

s22

**From:** s22 [redacted]@health.gov.au>  
**Sent:** Thursday, 16 December 2021 8:19 AM  
**To:** Nuich, Ivan  
**Cc:** s22 [redacted]; Recalls  
**Subject:** RE: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636. [SEC=OFFICIAL]

Hi Ivan

Thank you for letting me know, yes, my "reply all" to you and your colleagues was inadvertent.

I apologise for this oversight. Nonetheless, my message intended to update other TGA colleagues simply flags the likely tenor and direction of our further discussions later this morning which you are now aware of.

Look forward to talking soon.

Regards

s22

s22 [redacted]  
Australian Recall Coordinator  
and  
Director  
Recalls Section  
Manufacturing Quality Branch

Sent from Workspace ONE Boxer

On 15 December 2021 at 10:17:46 pm AEDT, Nuich, Ivan s22 [redacted]@Edgewell.com> wrote:

**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 s22 [redacted]

I may have been inadvertently copied on this email.

Regards  
Ivan

**Ivan Nuich**  
**RVP - OCEANIA**

M s22 [redacted] | 11 Talavera Road, Macquarie Park, NSW 2113, Australia

From: s22 @health.gov.au  
Sent: Wednesday, 15 December 2021 7:01 PM  
To: Nuich, Ivan s22 @Edgewell.com>; Recalls <Recalls@health.gov.au>  
Cc: s22 @health.gov.au>; s22 @health.gov.au>;  
s22 @health.gov.au>; Keefe-McGuinness, Michelle <s22 @Edgewell.com>; Clare, Belinda s22 @Edgewell.com>; s22 @health.gov.au>; KAY, Elspeth <Elspeth.Kay@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>  
Subject: RE: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636.  
[SEC=OFFICIAL]

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Thanks s22

s22 / Elspeth / s22 / s22 / Lisa – FYI below from late yesterday, following our internal meeting.

Following this, s22 and s22 participated in a teleconference with the sponsor and their lawyer this afternoon, where they raised a number of additional questions/statements:

- Where is the TGA laboratory testing conducted?;
- What is the margin of error for benzene during the testing (i.e. 1.8mg/kg to 2.2mg/kg etc)?;
- They had mentioned they conducted testing on the product prior to release and that the product was safe for supply.

The sponsor has requested another teleconference tomorrow morning which has been scheduled for 10.15am s22 and s22 have been invited given the above questions. I understand the sponsor will also be including their international regulatory team to discuss some of the technical details of the laboratory testing undertaken.

Unless any new, compelling information is presented that requires our further consideration, I will be pushing them to initiate the recall under the URPTG asap and inform them of our options if they decline to do so.

We'll keep you updated.

s22

s22  
Australian Recall Coordinator  
and  
Director  
Recalls Section

Australian Government Department of Health  
T: s22 | E: s22@health.gov.au  
Location: Sirius Building 7.S.144  
PO Box 100, Woden ACT 2606, Australia

*This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*

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**From:** Nuich, Ivan s22@Edgewell.com>  
**Sent:** Tuesday, 14 December 2021 6:07 PM  
**To:** Recalls <Recalls@health.gov.au>  
**Cc:** s22@health.gov.au>; s22@health.gov.au>; s22@health.gov.au>; s22@health.gov.au>; s22@Edgewell.com>; Clare, Belinda <s22@Edgewell.com>  
**Subject:** RE: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636. [SEC=OFFICIAL]

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

Hi s22

Thank you for the call just now regarding this issue. As mentioned, this is the first I am hearing about this. I have also checked with the colleagues who monitor the email address that you mentioned and they have not seen this notification.

We take the matter extremely seriously and will urgently work with our internal stakeholders on next steps.

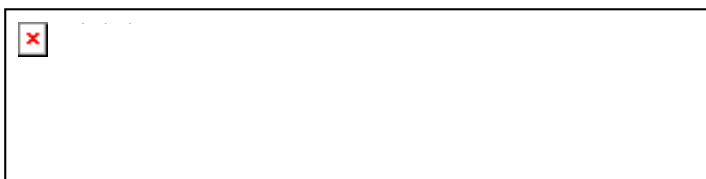
I will align with internal stakeholders in the next 24-48 hours and will most likely need to reach out to you for further discussions and guidance by the end of the week.

Regards and talk soon  
Ivan

**Ivan Nuich**  
**RVP - OCEANIA**

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: s22  
: 11 Talavera Road, Macquarie Park, NSW 2113, Australia



From: Recalls <[Recalls@health.gov.au](mailto:Recalls@health.gov.au)>  
Sent: Tuesday, 14 December 2021 5:10 PM  
To: Nuich, Ivan [s22@Edgewell.com](mailto:s22@Edgewell.com); Keeffe-McGuinness, Michelle [s22@Edgewell.com](mailto:s22@Edgewell.com)  
Cc: Recalls <[Recalls@health.gov.au](mailto:Recalls@health.gov.au)>; [s22@health.gov.au](mailto:s22@health.gov.au); [s22@health.gov.au](mailto:s22@health.gov.au); [s22@health.gov.au](mailto:s22@health.gov.au); [s22@health.gov.au](mailto:s22@health.gov.au)  
Subject: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636.  
[SEC=OFFICIAL]

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Hello Ivan and Michelle,

Thank you for taking my call ([s22@health.gov.au](mailto:s22@health.gov.au)).

Please find attached the correspondence sent to [ap.others.australia@edgewell.com](mailto:ap.others.australia@edgewell.com) on Thu 9/12/2021. You have both mentioned verbally that you were unaware of this email notice and the email address above is not manned.

Please note – this is the main contact within the TGA TBS portal.

I had also tried contacting Edgewell on the landline numbers provided on this system prior to calling your mobiles, all of which were either disconnected or routed to a battery manufacturing company.

Sponsors are requested to verify that the relevant staff contact details given in the TGA TBS Portal are up to date as per the guidance below:

<https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators> [tga.gov.au]

As noted within the attached “Notice of Compliance Test Failure” document, Benzene was detected in the listed medicines at levels above 2 mg/kg.

There is also a number of additional requirements and DUE DATES stated within this document – it is recommended to address these requirements as soon as possible and to contact

[s22@health.gov.au](mailto:s22@health.gov.au) if you have any concerns regarding the timing of addressing the requirements.

Based on the identified Benzene levels, a Consumer Level Recall for the 4 batches of product mentioned within the “Notice of Compliance Test Failure” Document is recommended.

Attached is a copy of the Uniform Recall Procedure for Therapeutic Goods (URPTG). There is further information regarding Consumer Level Recalls inside this guidance document.

Consumer level recall actions require a Communication Strategy, to help tailor notices for specific groups of consumers the impacted product may be sold to.

Please find attached a template Communication Strategy document if required.

As discussed with Ivan over the phone, the Recalls section is aiming to have a consumer level recall action agreed and underway prior to the 24<sup>th</sup> December 2021.

Once you have read and understood the information provided in this email, please feel free to contact me on the number in my signature to discuss any next steps.

I am happy to be involved with any teleconferences you may require with your National/International regulatory teams – However – As mentioned above, we are hoping to have an established action plan as soon as possible.

Please feel free to contact me to discuss any issues you may have.

Kind Regards,

s22

Recall Coordinator

Recalls Section

Manufacturing Quality Branch

Phone: s22

Email: s22@health.gov.au


Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

[www.tga.gov.au](http://www.tga.gov.au) [[tga.gov.au](http://tga.gov.au)]



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[SEC=OFFICIAL]