action will the TGA take in relation to these test results?

6. Does the testing provided by Veganic SKN [Doc 5 & 6] meet the Australian standard for SPF testing to list a sunscreen on the ARTG?

7. One of the test reports provided by Veganic SKN [Doc 6] was done on a date after both the sunscreens in questions were listed [
407959: 21 April 2023 & 405572: 01 March 2023] Does this comply with the TGA regulations for listing a sunscreen?

8. As stated above, more than 30 brands are selling this sunscreen using the same AUSTL, 407959, registered to the sponsor Veganic SKN. A regulatory consultant and former TGA policy advisor has told the ABC they believe this is not legal and makes it hard for the TGA to regulate. What is the TGA's response to this?

9. The ABC has also been advised that a number of these brands, including brands owned by Veganic SKN, could be breaching TGA advertising regulations with some of the claims being made on social media - as can be seen in the following links:

https://www.instagram.com/reel/DPdMPUyEVBW/
https://www.instagram.com/p/DQx2yA_kgwc/
https://www.instagram.com/p/DNEdESozGvQ/?hl=en
https://www.instagram.com/p/DRLdtz4gVF5/?hl=en&img_index=1
https://www.instagram.com/p/DLmCDNuhjH_/?hl=en&img_index=1
https://www.instagram.com/p/DRRE3-HE7ex/?hl=en&img_index=3

Does the TGA consider the type of messaging in the above to be a breach of TGA advertising regulations?

10. VeganicSKN has told the ABC it has information from the TGA, sourced through FOIs, that there are 21 active sunscreen ingredients that the TGA has no safety data on record for. Is this accurate? What is the TGA's response to this?

11. Veganic SKN has expressed concern publicly and to the ABC that sunscreen ingredients not allowed in the US and the EU (including 4MBC) are still allowed in sunscreens in Australia and that this poses a health risk to Australian consumers. Is it correct that 4MBC

is allowed to be used in sunscreens sold in Australia? If so, what is the TGA's response to Veganic SKN's claim that this poses a health risk to Australian consumers?

12. Veganic SKN has also told the ABC and publicly stated that some other sunscreen ingredients allowed by the TGA have also been linked to health risks. What is the TGA's response?

The story in question is for ABC's 7.30 and Background Briefing.
Please don't hesitate to call if you have any questions.
Many thanks,

S 22 [redacted]

OFFICIAL

From: S 22 [redacted]
Sent: Monday, December 1, 2025 16:07
To: S 22 [redacted]
Cc: S 22 [redacted]
Subject: RE: ABC TV interview request (sunscreens) [SEC=OFFICIAL]

Thanks S 22 ,
We'll get you a list of questions ASAP.
S 22 [redacted]

From: S 22 [redacted]
Sent: Monday, 1 December 2025 4:04 PM
To: S 22 [redacted]
Cc: S 22 [redacted]
S 22 [redacted]
Subject: RE: ABC TV interview request (sunscreens) [SEC=OFFICIAL]

OFFICIAL

Hi S 22 [redacted]
Unfortunately, no one from the TGA is available this week given that Estimates are on this week and other relevant spokespeople are not available.
Happy to provide a written response to any questions you have.
Thanks,

S 22 [redacted]

From: S 22
To: CLARKE, Avinash; LUTTON, Tracey
Cc: S 22 S 22 S 22
Subject: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Tuesday, 2 December 2025 5:05:02 PM
Attachments: image001.png
DOC 1_ AUST L 407959 26 NOV 2025.pdf
DOC 3_ AUST L 405572 14 November 2024.pdf
DOC 5_ Report Evaluation of Sun Protection SPF Determination.pdf
DOC 4_ AUST L 407959 28 NOV 2025.pdf
DOC 6_SBO4 ZTR203.03 Sunbase SSTL Test Report ISO 24444 FDA.pdf
DOC 2_AUST L 405572 19 June 2024_2.pdf
image002.png
image003.png

OFFICIAL

Good afternoon Avi and Tracey,
Please see the below media request for your appropriate action.
Note this is for TV, so it might be better to address the questions in one response if possible.
Grateful if you could liaise with each other to provide a consolidated response.

MEDIA FOR ACTION	
News Outlet	ABC News
AS clearance by	**12:30pm Thursday, 4 December 2025**

Query:

Myself and my colleagues S 22 are looking into zinc oxide from Advance ZincTek and zinc sunscreens made by Veganic SKN using Advance ZincTek zinc.

We have been provided with 2 x sets of preliminary 3 person panel SPF results which show that Natural Mineral Face Sheer Liquid Zinc Sunscreen AUSTL 4055752 may not be providing the SPF50 on its label. The indicative results are SPF 25 and SPF 18 [Doc 2 & 3].

We understand that this formula was recently cancelled from the ARTG but it is still for sale.

We have seen documentary evidence that the under performance of this product and concerns about the zinc oxide used in it were raised with the TGA in a pharmacovigilance report on 27 June 2024.

We have also been provided with 1 x set of preliminary 5 person panel SPF results showing Zinclear S01 AUSTL 407959 showing an SPF of 21 [Doc 1].

The ABC has also commissioned a 3 person panel SPF test on Zinclear S01 AUSTL 407959 which returned a result of SPF 25 [Doc 4].

The ABC understands that these results are indicative and preliminary and are not a 10 person panel.

The results in Doc 1- 4 were conducted by Eurofins Dermatest in Sydney.

The ABC has spoken to multiple SPF testing experts who say that these results are a serious red flag that the SPF of these sunscreen formulas is likely not to be anywhere near the SPF50 on the label. The SPF experts we have spoken to have examined all results attached and told us that, in their opinion, there is no scientific, statistical or valid way these results would reach SPF 50 even if testing was extended to a 10 person panel.

The ABC has established that the formula registered to Veganic SKN and using the 407959 AUSTL is now used by upwards of 30 brands, including Surf Life Saving Australia and Game Face.

The ABC asked Veganic SKN for the ISO 2444:2019 SPF results required to list these sunscreens and they provided two sets of results. One is a 10 person panel done according to the FDA method, not the method mandated by the Australian Standard [Doc 5]. One is a result by the Australian Sunscreen Safety Testing Laboratory, which is owned by Advance ZincTek and is also from May 2025, which is after both these sunscreens were listed on the ARTG [Doc 6]. Veganic SKN has not, at this point, provided us with information on which test results are for which product.

Many of these brands, including some owned by Veganic SKN, are marketing these products online using language and images that promote zinc sunscreen as a safe and natural alternative to toxic chemical sunscreens.

Questions:

1. What action did the TGA take when it was informed via a pharmacovigilance report in June 2024 of testing that suggested that sunscreens using Advance ZincTek zinc were likely not to be providing the SPF 50 on their labels?
2. The company responsible for the 2024 pharmacovigilance report has told the ABC that the TGA did not follow up with any requests for information regarding that report and was told any potential action by the TGA was confidential. They have expressed the opinion and concern that the TGA appears not to have acted in response to the concerns raised in that report. What is the TGA's response to this allegation? What action did the TGA take in relation to this safety report?
3. Test result [Doc 2] for a sunscreen with the AUSTL 405572 was attached to that pharmacovigilance report. Did the TGA check that this sunscreen held SPF rest reports as required by the regulations to demonstrate its SPF50 label? Was the TGA satisfied with these test results?
4. Is the TGA concerned about the additional test results attached to this email for the two sunscreen formulas with an AUSTL of 405572 and 407959?
5. What action will the TGA take in relation to these test results?
6. Does the testing provided by Veganic SKN [Doc 5 & 6] meet the Australian standard for SPF testing to list a sunscreen on the ARTG?
7. One of the test reports provided by Veganic SKN [Doc 6] was done on a date after both the sunscreens in questions were listed [407959: 21 April 2023 & 405572: 01 March 2023] Does this comply with the TGA regulations for listing a sunscreen?
8. As stated above, more than 30 brands are selling this sunscreen using the same AUSTL, 407959, registered to the sponsor Veganic SKN. A regulatory consultant and former TGA policy advisor has told the ABC they believe this is not legal and makes it hard for the TGA to regulate. What is the TGA's response to this?
9. The ABC has also been advised that a number of these brands, including brands owned by Veganic SKN, could be breaching TGA advertising regulations with some of the claims being made on social media - as can be seen in the following links:
   https://www.instagram.com/reel/DPdMPUyEVBW/
   https://www.instagram.com/p/DQx2yA_kgwc/
   https://www.instagram.com/p/DNEdESozGvQ/?hl=en

https://www.instagram.com/p/DRLdtz4gVF5/?hl=en&img_index=1
https://www.instagram.com/p/DLmCDNuhjH_/?hl=en&img_index=1
https://www.instagram.com/p/DRRE3-HE7ex/?hl=en&img_index=3
Does the TGA consider the type of messaging in the above to be a breach of TGA advertising regulations?

10. Veganic SKN has told the ABC it has information from the TGA, sourced through FOIs, that there are 21 active sunscreen ingredients that the TGA has no safety data on record for. Is this accurate? What is the TGA's response to this?
11. Veganic SKN has expressed concern publicly and to the ABC that sunscreen ingredients not allowed in the US and the EU (including 4MBC) are still allowed in sunscreens in Australia and that this poses a health risk to Australian consumers. Is it correct that 4MBC is allowed to be used in sunscreens sold in Australia? If so, what is the TGA's response to Veganic SKN's claim that this poses a health risk to Australian consumers?
12. Veganic SKN has also told the ABC and publicly stated that some other sunscreen ingredients allowed by the TGA have also been linked to health risks. What is the TGA's response?

Proposed response:

NOTE: Media responses should be drafted as a brief statement or as a 1-5 dot point response that essentially addresses the enquiry/argument. If necessary, include further information (technical/policy/legislative nuances) as background to provide context and help the journalist better understand the issue. Please note, in some cases it may be necessary to respond to each of the questions separately.

Kind regards,

S 22 [redacted]

OFFICIAL

From: S 22
Sent: Tuesday, 2 December 2025 4:53 PM
To: S 22
Cc: S 22
Subject: MEDIA ENQUIRY - ABC News - Sunscreens - deadline 3pm Thursday
[SEC=OFFICIAL]

OFFICIAL

HI team

Please see the below enquiry from ABC News with a deadline of 3pm Thursday. This is for TV, so it might be better to address the questions in one response if possible, especially as we are unable to be too specific when it comes to individual investigations etc. Please get in touch if you have any issues.

Thanks

S 22

OFFICIAL

From: S 22

Sent: Tuesday, 2 December 2025 4:27 PM

To: S 22

Cc: S 22

Subject: Re: ABC TV interview request (sunscreens) [SEC=OFFICIAL]

s.22, Duplicate email

eurofins | Dermatest

www.eurofins.com.au/dermatest

Eurofins Dermatest
20 – 22 King Street
Rockdale
NSW
2216
Australia

+61 2 9556 2601

Preliminary Evaluation of Sun Protection Factor Report

The preliminary evaluation was performed according to: s 47

Eurofins Dermatest Sample Number: s 47

Client: [redacted]

Product Description: Reef Safe SPF50 with Vitamin C EXP Jan 2027

Batch/Formula No.: s 47

Eurofins Dermatest Quote Number: s 47

Client Purchase Order Number: n/a

Test Condition: s 47

Nominated SPF: s 47

Date: s 47

Signoff Study Director: s 22

s 22

Protocol specific formatted reports will be provided on completion of the full study for this product

Preliminary Report

Test Protocol :	s 47	**Eurofins Sample No.**	s 47
Product Description :	Reef Safe SPF50 with Vitamin C EXP Jan 2027	**Client :**	[redacted]
Batch/Formula No.	s 47	**Report Date :**	s 47
Test Conditions :	s 47	**Contact :**	[redacted]

s 47

s 47

Test Product Avg. SPF	**21.1**		s 47		s 47

s 47

Preliminary Result : The indicative SPF when tested to the protocol specifications was **21**

s 47

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eurofins | Dermatest

www.eurofins.com.au/dermatest

Eurofins Dermatest
20 – 22 King Street
Rockdale
NSW
2216
Australia

+61 2 9556 2601

Preliminary Evaluation of Sun Protection Factor Report

The preliminary evaluation was performed according to: s 47

Eurofins Dermatest Sample Number: s 47

Client: [redacted]

Product Description: [redacted]

Batch/Formula No.: s 47

Eurofins Dermatest Quote Number: s 47

Client Purchase Order Number: n/a

Test Condition: s 47

Nominated SPF: s 47

Date: s 47

Signoff Study Director: s 22

s 22

Protocol specific formatted reports will be provided on completion of the full study for this product

Preliminary Report

Test Protocol :	s 47	**Eurofins Sample No.**	s 47
Product Description :	[redacted]	**Client :**	[redacted]
Batch/Formula No.	s 47	**Report Date :**	s 47
Test Conditions :	s 47	**Contact :**	[redacted]

The first test subject target SPF was set at : s 47

s 47

Test Product Avg. SPF	**25.4**		s 47		s 47

s 47

Preliminary Result : The indicative SPF when tested to the protocol specifications was **25**

s 47

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eurofins | Dermatest

www.eurofins.com.au/dermatest

Eurofins Dermatest
20 – 22 King Street
Rockdale
NSW
2216
Australia

+61 2 9556 2601

Preliminary Evaluation of Sun Protection Factor Report

The preliminary evaluation was performed according to: s 47

Eurofins Dermatest Sample Number: s 47

Client: [redacted]

Product Description: s 47

Batch/Formula No.: s 47

Eurofins Dermatest Quote Number: s 47

Client Purchase Order Number: n/a

Test Condition: s 47

Nominated SPF: s 47

Date: s 47

Signoff Study Director: s 22
s 22

Protocol specific formatted reports will be provided on completion of the full study for this product

eurofins | Dermatest

Preliminary Report

Test Protocol :	s 47	**Eurofins Sample No.**	s 47
Product Description :	SLSA726	**Client :**	[redacted]
Batch/Formula No.	s 47	**Report Date :**	s 47
Test Conditions :	s 47	**Contact :**	[redacted]

The first test subject target SPF was set at : s 47

s 47

Test Product Avg. SPF	**18.5**		s 47		s 47

s 47

Preliminary Result : The indicative SPF when tested to the protocol specifications was **18**

s 47

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eurofins | Dermatest

www.eurofins.com.au/dermatest

Eurofins Dermatest
20 – 22 King Street
Rockdale
NSW
2216
Australia

+61 2 9556 2601

Preliminary Evaluation of Sun Protection Factor Report

The preliminary evaluation was performed according to: s 47

Eurofins Dermatest Sample Number: s 47

Client: Australian Broadcasting Corporation

Product Description: Surf Life Saving Natural Mineral Face Sheer Liquid Zinc Sunscreen - Medium Tint

Batch/Formula No.: s 47

Eurofins Dermatest Quote Number: s 47

Client Purchase Order Number: n/a

Test Condition: s 47

Nominated SPF: s 47

Date: s 47

Signoff Study Director: s 22

s 22

Protocol specific formatted reports will be provided on completion of the full study for this product

Preliminary Report

Test Protocol :	s 47	**Eurofins Sample No.**	s 47
Product Description :	Surf Life Saving Natural Mineral Face Sheer Liquid Zinc Sunscreen - Medium Tint	**Client :**	Australian Broadcasting Corporation
Batch/Formula No.	s 47	**Report Date :**	s 47
Test Conditions :	s 47	**Contact :**	s 22

The first test subject SPF anchor was set at : s 47

s 47

Test Product Avg. SPF	**25.0**		s 47		s 47

s 47

Preliminary Result : The indicative SPF when tested to the protocol specifications was **25**

s 47

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REPORT

EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA) – STATIC

Study Number	**CASAZ0114/22-01, CASVE1424/22-01**
Report Number	**REL/CA/G0321/2022/CLI**
Sponsor	**Advance ZincTek Ltd.** **1821 Ipswich Road, Rocklea, QLD 4106, Australia** **VeganicSKIN** **243 Milton Rd, Milton QLD 4064** **(QL), Australia**
Site carrying out the test	**Abich Inc** **5160 Boulevard Décarie** **H3X 2H9 Montréal Canada**
Test Product	**Name: Sunscreen** **Batch: 756-1204 (Recipe 1329 SB2131) & 1329-2** **Product Type: Cream**
Date	**26/08/2022**
Study start and end dates	**18/11/2021 to 12/08/2022**

Contents

SUMMARY

On behalf of **Advance ZincTek Ltd. and VeganicSKIN,** on the test substance

Name:	**Sunscreen**
Batch:	**756-1204 (Recipe 1329 SB2131) & 1329-2**
Product Type:	**Cream**

an *in vivo* study has been carried out to evaluate the Sun Protection Factor (SPF) according to the Final Rule regarding the labeling and effectiveness testing for over-the-counter (OTC) sunscreen products, published by the FDA on June 17, 2011 (Final Rule 21 C.F.R. § 201.327, section VI).

The back of healthy subjects who voluntarily have decided to participate on the test has been irradiated with UVA/UVB rays produced by a certified artificial light source (Xenon arc Solar Simulator). The MED (Minimum Erythemal Dose) has been calculated 20±4 hours after the irradiation.

The study was performed in the laboratory facility of Abich Inc, in 5160 Décarie Boulevard-#330 Montréal (Québec) H3X 2H9 - Canada.

On the basis of the tests carried out, under the adopted experimental conditions, the sample of the test substance

Advance ZincTek Ltd. and VeganicSKIN

Name:	**Sunscreen**
Batch:	**756-1204 (Recipe 1329 SB2131) & 1329-2**
Product Type:	**Cream**

has a **mean of 52.7** and a **SPF label of 50**.

GLOSSARY

- **MED**, Minimum Erythemal Dose**:** is defined as the lowest ultraviolet (UV) dose that produces the first perceptible unambiguous erythema with defined borders appearing over most of the field of UV exposure, 16 to 24 hours after UV exposure;
- **MEDu,** Minimum Erythemal Dose on unprotected skin;
- **MEDp,** Minimum Erythemal Dose on protected skin;
- **tpMEDp,** Minimum Erythemal Dose on testing product protected skin;
- **ssMEDp,** Minimum Erythemal Dose on standard sunscreen product protected skin;
- **SPF,** Sun Protection Factor: indicator of the efficacy of sunscreen products against sunburn; it is a ratio calculated from the energies required to induce a minimum erythemal response with and without sun product applied to the skin of human volunteers, using ultraviolet radiation usually from an artificial source;
- **UV-R:** solar ultraviolet radiation in the range 290–400 nm;
  In particular:
  UVA: solar ultraviolet radiation in the range 320–400 nm;
  UVB: solar ultraviolet radiation in the range 290–320 nm;

DISCLAIMER

The test was performed with the assumption that the Sponsor, under its responsibility, provided to the personnel of Abich Inc. Lab. truthful information on any ingredient of the test product endowed with potential toxicological relevance.

On the basis of such information, a general assessment of the toxicological information concerning the product was preliminarily carried out and ethical implications as to its use during the present study have been considered.

The results reported herein do exclusively refer to the tested sample. This report may not be reproduced, neither entirely nor in part except with an explicitly written authorization from the laboratory.

EXPERIMENTAL PROCEDURE

1. AIM OF THE TEST

The aim of the test is to determine *in vivo* the static Sun Protection Factor (SPF) of a sunscreen product according to FDA Rules. The SPF testing procedure is carried out according to the FDA Final Rule 21 C.F.R.§ 201.327.

2. TEST SUBSTANCE

Sample Description:	**Name:**	**Sunscreen**
	Batch:	**756-1204 (Recipe 1329 SB2131) & 1329-2**
	Product Type:	**Cream**
Appearance:	**Thick white cream**	
Expected SPF:	**50+**	
Abich sample code	**CAS011/22-01, CAS330/22-01**	
PAO / Expiration date:	**n.a**	
Storage conditions:	**22 ± 4 °C**	
Reception date:	**18/11/2021 & 22/07/2022**	
Test Start Date:	**18/11/2021**	
Test End Date:	**12/08/2022**	

The characterization of the test substance is under responsibility of the Sponsor.

Upon arrival at the laboratory, the test material was assigned a unique code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested.

Samples are retained for a period of three months beyond submission of final report unless otherwise specified by the sponsor or if the sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission. Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

3. ASSAY SYSTEM

3.1 Regulatory aspects

This study has been carried out in compliance with the most recent recommendations of the World Medical Association Declaration of Helsinki - ethical principles for medical research involving human subjects (Helsinki Declaration 64th WMA General Assembly, Fortaleza, Brazil, October 2013) and according to the FDA Sunscreen Final Rule published on June 17, 2011 (final rule 21 C.F.R.§ 201.327, section VI).

3.2 Quality system

The test is carried out according to the written internal quality procedures of Abich Inc. by suitably skilled and trained personnel. All the procedures, where applicable, are in accordance with the principles of Good Laboratory Practice.

All relevant observations and data recorded during the test are filed in this report.

3.3 Characteristics of the panel

The study was performed on male and female volunteers, over the age of 18 years, who have been identified from the Abich Inc. database of volunteers.

Before the beginning of the study, each volunteer has read and signed an informative form (informed consent form), and has answered its questions exhaustively. Each volunteer has had the opportunity to ask any kind of questions regarding the study to which an exhaustive answer was given. The objectives of the test, the procedures and the possible related risks were explained to the volunteers.

The participation in the study was permitted only after having signed the informed consent. Only volunteers in good general health conditions were included in the study.

The original informed consent forms are filed at Abich Inc. All volunteers signed a consent allowing to treat personal data according to the Québec Law.

The subjects included in the SPF test shall be phototype I, II, or III according to Fitzpatrick or shall have an ITA° value >28° as determined by colorimetric methods. They must not be tanned on the test area. The correlation between the skin phototypes, the skin color and the ITA° value is as follows:

Skin Phototype	Skin Description	ITA° Value
I	VERY LIGHT	>55°
II	LIGHT	>41 to 55°
III	INTERMEDIATE	>28 to 41°
IV	TANNED (or MATT)	>10 to 28°
V	BROWN	>-30 to 10°
VI	BLACK	≤-30°

where ITA° = [arctg((L*-50)/b*)]x180/3.1416

Moreover, the following criteria of exclusion were applied:
- Children (SCCNFP/0557/02) and persons below the age of consent;
- Women who reported to be pregnant or lactating;
- Subjects taking medication that could interfere with the test results (i.e. photosensitizing, anti-inflammatory drugs);
- Subjects with dermatological disorders;
- Subjects with a history of adverse events related to sun exposure;
- Subjects accustomed to artificial tanning;
- Subjects with marks, blemishes or naevi, or hairs on the testing site;
- Subject participating in other simultaneous studies that might interfere with the test evaluation;
- Subjects with known hypersensitivity to sunscreens.

After the study start, the following withdrawal criteria were applied:

- Volunteers who did not follow the conditions as described in the Study Information Sheet;
- Volunteers who suffered any illness or accident or developed any condition which could affect the outcome of the study;
- Volunteers who did not longer wish to participate in the study.

There shall be a sufficient interval between two successive UV exposures to the same test site for resolution of discoloration resulting from previous tests.

4. STANDARD SUNSCREEN

The standard sunscreen is a control formulation containing 7% padimate O and 3 % oxybenzone.

It is used as a methodological control to verify the test procedure.

ABICH Standard code	STD-007
Name of product	FDA SPF Standard – P2 High SPF standard
Batch number	1902Y
Expiration date	October 2022

5. INSTRUMENTATION

UV Source: the UV irradiation was performed with a UV Solar Simulator Model 601-300 V2.5 from SolarLight Co., equipped with a Xenon Arc Lamp 300 W, in compliance with FDA - COLIPA standards. The device was equipped with Shutter (UVA-B) WG320 and UG 11 black glass filters and with a LLG of the appropriate size.

Solar Sim	Code	Last calibration
1	INS-023	March 2022
2	INS-075	March 2022
3	INS-145	January 2022
4	INS-160	April 2022
5	INS-169	April 2022

The table below reports the spectral emission in %RCEE (Relative Cumulative Erythemal Effectiveness) with acceptability limits:

Spectral range (nm)	%RCEE lower limit	%RCEE upper limit
< 290		< 0.1
290-300	1.0	8.0
290-310	49.0	65.0
290-320	85.0	90.0
290-330	91.5	95.5
290-340	94.0	97.0
290-400	99.9	100.0

The output signal of the Solar Simulator was evaluated with the aid of a certified Dose Control System (DCS-2.0) with an LLG adaptor and with two detectors (Erythema detector PMA2108 LLG and UVA detector PMA 2118 LLG.

Chromameter: The skin phototype of the volunteers was measured with a Konica-Minolta CR-400. Colorimetric readings were expressed in ITA values.

Analytical balance:

Balance	Code	Model
1	INS-132	Mettler Toledo (220g ± 0.0001g)
2	INS-115	Sartorius Entris™ II Essential (120g ± 0.0001g)
3	INS-152	Sartorius Entris® II Essential (120g ± 0.0001g)
4	INS-164	Sartorius Entris® II Essential (120g ± 0.0001g)

Doctor bed: to position the volunteers.

Gilson positive pipette, syringe or spatula (for solid products): used to weigh and apply the products.

Dermographic pen: to delineate the skin area of application of the products and the area of contact with the six probes.

Plexiglass support: (dimensions 5 cm x 10 cm) to define the area of application of the product.

Latex Finger cot: for the product application.

Ambient Thermometer: to verify the room temperature during the test.

6. AMBIENT CONDITIONS

Product application, UV exposures and MED assessment were carried out in stable conditions, with the room temperature kept between 18 and 26 °C.

7. PRODUCT APPLICATION

An amount of test product (2.0 mg/cm^2) is applied on each specific test site on the back of the volunteer and gently spread with the finger covered by a latex finger cot. The quantity of product applied is verified by weighing the disposed amount and the remaining amount on the finger cot followed by a double-weighing procedure.

A *Latex* finger cot *was* used.

A double weighing procedure was incorporated as follows: positive pipette with pipette tip/syringe/spatula + product + latex finger cot, prior to and after application to ensure the required quantity was delivered.

To ensure a uniform distribution, little droplets of the product were deposited with a positive pipette/syringe/spatula, then spread over the test site with light finger pressure. Spreading time is in the range of 20 to 50 seconds. Product is applied as evenly as possible.

Homogeneity of the application is verified by using a Woods lamp.

The length of the UV rays pathway through the sample must be homogeneous in each point of the testing site.

8. SITE OF EXPOSURE

The site of exposure is an area of 50 cm^2 in the inter-scapular region of the back. The sites did not present skin damages nor naevi nor hair or any other anomaly which could prevent regular testing and was not tanned. Skeletal protrusions and extreme areas of curvature were avoided.

The ITA value of each testing site was obtained by the Chromameter. Three measurements on each sub site. The ITA value was then used to determine the skin phototype and MEDu

Each test site encompasses six round shaped sub-sites of about 1 cm^2 each in size, corresponding to the optical guides of the Solar UV Simulator. The minimum distance between the borders of each exposure sub-site is 0.8 cm. A dermal graphic pen was used to mark the sites of exposure.

According to the Experimental Plan, test sites were randomised in order to reduce standard error due to skin tone differences.

The unprotected test site used to determine the MEDu is in close proximity to the MEDp test sites.

9. TIME BETWEEN PRODUCT APPLICATION AND UV EXPOSURE

Exposure of the test site to the sequence of UV doses started 15 minutes after the application of the product.

10. EQUIPMENT

UV Source: the UV irradiation was performed with a UV Solar Simulator Model 601-300 V2.5 from SolarLight Co., equipped with a Xenon Arc Lamp 300W, in compliance with FDA - ISO standards. The device was equipped with Shutter (UVA-B) WG320 and UG 11 black glass filters and with an LLG of the appropriate size.

Solar Simulator	Last calibration
1	March 2022
2	March 2022
3	January 2022
4	April 2022
5	April 2022

The table below reports the spectral emission in %RCEE (Relative Cumulative Erythemal Effectiveness) with acceptability limits:

Spectral range (nm)	%RCEE lower limit	%RCEE upper limit
<290		<0.1%
290-300	1.0	8.0
290-310	49.0	65.0
290-320	85.0	90.0
290-330	91.5	95.5
290-340	94.0	97.0
290-400	99.9	100.0

The output signal of the Solar Simulator was evaluated with the aid of a certified Dose Control System (DCS-2.0) with an LLG adaptor and with a detector (Erythema detector PMA2108 LLG).

Uniformity of the beam is measured using PMA2174 Digital Quadrant Sensor every six months or when any modifications are made to the lamp optical components, or when non – uniform erythema spots are seen in test subsites. The uniformity of the beam should be ≥90% (last calibration: April-May 2022).

Chromameter: The skin phototype of the volunteers was measured with a Konica-Minolta CR-400. Colorimetric readings were expressed in ITA values (last calibration: January-March 2022).

Analytical balance: to weight the products.

Balance	Model	Last calibration
1	Mettler Toledo (220g ± 0.0001g)	April 2022
2	Sartorius Entris™ II Essential (120g ± 0.0001g)	May 2022
3	Sartorius Entris® II Essential (120g ± 0.0001g)	April 2022
4	Sartorius Entris® II Essential (120g ± 0.0001g)	April 2022

Doctor bed: to position the volunteers.

Gilson positive pipette, syringe or spatula (for solid products): used to weigh and apply the products.

Dermographic pen: to delineate the skin area of application of the products and the area of contact with the six probes.

Plexiglass support (dimensions 5 cm x 10 cm): to define the area of application of the product.

Environmental Thermometer: to verify the room temperature during the test.

11. UV EXPOSURES

A warm up of about 10 minutes was allowed for the UV Solar Simulator to stabilize before starting the exposure of the subjects. Volunteers were exposed in prone position to the appropriate amount of UV radiation.

The irradiation time changed according to the MED calculated for each subject (the MED for the unprotected skin of phototypes I, II and III)

The UV exposures for FDA STANDARD (7% Padimate O / 3% Oxybenzone) and test material were calculated from previously determined MED on unprotected skin and the intended SPF.

For all the exposures (MED, test product and standard product), a minimum of six different doses were administered using the appropriate geometric progression:

25% (0.51X, 0.64X, 0.80X, 1.00X, 1.25X and 1.56X) for **MEDu SPF < 8,**
20% (0.58X, 0.69X, 0.83X, 1.00X, 1.20X and 1.44X) for **8 ≤ SPF ≤ 15**
15% (0.66X, 0.76X, 0.87X, 1.00X, 1.15X and 1.32X) for **SPF > 15**

Before the UV exposure of each site, the output UV irradiance of each of the six guides of the Solar Multiport was verified with the detector.

12. MINIMAL ERYTHEMAL DOSE (MED)

The MED is defined as the lowest UV dose that produces the first perceptible unambiguous erythema with defined borders appearing over the most of the field of UV exposure, 16 to 24 h after UV exposure.

13. PRODUCT REMOVAL

After the UV exposures, standard and tested products were gently removed from the skin of the volunteer with a cotton pad.

14. MED ASSESSMENT PROCEDURE

For each test subject, an initial MEDu is determined by administering a series of UV doses within an unprotected site using an accurately calibrated solar simulator. The doses are selected following a geometric series represented by 1.25^n.

The MED for unprotected skin (MEDu), the MED for the testing product protected skin (tpMEDp) and the MED for the standard sunscreen product (ssMEDp) were determined on the same day.

The MED were assessed 20±4 hours after the UV exposure. The MED were assessed visually by a trained specialist. Visual assessment was performed with sufficient and uniform illumination (>500 lux).

The MED for each site is identified as the lowest dose to generate a perceptible, unambiguous erythema covering most of the field of the UV exposure and with clearly defined borders.

MED are expressed in terms of energy/surface (mJ/cm^2).

15. SUN PROTECTION FACTOR

An individual Sun Protection Factor (SPFi) value for a product is defined as the ratio of the MED of product protected skin - tpMEDp (mJ/cm^2) and the MED of unprotected skin - MEDu (II) (mJ/cm^2) for the same subject.

$$SPFi = tpMEDp / MEDu (II)$$

The SPF for the product is the arithmetic mean of all valid SPFi obtained from all the subjects in the test, expressed to one decimal place.

16. DATA REJECTION CRITERIA

Test data shall be rejected under the following circumstances:

– The exposure series on a subject fails to elicit an erythemal response on a test site 20±4 h after

exposure;
- Erythemal responses within an exposure series are randomly absent 20±4 h after exposure;
- All sub-sites in the exposure series show an erythemal response 20±4 h after exposure;
- The subject was non-compliant.

17. EXPERIMENTAL DESIGN

DAY 1:

Conducted ITA measurement

UV exposure for initial unprotected test site MEDu (I) (mJ/cm^2).

For each test subject, administer a series of UV radiation doses expressed as mJ/cm^2 to the test subsites within an unprotected test site using an accurately calibrated solar simulator. Select doses that are a geometric series represented by 1.25 n (i.e., each dose is 25 percent greater than the previous dose).

DAY 2:

Evaluation of the initial unprotected test site MEDu I

Each test subsite should be outlined with Dermographic pen. Test subsites are the locations to which UV radiation is administered within a test site. Test subsites should be separated from each other by at least 0.8 cm

Apply the sunscreen test product and the SPF standard at 2.0 mg/cm^2 to their respective test sites. A latex finger cot compatible with the sunscreen product is used to spread the product and standard homogenously over randomly chosen test sites on the back of the volunteers.

Wait at least 15 minutes after applying a sunscreen product or standard before exposing the test sites to UV radiation

UV exposure for final unprotected MEDu (II) (mJ/cm^2), standard P2 ssMEDp (mJ/cm^2), and testing product tpMEDp (mJ/cm^2) at the appropriate test sites.

DAY 3:

Evaluation of erythema on test subsites.

The person who evaluates the test should not be the same person who applied the sunscreen drug product to the test site or administered the UV doses. After UV doses are administered, all immediate responses should be recorded.

The final unprotected MEDu (II) (mJ/cm^2), standard P2 ssMEDp (mJ/cm^2), and testing product tpMEDp (mJ/cm^2) are typically determined the day following determination of the initial MEDu (I) (mJ/cm^2).

RESULTS EXPRESSION AND INTEPRETATION

The SPF result for the test product is calculated as the arithmetical mean of all valid individual SPF_i values.

The study must be carried out on at least 10, and not more than 13 subjects.

The standard deviation (s) from the SPFi values and the standard error (SE), which equals s/√n (where n equals the number of subjects who provided valid test results) are calculated. The t value from Student's t distribution table corresponding to the upper 5-percent point with n—1 degrees of freedom must be calculated.

The labeled SPF value is equal to the largest whole number less than:

mean SPF - (t*SE)

In order for the SPF determination of a test product to be considered valid, the SPF value of the standard sunscreen should fall within the standard deviation range of the expected SPF (16.3 ± 3.43).

ARCHIVING

The study protocol, the raw data and the final report will be kept in Abich Inc laboratory 5160 Décarie Boulevard-suite # 330 Montréal (Québec) H3X 2H9 - Canada for a minimum period of 5 from the issue of the final report and according to internal SOP.

The control sample of the test substance and eventual specific reference material will be kept for 3 months from the end of the test, except if differently and specifically required by the sponsor.

The sponsor, upon drafting a suitable contract, may request an extension of the conservation time of all or part of the materials or their restitution.

DEVIATIONS

No deviation from the study protocol was highlighted during the test.

RESULTS

TABLE 1 - TESTING PRODUCT SPF

Subject number	Code volunteer	Gender	Age	ITA°	Phototype	MEDu (mJ/cm2)	tpMEDp (mJ/cm2)	SPFi	SPFstd
1	MABO0618	F	27	44.3	II	30.2	1610.0	53.2	14.2
2	ADJA1764	F	39	46.6	II	26.7	1467.4	55.0	18.7
3	ANFR1070	F	49	42.8	II	26.3	1578.0	60.0	18.7
4	JEGA1184	F	35	59.5	I	26.7	1467.4	55.0	14.2
5	LIGA1086	F	30	41.3	II	38.1	2093.6	55.0	16.3
6	NIMO2229	M	33	38.7	III	47.7	2283.3	47.9	16.3
7	MARU2166	F	33	44.2	II	39.1	2149.0	55.0	14.2
8	ERCA1736	F	32	42.2	II	39.1	2149.0	55.0	16.3
9	GAAC2245	F	33	48.2	II	34.0	1480.0	43.5	18.7
10	CARE2244	F	38	46.7	II	34.0	1628.0	47.8	16.3
11	SOFU2269	F	45	54.7	II	20.0	1099.3	55.0	16.3
12	GAAP2499	F	57	43.6	II	30.2	1512.3	50.0	14.2
13	SAFR1142	F	46	54.7	II	20.5	1082.4	52.8	14.2
						MEAN SPF		52.7	16.0
						STANDARD DEV (s)		4.3	1.8
						STANDARD ERROR (SE)		1.2	1.1
						Upper 5% t DIST		1.8	7.1
						A (t*SE)		2.1	Complies
						mean SPF - (t * SE)		**50.6**	14.0
						N° subjects		13.0	13.0
						LABEL SPF		**50.0**	**N/A**

CONCLUSION

On the basis of the tests carried out, under the adopted experimental conditions, the sample of the test substance

Advance ZincTek Ltd. and VeganicSKIN

Name:	**Sunscreen**
Batch:	**756-1204 (Recipe 1329 SB2131) & 1329-2**
Product Type:	**Cream**

has a mean **Sun Protection Factor (SPF) of 52.7**

The product can be labeled as **SPF 50.**

The standard sunscreen has a mean of 16.0 (expected SPF =16.3 ± 3.43).

S 22

ANNEX A Information sheet and consent form template

Consent Form Template

TO BE COMPLETED BY THE TECHNICIAN:

FIRST AND LAST NAME: _____ VOL. CODE:

_____

StudyNumber:

_____;_____;_____

_____;_____;_____

_____

Type of Test:

_____

__

Duration of the entire study: _____ Type of Substance Tested:

_____

Duration of the sessions: _____ Compensation:

_____

Product Application Methods:

_____

TO BE COMPLETED BY THE VOLUNTEER:

Good general state of health: YES □ NO □ Pregnant or Nursing: YES □ NO □

Skin Diseases: YES□ NO □ If yes, specify

_____

Current Medications: YES□ NO □ If yes, specify

_____

Subject with known allergies: YES □ NO □ If yes, specify

Subject sensitive to solar radiation or had shown an abnormal response (to solar test): YES □ NO □

I have participated in a sunscreen test (in ABICH or in other test center) in the past 2 months: YES □ NO □

_____

_____

_____

_____

_____

_____

The volunteer attests that he/she has given his/her personal consent to participate in this study after being made fully aware of the type of study, the type of substance to be tested in compliance with 1223 European Cosmetic Regulations or Health Canada cosmetic regulation or Sunscreen Monograph Version 2.0 or FDA cosmetic regulation, the manner in which the study will be conducted, and its purpose.

Declaration of Helsinki

The volunteer was given the opportunity to ask questions which were answered comprehensively.
The volunteer has the right to make requests for clarification deemed appropriate at any time, both now and throughout the study period, by directly contacting:

Test Center ABICH – 5160, Décarie Blvd., Suite 340, Montréal (Québec) H3X 2H9 CANADA
TEL: 514-507-9982 E-MAIL: info@abich.ca

The volunteers may refuse to participate or may withdraw at any time.
If the volunteer decides to end his/her participation in the study, no legal action will be taken on our part, however any and/or all compensation and or/benefits will be forfeited.
The volunteer is asked to communicate his/her decision to end his/her participation in the study at least 48 hours in advance.
The personal information of the volunteer will be kept confidential. The volunteer will receive a copy of this document.
The volunteer declares to be in good health.

Abich reserves the right to terminate the participation of a volunteer:

- if the volunteer misses up to one session;
- if the volunteer removes the product from the test area during sunscreen test;
- If the volunteer did not follow the instruction given by the technician.

If changes are made to the study or new information becomes available, the volunteer will be informed.
The potential harm related to the sunscreen testing studies are the ones related to the UV exposure.

Confidentiality will be respected and no information that discloses the identity of the participant will be published without consent unless required by law. However, records identifying the participant may be given to and inspected by Health Canada/PHAC senior officials, and the REB members, for the purpose of monitoring the study.

If the volunteer has questions about their rights as a research participant, he/she may contact:

Manager, Research Ethics Board Secretariat
70 Colombine Driveway
9th Floor, Room 941C
Brooke Claxton Building, Postal Locator: 0909C
Tunney's Pasture
Ottawa, Ontario, K1A 0K9
Phone number (613) 941-5199 Fax (613) 941-9093 Email: hc.reb-cer.sc@canada.ca
(Collect Calls will be accepted)

TO BE COMPLETED BY THE VOLUNTEER:

By signing this form, I agree that:

1 The study has been explained to me: YES ☐ NO ☐

2 All my questions were answered: YES ☐ NO ☐

3 Possible harm and discomforts of this study have been explained to me: YES ☐ NO ☐

4 I understand that I have the right not to participate and the right to stop at any time: YES ☐ NO ☐

5 I understand that I may refuse to participate without consequence: YES ☐ NO ☐

6 I have a choice of not answering any specific questions: YES ☐ NO ☐

7 I am free now, and in the future, to ask any questions about the study: YES ☐ NO ☐

8 I have been told that my personal information will be kept confidential: YES ☐ NO ☐

9 I have read a description of the Volunteer Protocol Sheet – Number: _____YES ☐ NO ☐

10 I give my consent to participate in SPF water resistance testing where the length of water immersion is from 40 to 80 minutes and the water temperature is 30 ± 2°C: YES ☐ NO ☐

11 I understand that I will receive a signed copy of this consent form: YES ☐ NO ☐

I understand that a surveillance camera will be used in the SPF room and Jacuzzi room for safety purposes and that the footage will not be recorded or kept by ABICH Inc.

I, the undersigned, *(Surname, first name)*:
_____

- Give my consent to participate in the studies described in page 1, relating to certain marketed and/or experimental cosmetic, beauty or dermatological products, devices or services (the "Products"), conducted by ABICH INC. (the "Service Provider") and/or to provide my opinion on the Products that are currently being sold or may be marketed in the future.

- Acknowledge that ABICH Inc. has clearly explained and described the study identified above to me, in terms of objectives, nature, duration, location, conditions of performance and constraints, so as to ensure that my consent to participate in the study is fully informed. I declare having properly understood all such information.

The Service Provider is mandated by a Sponsor.

Before you agree to take part in the Study, it is important that you read, understand and approve the following with regard to the Study:

1. PRODUCT(S)

I understand that the Products that I will use and/or review may be under development and may not be available to the general public.
All Products (including their packaging) which may be entrusted to me by the Service Provider for the purposes of the Study remain the property of the Sponsor. I must keep these Products confidential: do not discuss them with third parties or post about them on social media, nor share them with any third party. I must only use the Products for the purposes of the Study.

I should inform the Service Provider immediately if any of the Products are lost or stolen. When the Study is complete, I will return to the Service Provider all of the Products entrusted to me.

I acknowledge being informed that every measure has been taken in advance to minimise possible side effects. However, if any side effects do occur, or if I have any questions about the Study, I may contact the Service Provider.

Test Center ABICH - 5160, Décarie Blvd., Suite 340, Montréal (Québec) H3X 2H9 CANADA
TEL: 514-507-9982 E-MAIL: info@abich.ca
Opening hours: Monday to Friday, 9.00-12.30 and 14.00-17.00

In case of an emergency, seek the advice of a medical professional.

2. INSTRUCTIONS

The Service Provider provides me the instructions on how to use the Products, how the test will be carried out, and how to submit my feedback (if applicable), hereafter referred to as the Study Protocol.
I agree to follow all of the instructions for the Products, the testing process and the feedback Protocol (feedback in questionnaires, logging on to dedicated Study portal, attending face to face or group interviews, etc.).

3. RESTRICTIONS ON PARTICIPATION

I must inform the Service Provider of any known allergies, current medical treatment, and skin problems.
I cannot take part in the study if I am pregnant or breastfeeding at any time during the study.

4. PHOTOS

If the Study requires me to use the Products at home, I will follow the predefined protocol to post comments, videos, and photos of myself on the dedicated Study portal.

If the Study involves face-to-face individual or group interviews with the Service Provider and/or Sponsor, I consent to being observed, photographed, filmed and interviewed by the employees or representatives of the Service Provider or Sponsor.

By signing this informed consent form, I am giving the Sponsor permission to use and exploit my image as captured during the Study. The term “image” includes all static moving images, as well as my voice as recorded during the Study. The Sponsor is authorized to edit, delete, crop, or dub my original image for translation purposes, etc., as necessary for the purposes of the Study.

I give the Sponsor permission to use my image for internal purposes and/or scientific publication, and in any event for strictly non-commercial purposes. No link shall be established by the Sponsor between my name and my image when using/exploiting this image.

This permission is granted, without remuneration, for 10 years from the end of the study, a period which may be extended by as long as the product is on sale, without any limitation to the number of copies or media used.

I am entitled to withdraw this permission at any time by informing the Sponsor in writing by recorded delivery.

5. PERSONAL DATA

I hereby expressly consent to the collection and processing of my personal data by ABICH Inc, acting on behalf of the sponsor of the study, acting as data controller. In order to avoid knowledge of the sponsor's name to influence the study results, the identity of the sponsor will be disclosed to me upon completion of the study, if applicable. If, upon disclosure, I wish my data not to be retained, such data will be destroyed. I further understand that it may be processed for the purposes of the study, as defined in the attached information notice, and will be used to:

- improve the knowledge of consumers;
- evaluate the efficacy as well as the tolerance of cosmetic and/or dermatological products/devices;
- measure and evaluate the risks of cosmetic and/or dermatological products/devices;
- build a knowledge database on cosmetic and/or dermatological products/devices;
- other purposes: _____

My personal data will not be used for any other purposes without my prior written consent. It will be kept for a period of 10 years after completion of the Study, unless I expressly accept a longer duration.

IT service providers, among which some may be established outside the European Union and in particular in the USA and/or Canada, may have access to my personal data, *inter alia* for the purposes of hosting or technical maintenance services. Moreover, in order to compare and enrich the data collected through the study, it may be transferred to affiliates the sponsor of the study in other countries of the world.
The sponsor of the study will ensure that the level of protection of my data is equivalent to the level required within the European Union, the USA and/or Canada, in accordance with the provisions of article 69 of the "Informatique et Libertés" Law of January 6th 1978 (https://www.cnil.fr/).

I can, in accordance with the provisions of the "Informatique et Libertés" Law, ask to receive a copy of my personal data by contacting the CRO. I also have the right to rectify the data and oppose processing thereof. I can exercise this right at any time by contacting the ABICH Inc.

Test Center ABICH - 5160, Décarie Blvd., Suite 340, Montréal (Québec) H3X 2H9 CANADA
TEL: 514-507-9982 E-MAIL: info@abich.ca

6. PROTECTION OF DATA COLLECTED

Only authorized personnel will ever be able to access my personal data, and will maintain its confidentiality.

7. CONFIDENTIALITY

I will not share or use any knowledge gained about the Products used in the Study while it is underway, nor for a period of 10 years after it ends, extended if necessary, by as long as the product remains on sale. I will not share any document pertaining to the Study. I will destroy any such documents.

8. FEEDBACK AND IDEAS

I acknowledge that I may have to make suggestions regarding new products, devices and/or services in the cosmetic, beauty and dermatological sectors, and provide my Feedback on the Products and/or services that I test/use. In return for agreeing to take part in the Study and any other compensation specified in this document, I transfer all of my intellectual property rights over these Suggestions to the Sponsor, who will have full ownership thereof.

9. WITHDRAWAL FROM STUDY

Participation in the Study is voluntary, and I acknowledge that I am free to decide not to take part, or to withdraw from the Study at any time, with no further obligations or penalties. I am also informed that the Service Provider or Sponsor may choose to end my participation at any time, without requiring my consent.

10. CONSIDERATION

In return for the expenses incurred and constraints associated with participation in the Study, and according to the ABICH INC. internal procedure, I will receive compensation from the Service Provider. If I cause the Study to be terminated or it is modified, the allowance will be calculated based on my actual participation.

11. CONSENT

I agree to the processing of my sensitive personal data acquired during the study (health data…): YES ☐ NO ☐

I accept the transfer of my personal data outside Canada: YES ☐ NO ☐

If I tick either of the "no" boxes above, I cannot participate in the Study.

I have had the opportunity to ask questions, all of which have been answered. I hereby give my informed consent to participate in the Study.

Signed in duplicate (2), one copy of which has been given to the Service Provider and the other retained by myself.

ABICH Inc
Made in:

_____

Date: _____/____/_____
(DD) / (MM) / (YYYY)

Volunteer
Made in:

_____

Date: _____/____/_____
(DD) / (MM) / (YYYY)

Information Sheet

Sun Protection Factor (SPF) Determination According to FDA and ISO regulations

FIRST AND LAST NAME: _____ VOL. CODE: _____

Aim of the test
The aim of this test is to determine the sun protection factor (SPF) of a sunscreen product according to the FDA and ISO regulations on healthy volunteers.

IMPORTANT: Potential risks of the study
Please be advised that this study might have some potential risks such as:

- It is extremely important that the volunteer does not move or change position during the test. There is a risk of sunburn, in case if the UV light leaves the protected area and unprotected skin is exposed.
- After the test, some red or tanning marks can remain for a period of time depending on volunteer's skin type.
- There can be signs of irritation or sensitization on the tested area during or after the test.
- I have seen an example of possible Erythemal Response following SPF Testing in the form: _____

Use of medication
Please report to the staff of Abich Inc. Laboratory the use of any drug, particularly anti – inflammatory drugs (e.g., Ibuprofen, Naproxen, Motrin, Advil, etc.), steroids, antibiotics and/or antihistamines during the study.

Set points

- It is mandatory that the volunteer bathes or washes before the sessions.
- During the exposure session, please refrain from: move or change position while using the solar simulator or during the application of products.
- For the duration of the whole test, please refrain from: exposing the test area to sun.
- It is extremely important that the volunteer follows the directions regarding the appointment times provided by Abich personnel.
- The volunteer is responsible to follow the calendar and to respect the appointments and opening hours of the laboratory.

OPENING HOURS:

MONDAY TO FRIDAY 8:30 to 12:30 and 14:00 to 17:00

It is extremely important that the test be done from the beginning to the end. We (Abich personnel) reserve the right to terminate the participation of a volunteer if the volunteer misses up to one session during the period of testing. The termination includes the whole compensation stated in the Inform Consent.

Duration
The study consists of 3 sessions: pre-test, test and follow up.

	Day 1	Day 2	Day 3
Duration	20 min	3h30 to 7h	20 min
Aim	Pre-test	Test	Follow up

Description	**12** A measure of the skin color will be taken. **13** A series of UV radiation doses will be applied on unprotected test site of the volunteer's back to determine the test MEDu.	**14** The technician will delimit test sites on the back of the volunteer. **15** A measure of the skin color will be taken **16** The products will be applied to randomly chosen test sites. **17** All the squares will be exposed to UVA and UVB lights that simulate sun rays. The exposure is controlled and the duration depends on the skin color and level of protection of the product. Water resistance testing **18** The procedure for water immersion requires the volunteer to be submerged in water for a period of 40 or 80 minutes and water temperature of 30ºC ± 2ºC.	**19** The technician will evaluate the back of the volunteer.
Volunteer's comments			

ABICH Inc.

_____

Date: _____/_____/_____
(DD) / (MM) / (YYYY)

Volunteer:

_____

Date: _____/_____/_____
(DD) / (MM) / (YYYY)

ANNEX B Solar simulator certificate

Solar Light Company, Inc. Project No. 27371 Rev.A

SPECTRORADIOMETRIC MEASUREMENTS of
MODEL 601-300 V2.5 MULTIPORT, UV SOLAR SIMULATOR
Serial Number #21973
March 24, 2022

Certificate of Compliance

This certifies that the model
601-300 V2.5 UV Multiport
Serial Number 21973 with Shutter Serial Number 601327
and lamp Serial Number YL0011
complies with the specifications set forth in the;

ISO 24444:2019 Cosmetics — Sun protection test methods — *In-vivo* determination of SPF (Sun Protection factor)
COLIPA: International Sun Protection Factor (SPF) Test Method, May 2006
Federal Register: Vol. 72, No. 117 / Friday, June 17, 2011 / Rules and Regulations

ISO 24442:2011 Cosmetics — Sun protection test methods — *In-vivo* determination of sunscreen UVA protection (2011-12-15)
Japan Cosmetic Industry Association - J.C.I.A - Measurement Standards for UVA Protection (1999)

Compliancy is performed according to rules and regulations of above standards, and is not intended to extend past these parameters. Lamp must be installed as detailed in manual. After initial lamp installation, it is the owner's responsibility to stay within their standard's regulations.

Project Number: *27371*
Date complete: *March 24, 2022*
Date Due: *March 24, 2023*

Measurements performed by:

S 22 [redacted]

Page 1

SPECTRORADIOMETRIC MEASUREMENTS of MODEL 601-300 V2.5 MULTIPORT, UV SOLAR SIMULATOR

Serial Number #20430
March 3, 2022

Certificate of Compliance

This certifies that the model
601-300 V2.5 UV Multiport
Serial Number 20430 with Shutter Serial Number 601325
and lamp Serial Number YK2258
complies with the specifications set forth in the;

ISO 24444:2019 Cosmetics — Sun protection test methods — *In-vivo* determination of SPF (Sun Protection factor)
COLIPA: International Sun Protection Factor (SPF) Test Method, May 2006
Federal Register: Vol. 72, No. 117 / Friday, June 17, 2011 / Rules and Regulations

ISO 24442:2011 Cosmetics — Sun protection test methods — *In-vivo* determination of sunscreen UVA protection (2011-12-15)
Japan Cosmetic Industry Association - J.C.I.A - Measurement Standards for UVA Protection (1999)

Compliancy is performed according to rules and regulations of above standards, and is not intended to extend past these parameters. Lamp must be installed as detailed in manual. After initial lamp installation, it is the owner's responsibility to stay within their standard's regulations.

Project Number: *27360*
Date complete: *March 03, 2022*
Date Due: *March 03, 2023*

Measurements performed by:

S 22 [redacted]

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SPECTRORADIOMETRIC MEASUREMENTS of
MODEL 601-300 V2.5 MULTIPORT, UV SOLAR SIMULATOR
Serial Number #28524
January 19, 2022

Certificate of Compliance

This certifies that the model
601-300 V2.5 UV Multiport
Serial Number 28524 with Shutter Serial Number 601646
and lamp Serial Number YI1837
complies with the specifications set forth in the;

ISO 24444:2019 Cosmetics — Sun protection test methods — *In-vivo* determination of SPF (Sun Protection factor)
COLIPA: International Sun Protection Factor (SPF) Test Method, May 2006
Federal Register: Vol. 72, No. 117 / Friday, June 17, 2011 / Rules and Regulations

ISO 24442:2011 Cosmetics — Sun protection test methods — *In-vivo* determination of sunscreen UVA protection (2011-12-15)
Japan Cosmetic Industry Association - J.C.I.A - Measurement Standards for UVA Protection (1999)

Project Number: *26968*
Date complete: *January 19, 2022*
Date Due: *January 19, 2023*

Measurements performed by:

S 22 [redacted]

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SPECTRORADIOMETRIC MEASUREMENTS of MODEL 601-300 V2.5 MULTIPORT, UV SOLAR SIMULATOR

Serial Number #28852
April 1, 2022

Certificate of Compliance

This certifies that the model
601-300 V2.5 UV Multiport
Serial Number 28852 with Shutter Serial Number 601674
and lamp Serial Number YK0519
complies with the specifications set forth in the;

ISO 24444:2019 Cosmetics — Sun protection test methods — *In-vivo* determination of SPF (Sun Protection factor)
COLIPA: International Sun Protection Factor (SPF) Test Method, May 2006
Federal Register: Vol. 72, No. 117 / Friday, June 17, 2011 / Rules and Regulations

ISO 24442:2011 Cosmetics — Sun protection test methods — *In-vivo* determination of sunscreen UVA protection (2011-12-15)
Japan Cosmetic Industry Association - J.C.I.A - Measurement Standards for UVA Protection (1999)

Project Number: *27238*
Date complete: *April 1, 2022*
Date Due: *April 1, 2023*

Measurements performed by:

S 22 [redacted]

Page 1

SPECTRORADIOMETRIC MEASUREMENTS of
MODEL 601-300 V2.5 MULTIPORT, UV SOLAR SIMULATOR
Serial Number #28859
April 22, 2022

Certificate of Compliance

This certifies that the model
601-300 V2.5 UV Multiport
Serial Number 28859 with Shutter Serial Number 601681
and lamp Serial Number YK0299
complies with the specifications set forth in the;

ISO 24444:2019 Cosmetics — Sun protection test methods — *In-vivo* determination of SPF (Sun Protection factor)
COLIPA: International Sun Protection Factor (SPF) Test Method, May 2006
Federal Register: Vol. 72, No. 117 / Friday, June 17, 2011 / Rules and Regulations

ISO 24442:2011 Cosmetics — Sun protection test methods — *In-vivo* determination of sunscreen UVA protection (2011-12-15)
Japan Cosmetic Industry Association - J.C.I.A - Measurement Standards for UVA Protection (1999)

Project Number: *27580*
Date complete: *April 22, 2022*
Date Due: *April 22, 2023*

Measurements performed by:

S 22 [redacted]

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ANNEX C Standards certificate

QUALITY CONTROL
24/11/2021

Cosmetech

LABORATORIES, INC.
39 PLYMOUTH STREET • SUITE 4 • FAIRFIELD, NEW JERSEY 07004-1688
TELEPHONE (973) 882-5151 • FAX (973) 882- 1222

Certificate of Compliance

Product: FDA SPF STANDARD CERTIFIED FORMULA
P2 CERTIFIED FORMULA

Lot No.: 1902Y

Manufacture Date: October 12, 2021

The above referenced standard was manufactured using the ingredients and manufacturing process for the **FDA SPF Standard** 21 CFR 201.327(i)(2) as outlined in the Federal Register/Vol.76. No.117/Friday.June 17, 2011/Rules and Regulations, for the **P2** High SPF Reference Formula as outlined in the International Standard ISO 24444:2019 **and** for the **P2** Water Resistant Reference Sun Product as outlined in the International Guidelines for Evaluating Sun Product Water Resistance (COLIPA, 2005).

S 22

REFERENCES

1. FEDERAL REGISTER Vol.76 N°117 June 17, 2011 Part IV
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration
21 CFR Parts 201 and 310. [Docket N° FDA-1978-N-0018] (Formerly Docket N° 1978N-0038)
RIN 0910-AF43 Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Final Rule.

2. Fitzpatrick, t.b., The validity and practicability of sun-reactive skin types I through VI. Arch. Dermatol. 124, pp. 869-871, 1988.

3. Declaration WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects
Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

4. Title 21 of US Code of Federal Regulation (CFR) part 50

5. Adapting SPF testing Methods for Mineral Sunscreen Density Mar 1, 2011.

Sunscreen Safety Testing Laboratory (SSTL)

Determination of SPF (ISO 24444:2020/ AS/NZS 2604: 2021 and FDA Static)

The Sun Protection Factor (SPF) of the test product was first recalculated according to the ISO 24444:2020 international in vivo protocol as specified in AS/NZS 2604: 2021. This test involves recruiting a panel of healthy, consenting adults, with MED (Minimal Erythema Dose) determined for untreated, reference, and product-treated skin sites following strictly controlled application and irradiation. For Recipe 1329, twelve volunteers were enrolled; each underwent controlled UVA/UVB irradiation as per ISO 24444:2020 guidelines, and erythema responses were evaluated 20 ± 4 hours after exposure. The SPF for each participant was calculated as the ratio of tpMEDp (product-treated site) to MEDu (untreated site), generating individual SPF values, from which the group mean, standard deviation, and confidence intervals were derived. The resulting labeled SPF was determined using the prescribed ISO protocol (mean minus the t-statistic times the standard error), ensuring compliance with international regulatory standards for SPF labeling and statistical reliability.

In addition, in-vivo static SPF testing was also performed in accordance with FDA 21 CFR §201.327, ensuring full compliance with U.S. regulatory methodology. In this protocol, 10 consenting participants were irradiated with UVA/UVB rays on defined untreated, sunscreen standard, and product test sites. The Minimal Erythemal Dose (MED) of each test site was calculated 20 ± 4 hours post-irradiation, and the standardized SPF analysis and subject inclusion/exclusion criteria were followed exactly as specified by the FDA Final Rule. All testing was conducted at the Sunscreen Safety Testing Laboratory (SSTL), 15 Suscatand Street, Rocklea, QLD, 4106, Australia, under accredited laboratory supervision and regulatory oversight.

Sponsor: VeganicSKN Limited

Sample Name: ZinClear SB04

Test Start Date: 19th MAY 2025

Test End Date: 21st MAY 2025

Mean SPF: 54.3

Label SPF: 50

Prepared by: **Authorised by:**

S 22

Results Verified By:

Anastasia Wilkes-Robinson

TABLE OF CONTENTS

SUMMARY

In vivo static SPF study has been carried out on the test substance. The testing was conducted in accordance with the ISO 24444:2020 international in vivo protocol as specified in AS/NZS 2604: 2021 and FDA Final Rule for over-the-counter (OTC) sunscreen products, CFR 21 §201.327, at the Sunscreen Safety Testing Laboratory (SSTL) facility in Rocklea, QLD, Australia.

Name: ZinClear SB04

Product Type: Cream

The back of 10 healthy, consenting participants was irradiated with UVA/UVB rays. The Minimal Erythemal Dose (MED) was calculated 20 ± 4 hours after irradiation. On the basis of the tests carried out, under the adopted experimental conditions, the sample of the test substance has a mean SPF of 54.3 and a calculated label SPF of 50

TEST PROCEDURE

Objective

To determine the Sun Protection Factor (SPF) of the test substance in accordance with ISO 24444:2020 international in vivo protocol as specified in AS/NZS 2604: 2021 and FDA CFR 21 §201.327 guidelines.

Test Product

Sponsor: VeganicSKN Limited

Sample Name: ZinClear SB04

Appearance: White Cream

Expected SPF: 50+

Assay System

This study was carried out in compliance with the ISO 24444:2020 and FDA Sunscreen Final Rule 21 C.F.R.§ 201.327 and followed the written internal quality procedures of SSTL, performed by suitably skilled and trained personnel. The test panel consisted ≥ 10 eligible participants of various genders and ages, all with skin types I, II, or III. Prior to the study, all participants had their medical history, skin type, and suitability for testing confirmed by a health professional, and all provided legally effective written informed consent. A maximum of 3 participants/results shall be rejected from the test panel, ensuring the valid minimum number of participants (n=10) is met.

Skin Phototype	Skin Description	ITA° Value
I	Very Light	>55°
II	Light	>41 to 55°
III	Intermediate	>28 to 41°
IV	Tanned (or matt)	>10 to 28°
V	Brown	>-30 to 10 °
VI	Black	≤-30°

Participants

Participants were volunteers to be involved in the test study and received monetary reimbursement for their time. Prior to participation, participants were required to go to their doctor or health professional to review their medical history, get a skin check and confirm skin type and suitability for their participation in the test.

Legally effective written informed consent was received from all test subjects prior to participation. All participants were of locally regulated age of consent.

Participants then underwent an initial screening test, to determine their skin type and suitability for testing. Participants of good health, with skin type I, II or III were deemed suitable for inclusion in the testing.

Moreover, the following criteria of exclusion were applied:

- Children and persons below the age of consent
- Women who reported to be pregnant or lactating
- Subjects taking medication that could interfere with the test results
- Subjects with dermatological disorders
- Subjects with a history of adverse events related to to sun exposure
- Subjects accustomed to artificial tanning

- Subjects with marks, blemishes or naevi or hairs on the testing site
- Subject participating in other simultaneous studies that might interfere with the test evaluation
- Subjects with known hypersensitivity to sunscreens

After the study start, the following withdrawal criteria were applied

- Volunteers who did not follow the conditions as described in the Study Information Sheet
- Volunteers who suffered any illness or accident or developed any condition which could affect the outcome of the study
- Volunteers who did not longer wish to participate in the study

Sunscreen (SPF) Standard

The sunscreen (SPF) standard is a control formulation and is used as a methodological control to verify the test procedure.

The standard has an estimated SPF of 16.3. A SPF standard result of 16.3 ± 3.43 was considered a pass, verifying subsequent test results.

Equipment

Skin Typing

Skin typing was conducted using a GS7700 Grating Spectrophotometer with an 8mm flat aperture. In-use calibration checks are completed before use and subsequently every 4 hours during testing and annual calibrations are performed by an external testing laboratory*.

Analytical Balance

Mettler Toledo XSR105 Dual Range analytical balance is utilized for sample weighing. Daily and monthly weight checks are performed with external calibration weights, supplemented by an annual calibration by an external testing laboratory*.

UV Source

The UV irradiation was performed with a Solarlight® Model 601 v2.5 Multichannel SPF Testing Solar Simulator. A dose controller and connected full spectrum and UV-B detectors are utilized with the system to measure the UV output of the instrument. Annual calibration/maintenance is performed by an external company.

Skin Safe Marker

Skin safe markers were utilized to outline each test site and test subsites, for easy identification and visualization.

Hygrometers

Utilized to record temperature and humidity of testing rooms. Calibration annually by an external laboratory*.

Timers

Utilized for drying and irradiation times. Calibrated annually by an external laboratory*.

* annual calibrations are performed by NATA certified external testing laboratories.

Product Application

Product is applied at a dose of 2mg per cm^2 to test sites (describe above). A syringe is used to dispense the product in small droplets evenly distributed across the test site, in a positive displacement weighing method. A finger cot it worn by the technician when gently spreading the sample evenly across the test site. The fingercot is weighed pre- and post- spreading to verify the amount of sample remaining on the test site. A final weight of 60mg ± 5mg of product must remain of the test site for valid testing. Product test sites are left to dry for a minimum of 15 minutes prior to UV exposure.

Test Sites

Test sites are located on each subject's back, between the beltline and the shoulder blades. Each test site encompasses six round sub-sites of about $1cm^2$ each in size, corresponding to the optical guides of the Solar Simulator. The minimum distance between the borders of each exposure sub-site is 0.8cm. a dermal graphic pen was used to mark the sites of exposure.

UV Exposure

Exposure of the test site to the sequence of UV dose started 15 minutes after the application of the product. Participants were in a prone position for the duration of the UV exposure. The head of the UV source instrument is securely positioned against the participant's back to prevent movement of the output head during testing. Irradiation times were dependent on the participant's individual skin type (I, II or III).

Exposure doses were administered with varying port progressions (between test subsites), dependent on the SPF of the test product:

SPF	Port Progression	% Progression
< 8	0.64x, 0.80x, 1.00x, 1.25x, 1.56x	25
8 - 15	0.69x, 0.83x, 1.00x, 1.20x, 1.44x	20
> 15	0.76x, 0.87x, 1.00x, 1.15x, 1.32x	15

Product Removal

After the UV exposure, standard and tested products were gently removed from the skin of volunteers with a cotton pad

Evaluation

Evaluation of the UV exposure is conducted 20 ± 4 hours post-irradiation, with participants lying in a similar position and lighting as to that of the UV exposure testing conditions. Evaluation is conducted by a secondary technician, who did not perform the product application or UV exposure, to ensure a blinded experiment.

SSTL Pty Ltd
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ABN: 67 644 075 249
FDA Establishment Identifier: 3022162119
www.sunscreensafetytestinglaboratory.com

DATA ANALYSIS

Rejection Criteria

Participants may be rejected under the following circumstances:

- Erythema is not present on any of the test site subsites
- Erythema is present at all subsites
- Erythema responses inconsistent with the series of UV doses administered
- Participant non-compliance
-

Sun Protection Factor

An individual SPF (SPFi) is calculated for each participant, as a ratio of the MED of the protected versus unprotected skin.

$$\boldsymbol{SPFi = \frac{tpMEDp}{MEDu}}$$

The final SPF is calculated by averaging the SPFi of all participants on the test panel. Statistical analysis is performed on the test panels results, as per FDA CFR21, with reference to ISO24444:2020 (regarding the Student t-test calculation). Label SPF is reported as the largest whole number less than:

$$\boldsymbol{\overline{SPF} = SPF - (t \times SE)}$$

Where t = t-value from Student's t distribution table corresponding to the upper 5% point with n-1 degrees of freedom and SE = standard error

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RESULTS

TABLE 1 – TESTING PRODUCT SPF

TEST PRODUCT: ZinClear SB04

Subject Number	Code Volunteer	Gender	Ages	ITA°	Phototype	MEDU (mJ/cm2)	tpMEDp (mJ/cm2)	SPFi	SPFstd
1	AMEL1229	F	31	51.8	II	19.1	1001.9	52.4	14.2
2	PAWI1453	F	27	41.4	II	21.5	1289.6	60.0	18.7
3	MERA1763	F	31	49.3	II	28.6	1263.9	44.3	18.7
4	LURO1701	F	26	38.7	III	36.6	2098.8	57.4	18.7
5	FABO1404	M	37	42.4	II	21.5	967.9	45.2	18.7
6	MABI1341	F	59	53.2	II	22.0	1166.0	53.7	14.2
7	CAPU1950	F	36	44.2	II	32.5	1627.3	50.0	16.3
8	LUST1419	M	57	55.4	I	19.1	1210.0	63.2	18.7
9	DAKO1522	M	19	52.4	II	25.3	1391.5	55.0	16.3
10	MARI1271	M	45	49.1	II	24.9	1574.9	63.3	18.7
						MEAN SPF		54.38	17.3
						STANDARD DEV (s)		6.74	1.9
						STANDARD ERROR (SE)		2.13	0.6
						Upper 5% t DIST		1.8	1.8
						A (t*SE)		3.9	1.1
						Mean SPF – (t*SE)		50.4	16.2
						N° subjects		10.0	10.0
						Label SPF		50	N/A

SPF CALCULATION ISO 24444:2020 AS SPECIFIED IN AS/NZS 2604: 2021

Determination of SPF – ISO 24444:2020

The Sun Protection Factor (SPF) for the test product was calculated in accordance with the ISO 24444:2020 in vivo protocol. Ten healthy adult volunteers participated, with each receiving controlled UVA/UVB irradiation on untreated (control), sunscreen standard, and test product application sites. The Minimal Erythema Dose (MED) for each site was determined 20 ± 4 hours post-exposure, following ISO protocol guidelines.

Individual SPF values were calculated as the ratio of MED for the product-treated skin to MED for untreated skin. The group statistics for the test product were as follows:

Mean SPF	54.38
Standard deviation	6.74
Standard error	2.13
t-statistic (95%, df=9)	1.83
Label SPF (ISO 24444:2020)	50

The SPF for labelling was reached using the ISO formula (mean SPF minus t-value times SE, rounded down). Reference standard control values were generated to verify run validity and protocol compliance.

These results demonstrate the test product meets requirements for a labelled SPF 50 claim under ISO 24444:2020.

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SUNSCREEN SAFETY TESTING LABORATORY

About the Laboratory

Sunscreen Safety Testing Laboratory (SSTL), a fully FDA accredited (pending with A2LA Assessment Accreditation Service) sunscreen testing laboratory specializing in comprehensive analysis of sunscreen products containing Antaria Pty. Ltd.'s ZinClear XP Zinc Oxide and/or Zinc Dispersion.

Our laboratory offers both In-vitro and In-vivo testing services for sunscreen products, adhering to established methodologies and standards such as FDA2011, ISO24444:2020, ISO24443:2021, Japan Star Rating, Boots 2008, ISO18861 & 16217.

We employ cutting-edge equipment like Model SPF-290AS Automated UV Transmitance/SPF Analyzer, 4" (10cm) 100W Pre-Irradiation Solar Simulator Kit Model LS1000-4S-009, and Model 601 Multiport SPF Testing 6 Output Solar Simulator to ensure accurate and reliable results.

Dr. Philip A Marshall (FRACI, CChem)

Dr. Philip Marshall (FRACI, CChem) brings an impressive background to our team with over 40 years of international and domestic experience in the pharmaceutical and healthcare industries. His extensive expertise spans drug design and discovery, medicinal chemistry, pharmaceutics, formulation design and development, quality assurance, Good Manufacturing Practice (GMP) compliance, and scientific and medical affairs. Dr. Marshall has served as an Expert Witness in numerous legal and patent matters both in Australia and internationally. As a prolific innovator, he is a co-inventor on several granted international patents in the areas of composition-of-matter, process, and formulation for pharmaceuticals. His wealth of knowledge strengthens our commitment to delivering exceptional sunscreen testing services at Sunscreen Safety Testing Laboratory.

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GLOSSARY

MED; Minimal Erythemal Dose,

MEDu; Minimal Erythemal Dose on unprotected skin

MEDp; Minimal Erythemal Dose on protected skin (i.e. with product / standard applied)

SPF; Sun Protection Factor

ssMEDp; Sunscreen Standard (SPF standard) Minimal Erythemal Dose on protected skin

tpMEDp; Test Product Minimal Erythemal Dose on protected skin

UVA; solar ultraviolet radiation in the range 320-400 nm

UVB; solar ultraviolet radiation in the range 290-320 nm

REFERENCES

1. Code of Federal Regulations Title 21 – Volume 4 - Part 201 Labelling – Subpart G Specific Labelling Requirements for Specific Drug Products, Section 201.327, Paragraph (i) SPF Test Procedure.

2. BS EN ISO 24444:2020. Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF).

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FDA Establishment Identifier: 3022162119
www.sunscreensafetytestinglaboratory.com

From: S 22
To: S 22
Cc: S 22
S 22 LUTTON, Tracey; CLARKE, Avinash
Subject: RE: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Tuesday, 2 December 2025 5:29:45 PM
Attachments: image004.png
image005.png
image006.png
image007.png
image008.png

Hi team,

Confirming that this request is not for RCB and we will leave with COMB.

Regards,

S 22

S 22

From: S 22
Sent: Tuesday, 2 December 2025 5:05 PM
To: CLARKE, Avinash ; LUTTON, Tracey
Cc: S 22 S 22
S 22
Subject: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email

From: S 22
To: S 22
Cc: S 22
Subject: FW: ABC TV interview request (sunscreens) [SEC=OFFICIAL]
Date: Tuesday, 2 December 2025 9:41:06 PM
Attachments: image001.png
DOC 1_ AUST L 407959 26 NOV 2025.pdf
DOC 3_ AUST L 405572 14 November 2024.pdf
DOC 5_ Report Evaluation of Sun Protection SPF Determination.pdf
DOC 4_ AUST L 407959 28 NOV 2025.pdf
DOC 6_SBO4 ZTR203.03 Sunbase SSTL Test Report ISO 24444 FDA.pdf
DOC 2_AUST L 405572 19 June 2024_2.pdf

OFFICIAL

Hi TGA,

Please see some additional information from the journalist for the ABC TV request. This is the same request that 22 sent earlier today, with a deadline of 3pm Thursday.

Thank you

S 22

OFFICIAL

From: S 22
Sent: Tuesday, 2 December 2025 7:40 PM
To: S 22
Cc: S 22
Subject: FW: ABC TV interview request (sunscreens) [SEC=OFFICIAL]

OFFICIAL

Hi again TGA media team,
I'm writing to alert you to a small correction to the email we sent earlier today (below) and some additional information.
In the second paragraph we have referred to an AUSTL number as 4055752 – this should say 405572.
Also, MooGoo is the company that raised these concerns and the company that prompted the pharmacovigilance report. The results formed part of the company's investigation into issues it was having with the same zinc (which it says has now been resolved by using a different zinc).
Please feel free to call to discuss this request.
Many thanks,

S 22

S 22

From: S 22
To: CLARKE, Avinash
Cc: S 22 S 22 S 22
Subject: RE: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Wednesday, 3 December 2025 9:00:07 AM
Attachments: image003.png
image004.png
image005.png

OFFICIAL

Good morning Avi,
In addition to the below, the journalist has alerted of a small correction to the email they sent yesterday and some additional information, see below.
Correction: In the second paragraph they have referred to an AUSTL number as **4055752** – this should say **405572**.
Additional question: MooGoo is the company that raised these concerns and the company that prompted the pharmacovigilance report. The results formed part of the company's investigation into issues it was having with the same zinc (which it says has now been resolved by using a different zinc).
Warm regards
S 22

OFFICIAL

From: 22
Sent: Tuesday, 2 December 2025 5:05 PM
To: CLARKE, Avinash ; LUTTON, Tracey
Cc: 22 ; S 22
22
<S 22 @tga.gov.au>; 22
Subject: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email

From: CLARKE, Avinash
To: S 22
Cc: S 22 ;S 22 JIN, Hongxia; LUTTON, Tracey; S 22
Subject: RE: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 12:35:34 PM
Attachments: image003.png
image004.png
image005.png

OFFICIAL

Hi Media Team,

Proposed input below (including MQB and RCB which is in green)

Thanks, Avi

OFFICIAL

OFFICIAL

From: S 22

Sent: Tuesday, 2 December 2025 5:05 PM

To: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; LUTTON, Tracey <Tracey.Lutton@health.gov.au>

Cc: 22 , S 22 22 >

Subject: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

OFFICIAL

Good afternoon Avi and Tracey,
Please see the below media request for your appropriate action.
Note this is for TV, so it might be better to address the questions in one response if possible.
Grateful if you could liaise with each other to provide a consolidated response.

MEDIA FOR ACTION	
News Outlet	ABC News
AS clearance by	**12:30pm Thursday, 4 December 2025**

Query:

Myself and my colleagues S 22 are looking into zinc oxide from Advance ZincTek and zinc sunscreens made by Veganic SKN using Advance ZincTek zinc.

We have been provided with 2 x sets of preliminary 3 person panel SPF results which show that Natural Mineral Face Sheer Liquid Zinc Sunscreen AUSTL 4055752 may not be providing the SPF50 on its label. The indicative results are SPF 25 and SPF 18 [Doc 2 & 3].

We understand that this formula was recently cancelled from the ARTG but it is still for sale.

We have seen documentary evidence that the under performance of this product and concerns about the zinc oxide used in it were raised with the TGA in a pharmacovigilance report on 27 June 2024.

We have also been provided with 1 x set of preliminary 5 person panel SPF results showing Zinclear S01 AUSTL 407959 showing an SPF of 21 [Doc 1].

The ABC has also commissioned a 3 person panel SPF test on Zinclear S01 AUSTL 407959 which returned a result of SPF 25 [Doc 4].

The ABC understands that these results are indicative and preliminary and are not a 10 person panel.

The results in Doc 1- 4 were conducted by Eurofins Dermatest in Sydney.

The ABC has spoken to multiple SPF testing experts who say that these results are a serious red flag that the SPF of these sunscreen formulas is likely not to be anywhere near the SPF50 on the label. The SPF experts we have spoken to have examined all results attached and told us that, in their opinion, there is no scientific, statistical or valid way these results would reach SPF 50 even if testing was extended to a 10 person panel.

The ABC has established that the formula registered to Veganic SKN and using the 407959 AUSTL is now used by upwards of 30 brands, including Surf Life Saving Australia and Game Face.

The ABC asked Veganic SKN for the ISO 2444:2019 SPF results required to list these sunscreens and they provided two sets of results. One is a 10 person panel done according to the FDA method, not the method mandated by the Australian Standard [Doc 5]. One is a result by the Australian Sunscreen Safety Testing Laboratory, which is owned by Advance ZincTek and is also from May 2025, which is after both these sunscreens were listed on the ARTG [Doc 6]. Veganic SKN has not, at this point, provided us with information on which test results are for which product.

Many of these brands, including some owned by Veganic SKN, are marketing these products online using language and images that promote zinc sunscreen as a safe and natural alternative to toxic chemical sunscreens.

Questions:

1. What action did the TGA take when it was informed via a pharmacovigilance report in June 2024 of testing that suggested that sunscreens using Advance ZincTek zinc were likely not to be providing the SPF 50 on their labels?
2. The company responsible for the 2024 pharmacovigilance report has told the ABC that the TGA did not follow up with any requests for information regarding that report and was told any potential action by the TGA was confidential. They have expressed the opinion and concern that the TGA appears not to have acted in response to the concerns raised in that report. What is the TGA's response to this allegation? What action did the TGA take in relation to this safety report?

3. Test result [Doc 2] for a sunscreen with the AUSTL 405572 was attached to that pharmacovigilance report. Did the TGA check that this sunscreen held SPF rest reports as required by the regulations to demonstrate its SPF50 label? Was the TGA satisfied with these test results?
4. Is the TGA concerned about the additional test results attached to this email for the two sunscreen formulas with an AUSTL of 405572 and 407959?
5. What action will the TGA take in relation to these test results?
6. Does the testing provided by Veganic SKN [Doc 5 & 6] meet the Australian standard for SPF testing to list a sunscreen on the ARTG?
7. One of the test reports provided by Veganic SKN [Doc 6] was done on a date after both the sunscreens in questions were listed [407959: 21 April 2023 & 405572: 01 March 2023] Does this comply with the TGA regulations for listing a sunscreen?
8. As stated above, more than 30 brands are selling this sunscreen using the same AUSTL, 407959, registered to the sponsor Veganic SKN. A regulatory consultant and former TGA policy advisor has told the ABC they believe this is not legal and makes it hard for the TGA to regulate. What is the TGA's response to this?
9. The ABC has also been advised that a number of these brands, including brands owned by Veganic SKN, could be breaching TGA advertising regulations with some of the claims being made on social media - as can be seen in the following links:
   https://www.instagram.com/reel/DPdMPUyEVBW/
   https://www.instagram.com/p/DQx2yA_kgwc/
   https://www.instagram.com/p/DNEdESozGvQ/?hl=en
   https://www.instagram.com/p/DRLdtz4gVF5/?hl=en&img_index=1
   https://www.instagram.com/p/DLmCDNuhjH_/?hl=en&img_index=1
   https://www.instagram.com/p/DRRE3-HE7ex/?hl=en&img_index=3
   Does the TGA consider the type of messaging in the above to be a breach of TGA advertising regulations?
10. Veganic SKN has told the ABC it has information from the TGA, sourced through FOIs, that there are 21 active sunscreen ingredients that the TGA has no safety data on record for. Is this accurate? What is the TGA's response to this?
11. Veganic SKN has expressed concern publicly and to the ABC that sunscreen ingredients not allowed in the US and the EU (including 4MBC) are still allowed in sunscreens in Australia and that this poses a health risk to Australian consumers. Is it correct that 4MBC is allowed to be used in sunscreens sold in Australia? If so, what is the TGA's response to Veganic SKN's claim that this poses a health risk to Australian consumers?
12. Veganic SKN has also told the ABC and publicly stated that some other sunscreen ingredients allowed by the TGA have also been linked to health risks. What is the TGA's response?

COMB Proposed response:

Questions 1 to 3

- s 47 [redacted]
- The TGA takes signals seriously and investigates where appropriate, however we do not comment on individual matters, including whether a business is subject to investigation or

compliance action.

Questions 4 to 5

- The TGA is concerned about preliminary data that may indicate a sunscreen does not meet its claimed SPF.
- We will consider the material and determine whether further investigation is warranted, and if required, take regulatory action as appropriate.

Questions 6 and 7

- Sponsors of sunscreens are required to comply with the testing requirements of the Australian/New Zealand Standard for sunscreens.
- However, sponsors may wish to obtain additional supporting SPF testing data after listing and may do so e.g. if there are formulation changes to their sunscreen.

Question 8

- A product included in the ARTG can only be supplied in Australia displaying the name included in the ARTG for that product.
- It is common for sunscreens to use the same base formula provided by a common manufacturer. However, each different product must have its own ARTG number.
- The TGA is considering this issue, and if required, will take regulatory action as appropriate.

Question 9

- The TGA does not comment on individual matters, including whether a business is operating legally or if they are subject to investigation or compliance action.
- We also cannot advise whether the social media posts provided contain unlawful advertisements of therapeutic goods, as any report of alleged unlawful advertising, import, supply, or manufacture of therapeutic goods must undergo robust assessment, and if required, investigation.
- However, the TGA is aware of a number of marketing campaigns that promote zinc-based sunscreens over chemical-based sunscreens. These campaigns can present incomplete and alarmist narratives about sunscreen ingredients. The TGA has concerns regarding the potential for misinformation this creates which can cause unwarranted fear in consumers around using chemical-based sunscreens.
- In relation to mineral and chemical sunscreens:
    - Mineral sunscreens (also called physical sunscreens) use zinc oxide and/or titanium dioxide as their active ingredients to protect the skin by reflecting or scattering UV rays.
    - Chemical sunscreens absorb UV rays and convert them into heat energy, which is then released from the skin.
    - Both mineral and chemical sunscreens protect against UVR and offer advantages and disadvantages. For example, mineral sunscreens start working immediately upon application but can feel thicker and heavier and rub off more easily with sweat or water. While chemical sunscreens require 15-30 minutes to activate but are more lightweight and generally more water resistant.

The TGA recommends that consumers choose the product that they prefer as they are more likely to use it frequently.

TGA response to questions 10 to 12

Avi: I think we need to add a line about the process through which some permissible ingredients we grandfathered in relation to the 21 active sunscreen ingredients.

COMB input

- A number of ingredients that can be included in therapeutic sunscreens are those that were included in therapeutic goods supplied in Australia before the Therapeutic Goods Act 1990 came into operation. These ingredients were assessed to have an established safety profile (including history of safe use) based on prior regulatory oversight and market history. Since then, all new active and excipient ingredients have undergone a safety assessment by the TGA. If a person wishes to include an active or excipient ingredient that is not currently approved for use in listed medicines, the substance must be evaluated by the TGA before such use is permitted
- The public can be reassured that the TGA is fulfilling its regulatory role to continually monitor and review ingredients to maintain the highest standards of quality, safety and efficacy in the Australian market.
- The TGA monitors international developments in relation to safety issues for sunscreens and prioritises our ingredient reviews by considering the use of the ingredient in sunscreen products marketed in Australia.
- In response to international and domestic concerns in relation to certain sunscreen ingredients:
    - The TGA has conducted and published safety reviews on a number of sunscreen ingredients, see: Safety review of seven active sunscreen ingredients
    - As a result of this review, the TGA is currently considering restricting the amount of 3 ingredients in sunscreens. This is a conservative, precautionary measure based on potential signals from animal data studies, not human studies, when animals were exposed to these chemicals in high doses and for long periods of time, which is far beyond the amount that humans would be exposed to.
    - 4-Methylbenzylidene Camphor (4-MBC) is currently permitted for use only as an active ingredient in sunscreens, at concentrations not more than 4% in Australia. The TGA is currently reviewing 4-MBC but is yet to make any recommendations in relation to this ingredient. We will publish the outcome of this review when it is finalised, in the interest of providing transparency for Australian consumers.
- The TGA reiterates that expert clinical advice remains that the benefits of all sunscreens available in Australia continue to far outweigh any risks and Australians are urged to continue using sunscreens.

NOTE: Media responses should be drafted as a brief statement or as a 1-5 dot point response that essentially addresses the enquiry/argument. If necessary, include further information (technical/policy/legislative nuances) as background to provide context and help the journalist better understand the issue. Please note, in some cases it may be necessary to respond to each of the questions separately.

From: CLARKE, Avinash
To: S 22
Cc: S 22 JIN, Hongxia; LUTTON, Tracey; S 22
Subject: RE: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 12:38:53 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Sorry – minor correction to date of Act.

A

Avinash Clarke

S 22

OFFICIAL

From: CLARKE, Avinash

Sent: Thursday, 4 December 2025 12:35 PM

To: S 22

Cc: S 22

JIN, Hongxia ; LUTTON, Tracey ; S 22

Subject: RE: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

S 22 duplicate email

From: S 22

Sent: Tuesday, 2 December 2025 5:05 PM

To: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; LUTTON, Tracey <Tracey.Lutton@health.gov.au>

Cc: 22 ;
S 22
22

Subject: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

OFFICIAL

- Mineral sunscreens (also called physical sunscreens) use zinc oxide and/or titanium dioxide as their active ingredients to protect the skin by reflecting or scattering UV rays.
- Chemical sunscreens absorb UV rays and convert them into heat energy, which is then released from the skin.
- Both mineral and chemical sunscreens protect against UVR and offer advantages and disadvantages. For example, mineral sunscreens start working immediately upon application but can feel thicker and heavier and rub off more easily with sweat or water. While chemical sunscreens require 15-30 minutes to activate but are more lightweight and generally more water resistant.
- The TGA recommends that consumers choose the product that they prefer as they are more likely to use it frequently.

TGA response to questions 10 to 12

Avi: I think we need to add a line about the process through which some permissible ingredients we grandfathered in relation to the 21 active sunscreen ingredients.

COMB input

- A number of ingredients that can be included in therapeutic sunscreens are those that were included in therapeutic goods supplied in Australia before the Therapeutic Goods Act 1989 came into operation. These ingredients were assessed to have an established safety profile (including history of safe use) based on prior regulatory oversight and market history. Since then, all new active and excipient ingredients have undergone a safety assessment by the TGA. If a person wishes to include an active or excipient ingredient that is not currently approved for use in listed medicines, the substance must be evaluated by the TGA before such use is permitted
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- The TGA monitors international developments in relation to safety issues for sunscreens and prioritises our ingredient reviews by considering the use of the ingredient in sunscreen products marketed in Australia.
- In response to international and domestic concerns in relation to certain sunscreen ingredients:
  - The TGA has conducted and published safety reviews on a number of sunscreen ingredients, see: Safety review of seven active sunscreen ingredients
  - As a result of this review, the TGA is currently considering restricting the amount of 3 ingredients in sunscreens. This is a conservative, precautionary measure based on potential signals from animal data studies, not human studies, when animals were exposed to these chemicals in high doses and for long periods of time, which is far beyond the amount that humans would be exposed to.
  - 4-Methylbenzylidene Camphor (4-MBC) is currently permitted for use only as an active ingredient in sunscreens, at concentrations not more than 4% in Australia.

From: S 22
To: HENDERSON, Nick; BEDFORD, Chris; DUFFY, Tracey
Cc: S 22 ; S 22 ; JIN, Hongxia; LUTTON, Tracey; S 22 CLARKE, Avinash; S 22 S 22
Subject: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 12:44:39 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Good afternoon all,
Please see the below media request for your clearance.
Note MQB and RCB input to question 9 in green. Remaining proposed response belongs to COMB.

MEDIA FOR CLEARANCE	
News Outlet	ABC News
AS cleared by	Avi Clarke, Hongxia Jin and Tracey Lutton
FAS Clearance by	**2pm today, 4 December – To allow Dep Sec by 3pm**

Query:

Myself and my colleagues S 22 are looking into zinc oxide from Advance ZincTek and zinc sunscreens made by Veganic SKN using Advance ZincTek zinc.

We have been provided with 2 x sets of preliminary 3 person panel SPF results which show that Natural Mineral Face Sheer Liquid Zinc Sunscreen AUSTL 4055752 may not be providing the SPF50 on its label. The indicative results are SPF 25 and SPF 18 [Doc 2 & 3].

We understand that this formula was recently cancelled from the ARTG but it is still for sale.

We have seen documentary evidence that the under performance of this product and concerns about the zinc oxide used in it were raised with the TGA in a pharmacovigilance report on 27 June 2024.

We have also been provided with 1 x set of preliminary 5 person panel SPF results showing Zinclear S01 AUSTL 407959 showing an SPF of 21 [Doc 1].

The ABC has also commissioned a 3 person panel SPF test on Zinclear S01 AUSTL 407959 which returned a result of SPF 25 [Doc 4].

The ABC understands that these results are indicative and preliminary and are not a 10 person panel.

The results in Doc 1- 4 were conducted by Eurofins Dermatest in Sydney.

The ABC has spoken to multiple SPF testing experts who say that these results are a serious red flag that the SPF of these sunscreen formulas is likely not to be anywhere near the SPF50 on the label. The SPF experts we have spoken to have examined all results attached and told us that, in their opinion, there is no scientific, statistical or valid way these results would reach SPF 50 even if testing was extended to a 10 person panel.

The ABC has established that the formula registered to Veganic SKN and using the

407959 AUSTL is now used by upwards of 30 brands, including Surf Life Saving Australia and Game Face.

The ABC asked Veganic SKN for the ISO 2444:2019 SPF results required to list these sunscreens and they provided two sets of results. One is a 10 person panel done according to the FDA method, not the method mandated by the Australian Standard [Doc 5]. One is a result by the Australian Sunscreen Safety Testing Laboratory, which is owned by Advance ZincTek and is also from May 2025, which is after both these sunscreens were listed on the ARTG [Doc 6]. Veganic SKN has not, at this point, provided us with information on which test results are for which product.

Many of these brands, including some owned by Veganic SKN, are marketing these products online using language and images that promote zinc sunscreen as a safe and natural alternative to toxic chemical sunscreens.

Questions:

1. What action did the TGA take when it was informed via a pharmacovigilance report in June 2024 of testing that suggested that sunscreens using Advance ZincTek zinc were likely not to be providing the SPF 50 on their labels?
2. The company responsible for the 2024 pharmacovigilance report has told the ABC that the TGA did not follow up with any requests for information regarding that report and was told any potential action by the TGA was confidential. They have expressed the opinion and concern that the TGA appears not to have acted in response to the concerns raised in that report. What is the TGA's response to this allegation? What action did the TGA take in relation to this safety report?
3. Test result [Doc 2] for a sunscreen with the AUSTL 405572 was attached to that pharmacovigilance report. Did the TGA check that this sunscreen held SPF rest reports as required by the regulations to demonstrate its SPF50 label? Was the TGA satisfied with these test results?
4. Is the TGA concerned about the additional test results attached to this email for the two sunscreen formulas with an AUSTL of 405572 and 407959?
5. What action will the TGA take in relation to these test results?
6. Does the testing provided by Veganic SKN [Doc 5 & 6] meet the Australian standard for SPF testing to list a sunscreen on the ARTG?
7. One of the test reports provided by Veganic SKN [Doc 6] was done on a date after both the sunscreens in questions were listed [407959: 21 April 2023 & 405572: 01 March 2023] Does this comply with the TGA regulations for listing a sunscreen?
8. As stated above, more than 30 brands are selling this sunscreen using the same AUSTL, 407959, registered to the sponsor Veganic SKN. A regulatory consultant and former TGA policy advisor has told the ABC they believe this is not legal and makes it hard for the TGA to regulate. What is the TGA's response to this?
9. The ABC has also been advised that a number of these brands, including brands owned by Veganic SKN, could be breaching TGA advertising regulations with some of the claims being made on social media - as can be seen in the following links:
   https://www.instagram.com/reel/DPdMPUyEVBW/
   https://www.instagram.com/p/DQx2yA_kgwc/
   https://www.instagram.com/p/DNEdESozGvQ/?hl=en
   https://www.instagram.com/p/DRLdtz4gVF5/?hl=en&img_index=1
   https://www.instagram.com/p/DLmCDNuhjH_/?hl=en&img_index=1
   https://www.instagram.com/p/DRRE3-HE7ex/?hl=en&img_index=3

Does the TGA consider the type of messaging in the above to be a breach of TGA advertising regulations?

10. Veganic SKN has told the ABC it has information from the TGA, sourced through FOIs, that there are 21 active sunscreen ingredients that the TGA has no safety data on record for. Is this accurate? What is the TGA's response to this?
11. Veganic SKN has expressed concern publicly and to the ABC that sunscreen ingredients not allowed in the US and the EU (including 4MBC) are still allowed in sunscreens in Australia and that this poses a health risk to Australian consumers. Is it correct that 4MBC is allowed to be used in sunscreens sold in Australia? If so, what is the TGA's response to Veganic SKN's claim that this poses a health risk to Australian consumers?
12. Veganic SKN has also told the ABC and publicly stated that some other sunscreen ingredients allowed by the TGA have also been linked to health risks. What is the TGA's response?

Proposed response:

Questions 1 to 3

s 47

- The TGA takes signals seriously and investigates where appropriate, however we do not comment on individual matters, including whether a business is subject to investigation or compliance action.

Questions 4 to 5

- The TGA is concerned about preliminary data that may indicate a sunscreen does not meet its claimed SPF.
- We will consider the material and determine whether further investigation is warranted, and if required, take regulatory action as appropriate.

Questions 6 and 7

- Sponsors of sunscreens are required to comply with the testing requirements of the Australian/New Zealand Standard for sunscreens.
- However, sponsors may wish to obtain additional supporting SPF testing data after listing and may do so e.g. if there are formulation changes to their sunscreen.

Question 8

- A product included in the ARTG can only be supplied in Australia displaying the name included in the ARTG for that product.
- It is common for sunscreens to use the same base formula provided by a common manufacturer. However, each different product must have its own ARTG number.
- The TGA is considering this issue, and if required, will take regulatory action as appropriate.

Question 9

- The TGA does not comment on individual matters, including whether a business is operating legally or if they are subject to investigation or compliance action.
- We also cannot advise whether the social media posts provided contain unlawful advertisements of therapeutic goods, as any report of alleged unlawful advertising, import, supply, or manufacture of therapeutic goods must undergo robust assessment, and if required, investigation.
- However, the TGA is aware of a number of marketing campaigns that promote zinc-based sunscreens over chemical-based sunscreens. These campaigns can

present incomplete and alarmist narratives about sunscreen ingredients. The TGA has concerns regarding the potential for misinformation this creates which can cause unwarranted fear in consumers around using chemical-based sunscreens.

- In relation to mineral and chemical sunscreens:
  - Mineral sunscreens (also called physical sunscreens) use zinc oxide and/or titanium dioxide as their active ingredients to protect the skin by reflecting or scattering UV rays.
  - Chemical sunscreens absorb UV rays and convert them into heat energy, which is then released from the skin.
  - Both mineral and chemical sunscreens protect against UVR and offer advantages and disadvantages. For example, mineral sunscreens start working immediately upon application but can feel thicker and heavier and rub off more easily with sweat or water. While chemical sunscreens require 15-30 minutes to activate but are more lightweight and generally more water resistant.
  - The TGA recommends that consumers choose the product that they prefer as they are more likely to use it frequently.

Questions 10 to 12

- A number of ingredients that can be included in therapeutic sunscreens are those that were included in therapeutic goods supplied in Australia before the Therapeutic Goods Act 1989 came into operation. These ingredients were assessed to have an established safety profile (including history of safe use) based on prior regulatory oversight and market history. Since then, all new active and excipient ingredients have undergone a safety assessment by the TGA. If a person wishes to include an active or excipient ingredient that is not currently approved for use in listed medicines, the substance must be evaluated by the TGA before such use is permitted
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  - The TGA has conducted and published safety reviews on a number of sunscreen ingredients, see: Safety review of seven active sunscreen ingredients
  - As a result of this review, the TGA is currently considering restricting the amount of 3 ingredients in sunscreens. This is a conservative, precautionary measure based on potential signals from animal data studies, not human studies, when animals were exposed to these chemicals in high doses and for long periods of time, which is far beyond the amount that humans would be exposed to.
  - 4-Methylbenzylidene Camphor (4-MBC) is currently permitted for use only as an active ingredient in sunscreens, at concentrations not more than 4% in Australia. The TGA is currently reviewing 4-MBC but is yet to make

any recommendations in relation to this ingredient. We will publish the outcome of this review when it is finalised, in the interest of providing transparency for Australian consumers.

- The TGA reiterates that expert clinical advice remains that the benefits of all sunscreens available in Australia continue to far outweigh any risks and Australians are urged to continue using sunscreens.

Kind regards,

S 22 [redacted]

OFFICIAL

From: CLARKE, Avinash
Sent: Thursday, 4 December 2025 12:35 PM
To: 22 [redacted]
Cc: S 22 [redacted] ; 22 [redacted] ; JIN, Hongxia ; LUTTON, Tracey ; S 22 [redacted]
Subject: RE: MEDIA FOR ACTION: Due 12:30pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email [redacted]

From: DUFFY, Tracey
To: CLARKE, Avinash; TGA MEDIA; HENDERSON, Nick; BEDFORD, Chris
Cc: S 22 ; S 22 JIN, Hongxia; LUTTON, Tracey; S 22 ; S 22
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 12:51:30 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Thanks Avi – nothing further from me.
Tracey

OFFICIAL

From: CLARKE, Avinash
Sent: Thursday, 4 December 2025 12:47 PM
To: S 22 ; HENDERSON, Nick ; BEDFORD, Chris ; DUFFY, Tracey
Cc: S 22 S 22 JIN, Hongxia ; LUTTON, Tracey ; S 22 S 22
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email

S 22

S 22

S 22

From: JIN, Hongxia
To: BEDFORD, Chris; TGA MEDIA; HENDERSON, Nick; DUFFY, Tracey
Cc: S 22 ; S 22 ; LUTTON, Tracey; S 22 ; CLARKE, Avinash; S 22
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 1:09:34 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png
image008.png
image009.png
image010.png
image011.png

OFFICIAL

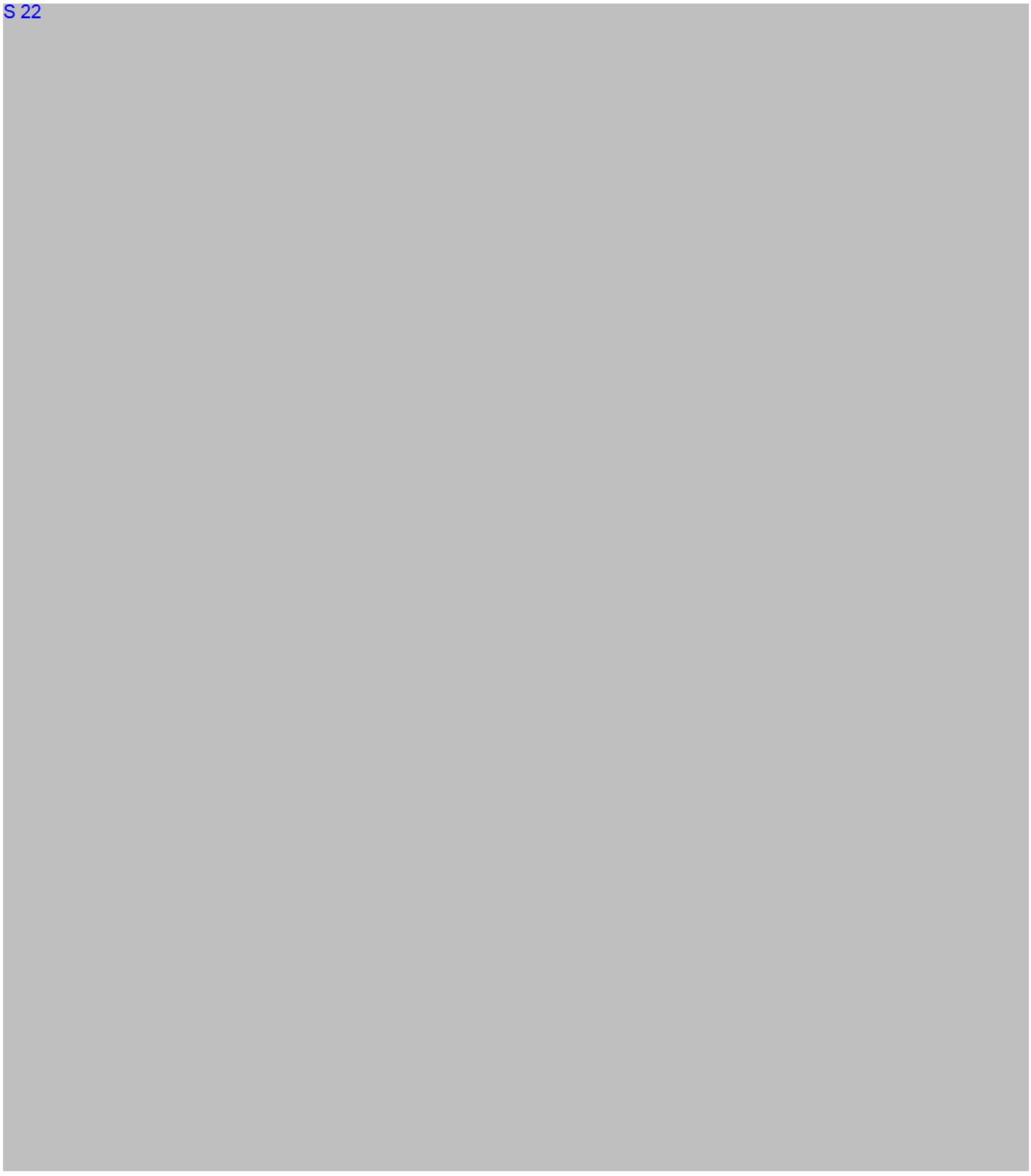
Hi all
We need to remove the highlighted sentence below under questions 1-3. There is actually no input from MQB for this media so won't require Tracey's clearance.
Thanks
Hongxia

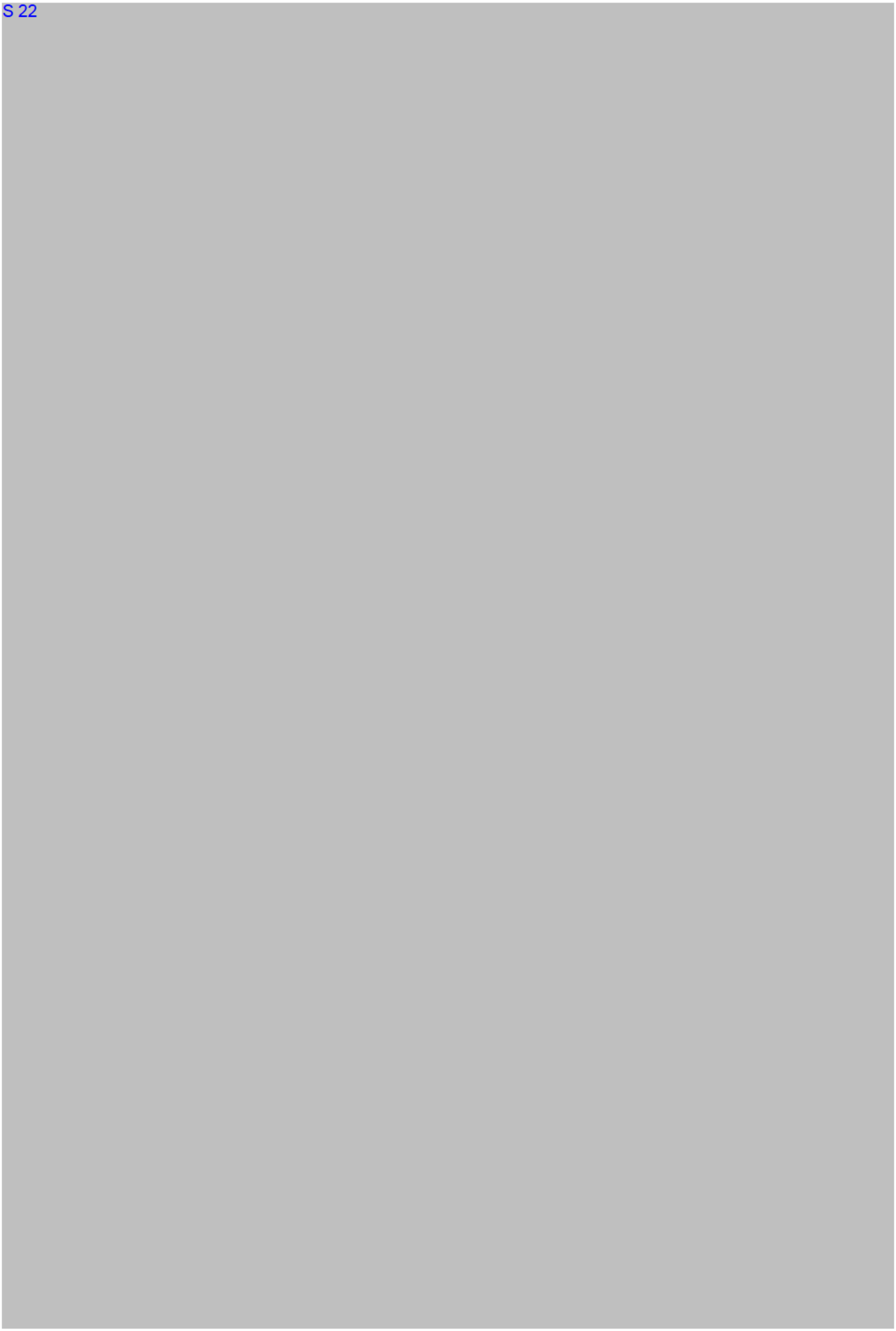
OFFICIAL

From: BEDFORD, Chris
Sent: Thursday, 4 December 2025 1:05 PM
To: TGA MEDIA ; HENDERSON, Nick ; DUFFY, Tracey
Cc: S 22 ; S 22 ; JIN, Hongxia ; LUTTON, Tracey ; S 22 ; CLARKE, Avinash ; S 22
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email


S 22

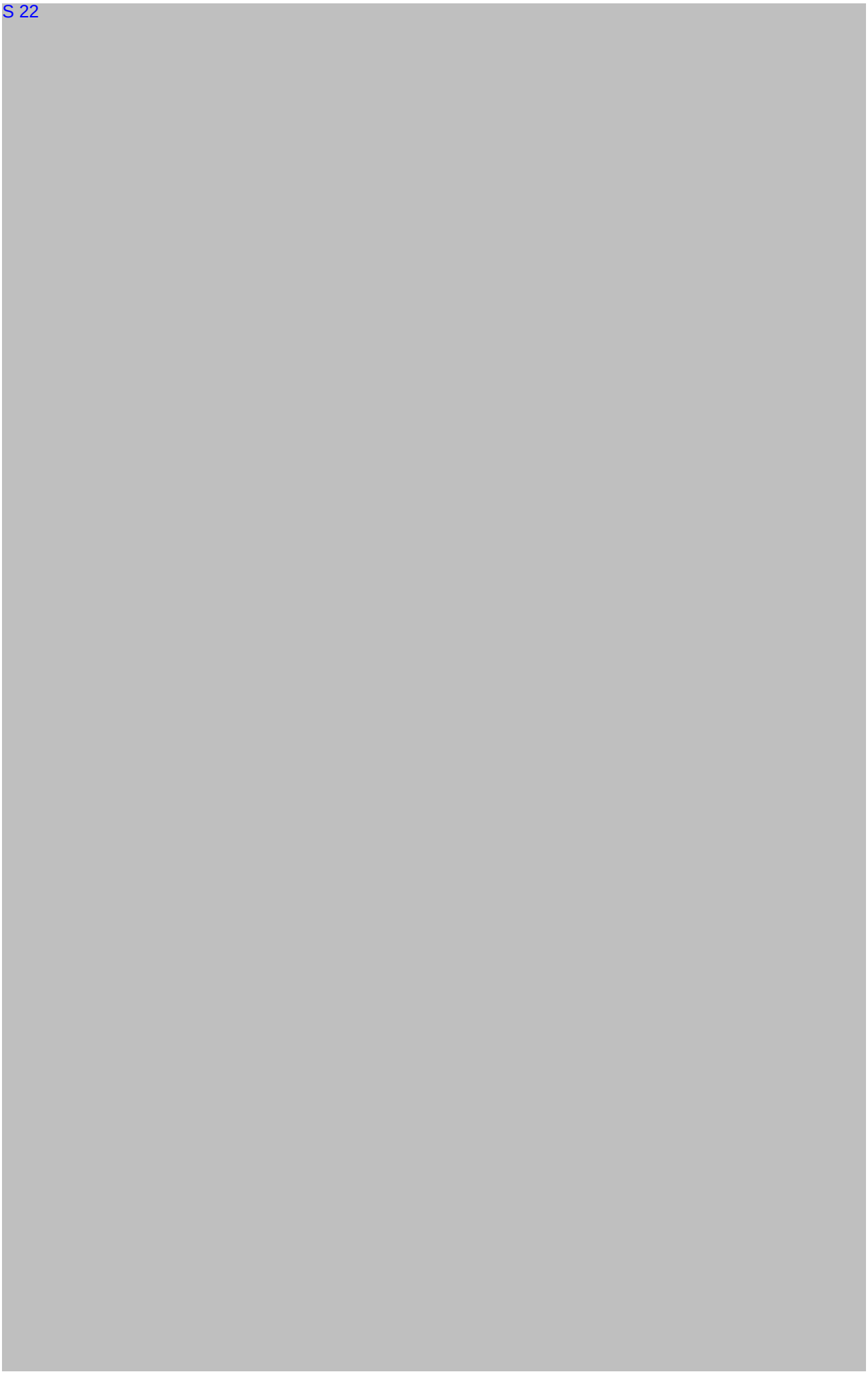

S 22



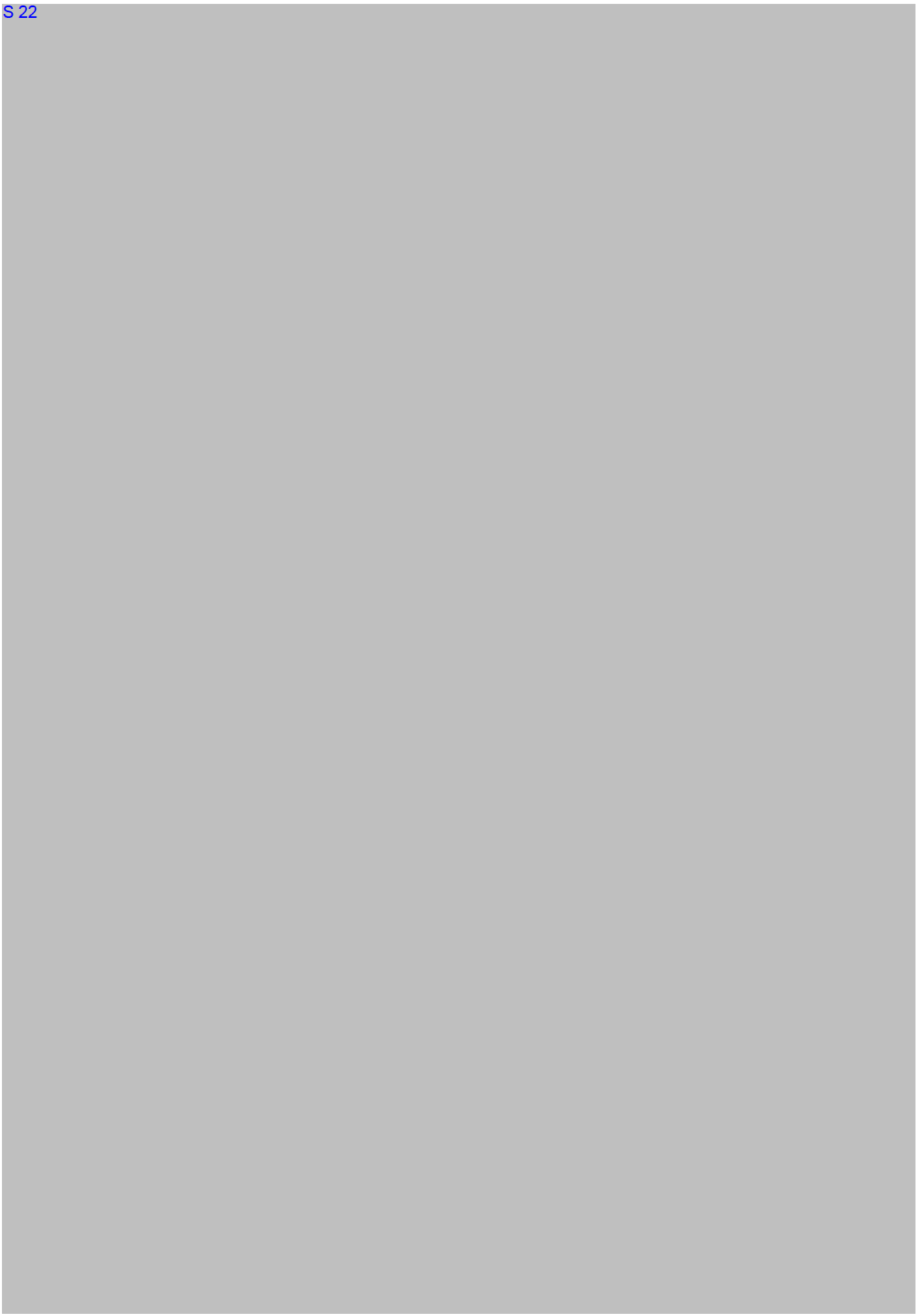
S 22

S 22

S 22



S 22



From: CLARKE, Avinash
To: s 22 ; HENDERSON, Nick; BEDFORD, Chris; DUFFY, Tracey
Cc: s 22 JIN, Hongxia; LUTTON, Tracey; s 22 s 22
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 12:46:59 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Hi All,

Apologies – inadvertently included a point on MQB inspection that should have been deleted. Updated text below.

A

Avinash Clarke

s.22

OFFICIAL

From: 22

Sent: Thursday, 4 December 2025 12:45 PM

To: HENDERSON, Nick ; BEDFORD, Chris ; DUFFY, Tracey

Cc: S 22 ; S 22 ; S 22 S 22 JIN, Hongxia ; LUTTON, Tracey ; S 22 ; CLARKE, Avinash ; S 22 S 22

Subject: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

OFFICIAL

Good afternoon all,

Please see the below media request for your clearance.

Note MQB and RCB input to question 9 in green. Remaining proposed response belongs to COMB.

MEDIA FOR CLEARANCE	
News Outlet	ABC News
AS cleared by	Avi Clarke, Hongxia Jin and Tracey Lutton
FAS Clearance by	**2pm today, 4 December – To allow Dep Sec by 3pm**

Query:

Myself and my colleagues 22 are looking into zinc oxide from Advance ZincTek and zinc sunscreens made by Veganic SKN using Advance ZincTek zinc.

We have been provided with 2 x sets of preliminary 3 person panel SPF results which show that Natural Mineral Face Sheer Liquid Zinc Sunscreen AUSTL 4055752 may not be

satisfied with these test results?

4. Is the TGA concerned about the additional test results attached to this email for the two sunscreen formulas with an AUSTL of 405572 and 407959?
5. What action will the TGA take in relation to these test results?
6. Does the testing provided by Veganic SKN [Doc 5 & 6] meet the Australian standard for SPF testing to list a sunscreen on the ARTG?
7. One of the test reports provided by Veganic SKN [Doc 6] was done on a date after both the sunscreens in questions were listed [407959: 21 April 2023 & 405572: 01 March 2023] Does this comply with the TGA regulations for listing a sunscreen?
8. As stated above, more than 30 brands are selling this sunscreen using the same AUSTL, 407959, registered to the sponsor Veganic SKN. A regulatory consultant and former TGA policy advisor has told the ABC they believe this is not legal and makes it hard for the TGA to regulate. What is the TGA's response to this?
9. The ABC has also been advised that a number of these brands, including brands owned by Veganic SKN, could be breaching TGA advertising regulations with some of the claims being made on social media - as can be seen in the following links:
   https://www.instagram.com/reel/DPdMPUyEVBW/
   https://www.instagram.com/p/DQx2yA_kgwc/
   https://www.instagram.com/p/DNEdESozGvQ/?hl=en
   https://www.instagram.com/p/DRLdtz4gVF5/?hl=en&img_index=1
   https://www.instagram.com/p/DLmCDNuhjH_/?hl=en&img_index=1
   https://www.instagram.com/p/DRRE3-HE7ex/?hl=en&img_index=3
   Does the TGA consider the type of messaging in the above to be a breach of TGA advertising regulations?
10. Veganic SKN has told the ABC it has information from the TGA, sourced through FOIs, that there are 21 active sunscreen ingredients that the TGA has no safety data on record for. Is this accurate? What is the TGA's response to this?
11. Veganic SKN has expressed concern publicly and to the ABC that sunscreen ingredients not allowed in the US and the EU (including 4MBC) are still allowed in sunscreens in Australia and that this poses a health risk to Australian consumers. Is it correct that 4MBC is allowed to be used in sunscreens sold in Australia? If so, what is the TGA's response to Veganic SKN's claim that this poses a health risk to Australian consumers?
12. Veganic SKN has also told the ABC and publicly stated that some other sunscreen ingredients allowed by the TGA have also been linked to health risks. What is the TGA's response?

Proposed response:

Questions 1 to 3

- The TGA takes signals seriously and investigates where appropriate, however we do not comment on individual matters, including whether a business is subject to investigation or compliance action.

Questions 4 to 5

- The TGA is concerned about preliminary data that may indicate a sunscreen does not meet its claimed SPF.
- We will consider the material and determine whether further investigation is warranted, and if required, take regulatory action as appropriate.

From: BEDFORD, Chris
To: s 22 HENDERSON, Nick; DUFFY, Tracey
Cc: s.22
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 1:04:39 PM
Attachments: image004.png
image005.png
image006.png
image007.png
image008.png
image009.png
image010.png
image011.png
image012.png
image013.png
image014.png

OFFICIAL

Thanks – fine with the RCB input.

Chris Bedford *(He/Him)*
First Assistant Secretary
Regulatory Practice & Support Division

Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
s.22

S 22

From: HENDERSON, Nick
To: 22 BEDFORD, Chris; DUFFY, Tracey
Cc: S 22 S 22 ; JIN, Hongxia; LUTTON, Tracey; S 22 CLARKE, Avinash; 22
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 1:36:24 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Thank you, a very comprehensive response

OFFICIAL

From: 22
Sent: Thursday, 4 December 2025 12:45 PM
To: HENDERSON, Nick ; BEDFORD, Chris ; DUFFY, Tracey
Cc: S 22 ; S 22 JIN, Hongxia ; LUTTON, Tracey ; S 22 ; CLARKE, Avinash ; ; S 22 S 22
Subject: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email

From: 22
To: LAWLER, Tony
Cc: S 22 ; 22 JIN, Hongxia; LUTTON, Tracey; 22 22 ; CLARKE, Avinash; 22 HENDERSON, Nick; 22 BEDFORD, Chris; DUFFY, Tracey
Subject: MEDIA FOR DEP SEC CLEARANCE: Due 3pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 1:48:05 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Good afternoon Tony,
Please see the below media request for your clearance.

MEDIA FOR DEP SEC CLEARANCE	
News Outlet	ABC News
FAS cleared by	Nick Henderson and Chris Bedford
Dep Sec Clearance by	**3pm Today, 4 December 2025**

Query:

Myself and my colleagues S 22 are looking into zinc oxide from Advance ZincTek and zinc sunscreens made by Veganic SKN using Advance ZincTek zinc.

We have been provided with 2 x sets of preliminary 3 person panel SPF results which show that Natural Mineral Face Sheer Liquid Zinc Sunscreen AUSTL 4055752 may not be providing the SPF50 on its label. The indicative results are SPF 25 and SPF 18 [Doc 2 & 3].

We understand that this formula was recently cancelled from the ARTG but it is still for sale.

We have seen documentary evidence that the under performance of this product and concerns about the zinc oxide used in it were raised with the TGA in a pharmacovigilance report on 27 June 2024.

We have also been provided with 1 x set of preliminary 5 person panel SPF results showing Zinclear S01 AUSTL 407959 showing an SPF of 21 [Doc 1].

The ABC has also commissioned a 3 person panel SPF test on Zinclear S01 AUSTL 407959 which returned a result of SPF 25 [Doc 4].

The ABC understands that these results are indicative and preliminary and are not a 10 person panel.

The results in Doc 1- 4 were conducted by Eurofins Dermatest in Sydney.

The ABC has spoken to multiple SPF testing experts who say that these results are a serious red flag that the SPF of these sunscreen formulas is likely not to be anywhere near the SPF50 on the label. The SPF experts we have spoken to have examined all results attached and told us that, in their opinion, there is no scientific, statistical or valid way these results would reach SPF 50 even if testing was extended to a 10 person panel.

The ABC has established that the formula registered to Veganic SKN and using the 407959 AUSTL is now used by upwards of 30 brands, including Surf Life Saving Australia and Game Face.

The ABC asked Veganic SKN for the ISO 2444:2019 SPF results required to list these sunscreens and they provided two sets of results. One is a 10 person panel done according to the FDA method, not the method mandated by the Australian Standard [Doc 5]. One is a result by the Australian Sunscreen Safety Testing Laboratory, which is owned by Advance ZincTek and is also from May 2025, which is after both these sunscreens were listed on the ARTG [Doc 6]. Veganic SKN has not, at this point, provided us with information on which test results are for which product.

Many of these brands, including some owned by Veganic SKN, are marketing these products online using language and images that promote zinc sunscreen as a safe and natural alternative to toxic chemical sunscreens.

Questions:

1. What action did the TGA take when it was informed via a pharmacovigilance report in June 2024 of testing that suggested that sunscreens using Advance ZincTek zinc were likely not to be providing the SPF 50 on their labels?
2. The company responsible for the 2024 pharmacovigilance report has told the ABC that the TGA did not follow up with any requests for information regarding that report and was told any potential action by the TGA was confidential. They have expressed the opinion and concern that the TGA appears not to have acted in response to the concerns raised in that report. What is the TGA's response to this allegation? What action did the TGA take in relation to this safety report?
3. Test result [Doc 2] for a sunscreen with the AUSTL 405572 was attached to that pharmacovigilance report. Did the TGA check that this sunscreen held SPF rest reports as required by the regulations to demonstrate its SPF50 label? Was the TGA satisfied with these test results?
4. Is the TGA concerned about the additional test results attached to this email for the two sunscreen formulas with an AUSTL of 405572 and 407959?
5. What action will the TGA take in relation to these test results?
6. Does the testing provided by Veganic SKN [Doc 5 & 6] meet the Australian standard for SPF testing to list a sunscreen on the ARTG?
7. One of the test reports provided by Veganic SKN [Doc 6] was done on a date after both the sunscreens in questions were listed [407959: 21 April 2023 & 405572: 01 March 2023] Does this comply with the TGA regulations for listing a sunscreen?
8. As stated above, more than 30 brands are selling this sunscreen using the same AUSTL, 407959, registered to the sponsor Veganic SKN. A regulatory consultant and former TGA policy advisor has told the ABC they believe this is not legal and makes it hard for the TGA to regulate. What is the TGA's response to this?
9. The ABC has also been advised that a number of these brands, including brands owned by Veganic SKN, could be breaching TGA advertising regulations with some of the claims being made on social media - as can be seen in the following links:
   https://www.instagram.com/reel/DPdMPUyEVBW/
   https://www.instagram.com/p/DQx2yA_kgwc/
   https://www.instagram.com/p/DNEdESozGvQ/?hl=en
   https://www.instagram.com/p/DRLdtz4gVF5/?hl=en&img_index=1
   https://www.instagram.com/p/DLmCDNuhjH_/?hl=en&img_index=1
   https://www.instagram.com/p/DRRE3-HE7ex/?hl=en&img_index=3

Does the TGA consider the type of messaging in the above to be a breach of TGA advertising regulations?

10. Veganic SKN has told the ABC it has information from the TGA, sourced through FOIs, that there are 21 active sunscreen ingredients that the TGA has no safety data on record for. Is this accurate? What is the TGA's response to this?
11. Veganic SKN has expressed concern publicly and to the ABC that sunscreen ingredients not allowed in the US and the EU (including 4MBC) are still allowed in sunscreens in Australia and that this poses a health risk to Australian consumers. Is it correct that 4MBC is allowed to be used in sunscreens sold in Australia? If so, what is the TGA's response to Veganic SKN's claim that this poses a health risk to Australian consumers?
12. Veganic SKN has also told the ABC and publicly stated that some other sunscreen ingredients allowed by the TGA have also been linked to health risks. What is the TGA's response?

FAS cleared response:

Questions 1 to 3

- The TGA takes signals seriously and investigates where appropriate, however we do not comment on individual matters, including whether a business is subject to investigation or compliance action.

Questions 4 to 5

- The TGA is concerned about preliminary data that may indicate a sunscreen does not meet its claimed SPF.
- We will consider the material and determine whether further investigation is warranted, and if required, take regulatory action as appropriate.

Questions 6 and 7

- Sponsors of sunscreens are required to comply with the testing requirements of the Australian/New Zealand Standard for sunscreens.
- However, sponsors may wish to obtain additional supporting SPF testing data after listing and may do so e.g. if there are formulation changes to their sunscreen.

Question 8

- A product included in the ARTG can only be supplied in Australia displaying the name included in the ARTG for that product.
- It is common for sunscreens to use the same base formula provided by a common manufacturer. However, each different product must have its own ARTG number.
- The TGA is considering this issue, and if required, will take regulatory action as appropriate.

Question 9

- The TGA does not comment on individual matters, including whether a business is operating legally or if they are subject to investigation or compliance action.
- We also cannot advise whether the social media posts provided contain unlawful advertisements of therapeutic goods, as any report of alleged unlawful advertising, import, supply, or manufacture of therapeutic goods must undergo robust assessment, and if required, investigation.
- However, the TGA is aware of a number of marketing campaigns that promote zinc-based sunscreens over chemical-based sunscreens. These campaigns can present incomplete and alarmist narratives about sunscreen ingredients. The TGA has concerns regarding the potential for misinformation this creates which can cause unwarranted fear in consumers around using chemical-based sunscreens.

- In relation to mineral and chemical sunscreens:
  - Mineral sunscreens (also called physical sunscreens) use zinc oxide and/or titanium dioxide as their active ingredients to protect the skin by reflecting or scattering UV rays.
  - Chemical sunscreens absorb UV rays and convert them into heat energy, which is then released from the skin.
  - Both mineral and chemical sunscreens protect against UVR and offer advantages and disadvantages. For example, mineral sunscreens start working immediately upon application but can feel thicker and heavier and rub off more easily with sweat or water. While chemical sunscreens require 15-30 minutes to activate but are more lightweight and generally more water resistant.
  - The TGA recommends that consumers choose the product that they prefer as they are more likely to use it frequently.

Questions 10 to 12

- A number of ingredients that can be included in therapeutic sunscreens are those that were included in therapeutic goods supplied in Australia before the Therapeutic Goods Act 1989 came into operation. These ingredients were assessed to have an established safety profile (including history of safe use) based on prior regulatory oversight and market history. Since then, all new active and excipient ingredients have undergone a safety assessment by the TGA. If a person wishes to include an active or excipient ingredient that is not currently approved for use in listed medicines, the substance must be evaluated by the TGA before such use is permitted
- The public can be reassured that the TGA is fulfilling its regulatory role to continually monitor and review ingredients to maintain the highest standards of quality, safety and efficacy in the Australian market.
- The TGA monitors international developments in relation to safety issues for sunscreens and prioritises our ingredient reviews by considering the use of the ingredient in sunscreen products marketed in Australia.
- In response to international and domestic concerns in relation to certain sunscreen ingredients:
  - The TGA has conducted and published safety reviews on a number of sunscreen ingredients, see: Safety review of seven active sunscreen ingredients
  - As a result of this review, the TGA is currently considering restricting the amount of 3 ingredients in sunscreens. This is a conservative, precautionary measure based on potential signals from animal data studies, not human studies, when animals were exposed to these chemicals in high doses and for long periods of time, which is far beyond the amount that humans would be exposed to.
  - 4-Methylbenzylidene Camphor (4-MBC) is currently permitted for use only as an active ingredient in sunscreens, at concentrations not more than 4% in Australia. The TGA is currently reviewing 4-MBC but is yet to make any recommendations in relation to this ingredient. We will publish the outcome of this review when it is finalised, in the interest of providing transparency for Australian consumers.
- The TGA reiterates that expert clinical advice remains that the benefits of all

sunscreens available in Australia continue to far outweigh any risks and Australians are urged to continue using sunscreens.

Kind regards

S 22 [redacted]

OFFICIAL

From: HENDERSON, Nick
Sent: Thursday, 4 December 2025 1:36 PM
To: 22 [redacted] ; BEDFORD, Chris ; DUFFY, Tracey
Cc: S 22 [redacted] ; S 22 [redacted] ; JIN, Hongxia ; LUTTON, Tracey ; SS 22 [redacted] ; CLARKE, Avinash ; S 22 [redacted]
Subject: RE: MEDIA FOR CLEARANCE: Due 2pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email [redacted]

From: LAWLER, Tony
To: 22
Cc: S 22 S 22 JIN, Hongxia; LUTTON, Tracey; S 22 ; CLARKE, Avinash; S 22 ; HENDERSON, Nick; BEDFORD, Chris; DUFFY, Tracey
Subject: RE: MEDIA FOR DEP SEC CLEARANCE: Due 3pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 2:46:33 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Thanks S 22 , and all for bringing these together.
Cleared.
T

OFFICIAL

From: 22
Sent: Thursday, 4 December 2025 1:48 PM
To: LAWLER, Tony
Cc: S 22 S 22 ; JIN, Hongxia ; LUTTON, Tracey ; S 22 ; CLARKE, Avinash ; S 22 HENDERSON, Nick ; S 22 ; BEDFORD, Chris ; DUFFY, Tracey
Subject: MEDIA FOR DEP SEC CLEARANCE: Due 3pm Thursday, 04/12 - ABC News - Sunscreens [SEC=OFFICIAL]

s.22, Duplicate email

From: S 22
To: s22
Cc: S 22
Subject: DEP SEC CLEARED MEDIA - ABC News - Sunscreens [SEC=OFFICIAL]
Date: Thursday, 4 December 2025 2:50:18 PM
Attachments: image001.png
image002.png
image003.png

OFFICIAL

Good afternoon News,
Please see below HPRG's cleared media response.

CLEARED MEDIA	
Dep Sec cleared	Prof. Tony Lawler

Cleared response:

Questions 1 to 3

- The TGA takes signals seriously and investigates where appropriate, however we do not comment on individual matters, including whether a business is subject to investigation or compliance action.

Questions 4 to 5

- The TGA is concerned about preliminary data that may indicate a sunscreen does not meet its claimed SPF.
- We will consider the material and determine whether further investigation is warranted, and if required, take regulatory action as appropriate.

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  - The TGA recommends that consumers choose the product that they prefer as they are more likely to use it frequently.

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- The public can be reassured that the TGA is fulfilling its regulatory role to continually monitor and review ingredients to maintain the highest standards of quality, safety and efficacy in the Australian market.
- The TGA monitors international developments in relation to safety issues for sunscreens and prioritises our ingredient reviews by considering the use of the ingredient in sunscreen products marketed in Australia.
- In response to international and domestic concerns in relation to certain sunscreen ingredients:
  - The TGA has conducted and published safety reviews on a number of sunscreen ingredients, see: Safety review of seven active sunscreen ingredients
  - As a result of this review, the TGA is currently considering restricting the amount of 3 ingredients in sunscreens. This is a conservative, precautionary measure based on potential signals from animal data studies, not human studies, when animals were exposed to these chemicals in high doses and for long periods of time, which is far beyond the amount that humans would be exposed to.
  - 4-Methylbenzylidene Camphor (4-MBC) is currently permitted for use only as an active ingredient in sunscreens, at concentrations not more than 4% in Australia. The TGA is currently reviewing 4-MBC but is yet to make any recommendations in relation to this ingredient. We will publish the outcome of this review when it is finalised, in the interest of providing

transparency for Australian consumers.

- The TGA reiterates that expert clinical advice remains that the benefits of all sunscreens available in Australia continue to far outweigh any risks and Australians are urged to continue using sunscreens.

Kind regards

S 22

OFFICIAL

OFFICIAL

From: S 22

Sent: Tuesday, 2 December 2025 4:53 PM

To: S 22

Cc: S 22

Subject: MEDIA ENQUIRY - ABC News - Sunscreens - deadline 3pm Thursday [SEC=OFFICIAL]

s.22, Duplicate email

8/12/2025 11:12 am Edited

Urgent ABC - Sunscreens Media back with you S 22 [redacted]