

s22

From: Clare, Belinda s22 @Edgewell.com>
Sent: Monday, 20 December 2021 4:23 PM
To: Recalls; Nuich, Ivan; Pamelard, Christophe; s22
Subject: RE: [DRAFT] TGA Web-statement - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]
Attachments: D21-3453447 DRAFT Web statement - Banana Boat Sunscreen Products - AUST L 206508 311003 and 342636 (EPC Edits).docx

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Hi s22,

Please find attached our first edits. This document will still need to be reviewed by our regulatory team who are located in the US however we don't expect any major changes. We will have any additional feedback first thing tomorrow morning.

Kind regards,
Belinda

Belinda Clare
SENIOR MARKETING MANAGER

O: s47F | Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia
E: s22 @Edgewell.com W: Edgewell.com



From: Recalls <Recalls@health.gov.au>
Sent: Monday, 20 December 2021 3:46 PM
To: Clare, Belinda s22 @Edgewell.com>; Nuich, Ivan s22 @Edgewell.com>; Pamelard, Christophe <s22 @Edgewell.com>; s22
Subject: RE: [DRAFT] TGA Web-statement - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi Belinda,

Thank you for the email – just confirming, did you receive my voicemail regarding the web-statement? I am hoping to have the document reviewed and returned by 4:30 this afternoon if possible.

Kind Regards,

s22

Recall Coordinator
Recalls Section
Manufacturing Quality Branch

Phone: s22
Email: recalls@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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From: Clare, Belinda s22 @Edgewell.com>
Sent: Monday, 20 December 2021 3:36 PM
To: Recalls <Recalls@health.gov.au>; Nuich, Ivan s22 @Edgewell.com>; Pamelard, Christophe s22 @Edgewell.com>; s22
Subject: RE: [DRAFT] TGA Web-statement - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi s22 ,

Thank you for this. We will review and advise.

In the interest of time I wanted to share our draft customer letter (attached) for your review.

Please note:

- 1) Issue/risk – section to be updated to be in line with agreed web statement
- 2) Items highlighted in yellow to finalised

Kind regards,
Belinda

Belinda Clare
SENIOR MARKETING MANAGER

O: s47F | Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia
E: s22 @Edgewell.com W: Edgewell.com [nam04.safelinks.protection.outlook.com]



From: Recalls <Recalls@health.gov.au>

Sent: Monday, 20 December 2021 1:05 PM

To: Clare, Belinda s22@Edgewell.com; Nuich, Ivan s22@Edgewell.com; Pamelard, Christophe s22@Edgewell.com; s22@Edgewell.com

Subject: [DRAFT] TGA Web-statement - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hello Belinda,

Please find attached the DRAFT TGA Web-statement.

Please review the information and make any (factual only) changes to the document using the “tracked changes” feature or comments.


I will be away from my desk for the next 30 mins – feel free to contact me afterwards if there are any issues.

Kind Regards,

[s22](mailto:s22@Edgewell.com)
Recall Coordinator
Recalls Section
Manufacturing Quality Branch

Phone: [s22](tel:s22)
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
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From: Recalls

Sent: Monday, 20 December 2021 11:56 AM

To: 'Clare, Belinda' s22@Edgewell.com; Nuich, Ivan s22@Edgewell.com; Pamelard, Christophe s22@Edgewell.com; s22@Edgewell.com >

Subject: RE: TRIM: RE: Web-Statement Information - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

Hi Belinda,

Thank you for the very quick response – I will wait for the other documents you are finalising and if I have any issues afterwards I will contact you.

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 [tga.gov.au]



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From: s22@Edgewell.com>
Sent: Monday, 20 December 2021 11:47 AM
To: Recalls <Recalls@health.gov.au>; Nuich, Ivan s22@Edgewell.com>; Pamelard, Christophe s22@Edgewell.com> s22@gtlaw.com.au>
Subject: TRIM: RE: Web-Statement Information - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi s22,

Please find below our response.

- The main website that the Edgewell web-statement will be posted on is www.bananaboat.com.au [bananaboat.com.au]
- Edgewell Personal Care Consumer Service team Free Call **1800 761 186**
- Product renders attached
- Expiry date of the most recent batch supplied within Australia below

Product Name	ARTG Number	Batch	Exp
Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+	206508	21036AF	01/2
Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+	311003	20328BF	10/2
Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+	342636	20358AF	11/2

We are also finalising the following:

- Draft Australian Customer Letter and acknowledgement form
- Customer List
- Consumer Press Advertisement

We will have these documents with you shortly.

Kind regards,
Belinda

Belinda Clare
SENIOR MARKETING MANAGER

O: s47F [redacted] | Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia
E: s22 [redacted]@Edgewell.com W: Edgewell.com [nam04.safelinks.protection.outlook.com]



From: Recalls <Recalls@health.gov.au>
Sent: Monday, 20 December 2021 11:27 AM
To: Nuich, Ivan s22 [redacted]@Edgewell.com>; Pamelard, Christophe s22 [redacted]@Edgewell.com>; Clare, Belinda s22 [redacted]@Edgewell.com>; s22 [redacted]@Edgewell.com>
Cc: Recalls <Recalls@health.gov.au>
Subject: Web-Statement Information - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Good Morning Ivan,

I am in the process of completing the TGA DRAFT web-statement – some of the information that I require is below. Could you please provide the below information as soon as practically possible – the final web-statement will need to be reviewed by the TGA executives as well as a final review by yourself.

- The main website that the Edgewell web-statement will be posted on (i.e. [Banana Boat \[redacted\].com.au](http://Banana Boat [redacted].com.au))
 - This does not need to link DIRECTLY to the recall action (given that you have stated the Edgewell web-page may be delayed in being uploaded) – but consumers should be able to easily identify how to access the recall information from this link.
- Edgewell Personal Care Australia contact number for the public.
- Pictures of the 3 products involved with the recall (I have attached one example)
- The expiry date of the most recent batch supplied within Australia, involved in the recall
 - This will be referenced in the TGA web-statement so that consumers can identify product that may be supplied in the future as not being impacted by this recall action.

I will contact you shortly to get an update on the situation / timing.

Kind Regards,

s22 [redacted]
Recall Coordinator
Recalls Section
Manufacturing Quality Branch

Phone: s22 [redacted]
Email: s22 [redacted]@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
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From: Recalls
Sent: Friday, 17 December 2021 2:39 PM
To: 'Nuich, Ivan' <s22@Edgewell.com>; Pamelard, Christophe s22@Edgewell.com>; Clare, Belinda s22@Edgewell.com>; s22@Edgewell.com>
Cc: Recalls <Recalls@health.gov.au>
Subject: Initial Information - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

Hello Ivan,

To help the progress of this recall, I have outlined the information that we require to “agree” to the recall as below:

- Draft Australian Customer Letter and acknowledgement form (you have mentioned you are currently Drafting this)
 - Please include the TGA Reference number “RC-2021-RN-02404-1” somewhere easily identifiable within the letter.
- Customer List (please provide the below information as a minimum):

Customer Name	State	Suburb
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- Consumer level communication strategy (template is provided as attached)
 - The template does not need to be used/fully completed – the information that I require is what [s22](mailto:s22@Edgewell.com) mentioned during the teleconference today: A proposed strategy for reaching as many consumers as possible – i.e. facebook posts, web-statements, consumer group notifications etc – the document attached provides some examples.
- Consumer Press Advertisement (template attached)
- TGA Web-statement
 - The TGA is currently drafting this document and will provide a DRAFT version for your comments early next week
 - The Web-statement will require an image of each of the products being recalled (similar to the [Neutrogena web-statement \[tga.gov.au\]](http://www.tga.gov.au)) – Please provide a single image of each product you wish to be uploaded in the web-statement.

Once the above is Agreed upon, I will provide you a DRAFT summary of the TGA System for Australian Recall Actions (SARA) printout – this is a high-level summary of the issue that will be displayed publicly. It will mainly be information from the Customer letter.

Feel free to contact me to discuss.

Kind Regards,

[s22](mailto:s22@Edgewell.com)
Recall Coordinator
Recalls Section
Manufacturing Quality Branch

Phone: s22
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
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From: Nuich, Ivan s22 @Edgewell.com>
Sent: Thursday, 16 December 2021 4:53 PM
To: s22 @health.gov.au>; Recalls <Recalls@health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; Clare, Belinda s22 @Edgewell.com>; s22 Lake, Mary s22 @Edgewell.com>; Tannhauser, Annie s22 @Edgewell.com>; Pamelard, Christophe s22 @Edgewell.com>; Becvar, Paola C. s22 @Edgewell.com>; Rizzi, Joseph s22 @Edgewell.com>
Subject: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636

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Dear s22,

I refer to your Notice of Compliance Test Failure dated 9 December 2021, which came to Edgewell's attention on 14 December 2021. I also appreciate the subsequent conversations we have had with TGA's recalls and technical teams both yesterday and today.

Edgewell is prepared to undertake a voluntarily recall the 4 products identified in the TGA's Notice. Out of an abundance of caution, and as a responsible supplier of sunscreens in Australia, Edgewell is also prepared to conduct a broader recall in relation to these product lines, including any other batches that have already been supplied to Australian (and NZ) consumers in the last 3 years. As stated in our call with TGA's recalls and technical teams today, Edgewell is in the process of changing its manufacturer for these particular sunscreens and has no further stock on hand. Further information regarding the batches in question are listed below.

Whilst Edgewell is not intending to pursue a technical review under regulation 30 at this point in time, we would nevertheless appreciate sharing of the underlying testing data and results obtained by TGA. Our global team intends to undertake independent analysis of retention samples in parallel with the Australian recall to determine the full extent of this problem. In doing so, it will be helpful to understand and align with TGA's testing methodology. This will also help us ensure that our new range of sunscreens in this category, which will be manufactured in Australia, are fully compliant with the requirements for residual solvents.

As indicated by s22 on our call earlier today, we will proceed on the basis that the recall will be commenced next week, and look forward to working with TGA to align on the execution process.

I look forward to hearing from your recalls team regarding next steps.

Kind regards
Ivan Nuich
Ivan Nuich
RVP - OCEANIA

M s47F | 11 Talavera Road, Macquarie Park, NSW 2113, Australia

	Banana B High Prot Sunscre
ARTG	20
BATCH/EXP	21
EXPIRY	01
Confirmation of quarantine of stock from the affected batch that has not been distributed	No
The number of units of this batch in stock	No
The number of units of this batch distributed to date	65
A list of other batches of the same product that are currently held in stock and are within the expiry date	No
Confirm if any units have been exported	N
Evidence that other batches of the same product on the market are of acceptable quality, if available.	

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'Banana Boat' Sunscreen Sprays SPF 50+ (aerosol sunscreen)

Recall – Possible presence of benzene

Edgewell Personal Care Australia Pty Ltd is recalling all batches of the following 'Banana Boat' sunscreen sprays (aerosol sunscreen) because benzene has been detected in 4 batches of the products supplied in Australia.

The three products being recalled are:

- Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+, AUST L 206508
- Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+, AUST L 311003
- Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+, AUST L 342636.



Deleted: P

Commented [SR1]: Hover text: The removal of an affected therapeutic good from supply or use in the market

Commented [SR2]: WEBTEAM: The 3 original images are in folder: E21-436667. Please resize the 3 images as appropriate. See: <https://www.tga.gov.au/alert/neutrogena-ultra-sheer-body-mist-sunscreen-spray-spf-50-aerosol-sunscreen>

What should I do?

All batches with an expiry date of 31st January 2024 or earlier should not be used due to possible health risks linked to benzene.

Consumers should discard the products and visit the [Banana Boat](#) website to request a refund.

Commented [SR3]: EDGEWELL: Please confirm the process consumers will follow for receiving/progressing a refund.

All unsold product [of the affected batches](#) will be removed from the market.

What is benzene and what are the risks?

Benzene is classified as a human carcinogen, a substance that could potentially cause cancer depending on the level and extent of exposure. Benzene is not an ingredient in sunscreens but is suspected to be a contaminant from raw materials used in the products manufacture. The TGA is working with sponsors to investigate the source of benzene.

The Therapeutic Goods Administration (TGA) has limits on these types of solvents and benzene must be below a concentration of 2 parts per million (ppm) in medicines. This includes sunscreen products that are [listed medicines](#) in Australia.

Commented [BJ4]: Hover text/link to definition

The TGA laboratories recently completed product testing, which detected benzene at concentrations between 2.3 ppm and 5.2 ppm in four batches of the above products supplied in Australia. Exposure to benzene in these sunscreen products, at the levels detected, would not be expected to cause serious adverse health effects. However, to reduce the risk to consumers, **Edgewell Personal Care is recalling all batches of the affected products supplied within Australia.**

Commented [SR5R4]: "Unscheduled medicines with well-known low-risk ingredients"

If you have any concerns or questions about this issue, speak to your health professional or contact the Edgewell Personal Care Consumer Service team (Free Call) on 1800 761 186.

Reporting problems

Consumers and health professionals are encouraged to [report any problems or side effects with therapeutic goods](#). Your report will contribute to the TGA's monitoring of these products.

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a therapeutic good.