

s22

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

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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

+s22

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



From: Recalls
Sent: Tuesday, 14 December 2021 5:10 PM
To: Nuich, Ivan ; Keeffe-McGuinness, Michelle
Cc: Recalls ; s22; s22; s22; s22
Subject: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636. [SEC=OFFICIAL]

CAUTION: This message was sent from outside of Edgewell. Please use proper judgement and caution when opening attachments, clicking links, or responding to this email.

Hello Ivan and Michelle,

Thank you for taking my call s22.

Please find attached the correspondence sent to 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 24th 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](mailto:s22@health.gov.au)

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

www.tga.gov.au [tga.gov.au]

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