

From: Clare, Belinda  
To: Recalls; N. ch. I. au; Pamelard, Christophe; s22  
Subject: RE: Web-Statement Information - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]  
Date: Monday, 20 December 2021 11:48:26 AM  
Attachments: images001.png  
images002.png  
images003.png  
images004.png  
images005.png  
206508 - Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+ .png  
311003 - Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+ .png  
342636 - Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+ .png

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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](http://www.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	Expiry
Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+	206508	21036AF	01/2024
Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+	311003	20328BF	10/2023
Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+	342636	20358AF	11/2023

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

Office: s22 Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia

Email: s22 @Edgewell.com W Edgewell.com

From: Recalls

Sent: Monday, 20 December 2021 11:27 AM

To: Nuich, Ivan; Pamelard, Christophe; Clare, Belinda; s22

Cc: Recalls

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 |bananaboat.com.au](http://Banana Boat |bananaboat.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

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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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

Cc: Recalls <[recalls@health.gov.au](mailto: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 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://Neutrogena web-statement |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

Recall Coordinator

Recalls Section

Manufacturing Quality Branch

Phone: s22

Email: [recalls@health.gov.au](mailto:recalls@health.gov.au)

Therapeutic Goods Administration

Department of Health

PO Box 100

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

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From: Nuich, Ivan <[REDACTED]@Edgewell.com>

Sent: Thursday, 16 December 2021 4:53 PM

To: [REDACTED] <[REDACTED]@health.gov.au>; Recalls <Recalls@health.gov.au>; [REDACTED] <[REDACTED]@health.gov.au>

Cc: [REDACTED] <[REDACTED]@health.gov.au>; [REDACTED] <[REDACTED]@health.gov.au>; Clara, Beinda [REDACTED] <[REDACTED]@Edgewell.com>; [REDACTED]

Lake, Mary [REDACTED] <[REDACTED]@edgewell.com>; Tannhauser, Annie <[REDACTED]@edgewell.com>; Pamelard, Christophe [REDACTED] <[REDACTED]@Edgewell.com>; Becvar, Paola C. [REDACTED]

<[REDACTED]@edgewell.com>; Rizzi, Joseph <[REDACTED]@Edgewell.com>

Subject: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636

**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 [REDACTED]

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 recall and technical teams both yesterday and today.

Edgewell is prepared to undertake a voluntarily recall of 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 [REDACTED] 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.

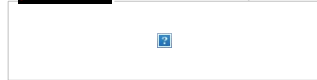
Kind regards

Ivan Nuich

Ivan Nuich

RVP OCEANIA

[REDACTED] | 11 Talavera Road, Macquarie Park, NSW 2113, Australia



	Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+	Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+	Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+	Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+
ARTG	206508	311003	311003	342636
BATCH/EXP	21036AF	20295AF	20328BF	20358AF
EXPIRY	01/2024	09/2023	10/2023	11/2023
Confirmation of quarantine of stock from the affected batch that has not been distributed	No SOH	No SOH	No SOH	No SOH
The number of units of this batch in stock	No SOH	No SOH	No SOH	No SOH
The number of units of this batch distributed to date	65,000	27,000	14,000	49,000
A list of other batches of the same product that are currently held in stock and are within the expiry date	No SOH	No SOH	No SOH	No SOH
Confirm if any units have been exported	None	2 500	2 500	15 000
Evidence that other batches of the same product on the market are of acceptable quality if available.	N/A	N/A	N/A	N/A

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50+

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175g NET

AUST L 206508



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SPF 50+

25% fewer ingredients\*  
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BROAD SPECTRUM - UVA/UVB PROTECTION  
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175 g NET

AUST L 311003



DRY  
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175g NET

AUST L 283966