

s22

From: Recalls
Sent: Wednesday, 20 July 2022 2:36 PM
To: Clare, Belinda; Nuich, Ivan; Pamelard, Christophe; s22
Subject: Final Letter - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]
Attachments: Final Letter - RC-2021-RN-02404-1.pdf

Dear Belinda,

Thank you for providing the certificate of destruction.

Please find attached the close out letter for the above recall action. This is now considered to be complete in accordance with the requirements of the Uniform Recall Procedure for Therapeutic Goods and has been finalised on the recalls database.

Please accept my sincere apologies for the delayed response.

Kind Regards,

s22
Recalls Section
Manufacturing Quality Branch

Medical Devices and Product Quality Division | Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care

T: s22 E: recalls@health.gov.au

Location: 27 Scherger Drive, Fairbairn Business Park, Canberra Airport ACT 2609

PO Box 100, Woden ACT 2606, Australia
www.tga.gov.au

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From: Clare, Belinda
Sent: Tuesday, 31 May 2022 9:56 PM
To: Recalls ; Nuich, Ivan ; Pamelard, Christophe ; s22
Subject: RE: TGA Request for list of non-responding customers - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi s22,

Thank you for your patience with this.

Recovery of recalled stock has now been finalised. Attached is the certificate of destruction.

Kind regards,
Belinda

Belinda Clare
SENIOR MARKETING MANAGER

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



From: Recalls <Recalls@health.gov.au>
Sent: Tuesday, 19 April 2022 12:25 PM
To: Clare, Belinda s22 [redacted] @Edgewell.com>; Nuich, Ivan s22 [redacted] @Edgewell.com>; Pamelard, Christophe s22 [redacted] @Edgewell.com>; s22 [redacted]
Subject: RE: TGA Request for list of non-responding customers - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi Belinda,

Thanks for the response and update.

I will await the COD and then formally close out the action.

Kind regards,
s22 [redacted]

s22 [redacted]
Recalls Officer
Recalls Section
Manufacturing Quality Branch

Phone: s22 [redacted]
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: Friday, 8 April 2022 1:04 PM
To: Recalls <Recalls@health.gov.au>; Nuich, Ivan s22@Edgewell.com; Pamelard, Christophe s22@Edgewell.com; s22@Edgewell.com
Subject: RE: TGA Request for list of non-responding customers - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Dear s22,

Apologies for the delay in my reply.

All affected stock has been isolated and destroyed by customers with the exception of s22 which have isolated all stock and a final pick up is being finalised. Once returned all stock will be destroyed. Destruction certificates will be provided mid-April.

There are two customers who have verbally acknowledged our recall communication but have not returned the customer acknowledgement forms. These customers are minor customers and sales would represent less than 1% of total.

- 1) s22 – Verbal confirmation of no stock on hand.
- 2) s22 - Verbal confirmation of no stock on hand.

Kind regards,
Belinda

Belinda Clare
SENIOR MARKETING MANAGER

O: s22 | 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: Thursday, 31 March 2022 2:16 PM
To: Clare, Belinda s22@Edgewell.com; Nuich, Ivan s22@Edgewell.com; Pamelard, Christophe s22@Edgewell.com; s22@Edgewell.com
Subject: TGA Request for list of non-responding customers - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Dear Belinda,

Thank you for the close out report.

I have noted that the certificates of destruction are still pending and will be sent to us when available. We will keep this action open in our system until these are received.

Are you able to provide a list of the non-responding customers?

Kind regards,

s22

s22

Recalls Officer

Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division

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, 21 March 2022 5:44 PM

To: Recalls <Recalls@health.gov.au>; Nuich, Ivan s22 @Edgewell.com>; Pamelard, Christophe

s22 @Edgewell.com>; s22

Subject: RE: Sponsor Agreement Letter - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi s22,

Please find attached the final report for the Banana Boat Aerosol Sunscreens Recall.

Kind regards,

Belinda

Belinda Clare

SENIOR MARKETING MANAGER

O: s22 | 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: Tuesday, 8 February 2022 12:50 PM
To: Clare, Belinda <s22@Edgewell.com>; Nuich, Ivan <s22@Edgewell.com>; Pamelard, Christophe <s22@Edgewell.com>; <s22@Edgewell.com>
Subject: RE: Sponsor Agreement Letter - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Dear Belinda,

Thank you for providing the 6 week report for the above recall.

Please note that the close out report is due by the 21/03/2022.

Kind Regards,

<s22@Edgewell.com>
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
www.tga.gov.au

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Our responses contain general information given to you without prejudice; it is not binding on the TGA. The information provided does not constitute legal advice and you should get your own independent legal advice to ensure all legislative requirements are met.

From: Clare, Belinda <s22@Edgewell.com>
Sent: Tuesday, 1 February 2022 8:32 PM
To: Recalls <Recalls@health.gov.au>; Nuich, Ivan <s22@Edgewell.com>; Pamelard, Christophe <s22@Edgewell.com>; <s22@Edgewell.com>

Cc: s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>
Subject: RE: Sponsor Agreement Letter - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi s22 [redacted],

Please find attached the 6 week report for the Banana Boat Aerosol Sunscreens Recall.

Kind regards,
Belinda

Belinda Clare
SENIOR MARKETING MANAGER

O: s22 [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: Clare, Belinda
Sent: Tuesday, 4 January 2022 4:46 PM
To: Recalls <Recalls@health.gov.au>; Nuich, Ivan s22 [redacted]@Edgewell.com>; Pamelard, Christophe s22 [redacted]@Edgewell.com>; s22 [redacted]
Cc: s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>
Subject: RE: Sponsor Agreement Letter - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

Hi s22 [redacted],

Please find attached the 2 week report for the Banana Boat Aerosol Sunscreens Recall.

Kind regards,
Belinda

Belinda Clare
SENIOR MARKETING MANAGER

O: s22 [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: Tuesday, 21 December 2021 4:16 PM
To: Clare, Belinda s22 [redacted]@Edgewell.com>; Nuich, Ivan s22 [redacted]@Edgewell.com>; Pamelard, Christophe

s22 [REDACTED]@Edgewell.com>; s22 [REDACTED]
Cc: s22 [REDACTED]@health.gov.au>; s22 [REDACTED]@health.gov.au>
Subject: Sponsor Agreement Letter - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hello Belinda,

Thank you for the documents and phone-calls.

Please find attached a copy of the TGA's assessment for the proposed recall.

Please see below the customised recall agreement actions (as is within the attached document):

- The strategy for this recall action is acceptable;
- The text of the Customer Letter and Acknowledgement Form are acceptable following implementation of the tracked changes in the attached document(s). These letters will be sent by the sponsor to all impacted customers on Wednesday 22/12/2021.
- The consumer communication strategy is still under negotiation, specifically regarding the timing of the media advertisements;
- The "Recall Action Commencement Date" display on the System for Australian Recall Actions (SARA) database will state 20/12/2021, although the date of this agreement letter states 21/12/2021. This is due to the automated system requirements for uploading recall actions;
- The Banana Boat website [https://www.bananaboat.com.au/ \[bananaboat.com.au\]](https://www.bananaboat.com.au/) will be updated to display a consumer recall notice page, in alignment with the distribution of the sponsor Customer Letter on Wednesday 22/12/2021; and
- The TGA state and territory notification as well as the TGA Web-Statement upload will occur at approximately 2pm on Wednesday 22/12/2021 to allow for distribution and receipt of the sponsor Customer Letter.

In regards to the banana boat website update, it is preferable to have this webpage updated around the time of your letter distribution in the event that consumers are made aware of the action immediately.

Please forward a signed copy of the final customer letter(s) to recalls@health.gov.au by 2:00pm, Wednesday 22/12/2021.

Please note – you may make minor grammatical or aesthetic changes to the letter prior to sending.

FYI: the Prime Minister has uploaded a Media Release to his website in relation to a National Awareness campaign for Skin Cancer. There is no mention of any sunscreen products/brands in particular.

[https://www.pm.gov.au/media/be-uv-aware-and-help-turn-tide-skin-cancer \[pm.gov.au\]](https://www.pm.gov.au/media/be-uv-aware-and-help-turn-tide-skin-cancer)

Please confirm receipt of this email.

Kind Regards,

s22 [REDACTED]
Recall Coordinator
Recalls Section
Manufacturing Quality Branch

Phone: s22 [REDACTED]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health

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From: Clare, Belinda s22@Edgewell.com>
Sent: Tuesday, 21 December 2021 1:32 PM
To: Recalls <Recalls@health.gov.au>; Nuich, Ivan s22@Edgewell.com>; Pamelard, Christophe s22@Edgewell.com>; s22@Edgewell.com>
Subject: RE: Updated customer letter and consumer actions - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi [s22](mailto:s22@Edgewell.com),
Please find attached edits to the customer letter. Please note in the benzene section we have removed the sentence "but is suspected to be a contaminant from raw materials used in the products manufacture". This statement is not supported by data and is a suspicion only.
In answer to your questions below

- Is any of the stock within the control of distributors or is the stock only currently under the control of supermarkets, pharmacies etc (retailers)? – [Stock will be at both distributor and retail level.](#)
- What action are consumers being requested to make?
 - Supermarkets may have their own internal policies for refunding/returning goods – however smaller chain pharmacies etc may not have such a clear policy for returns. [Smaller chain pharmacies are being asked to return goods through the normal supply chain process.](#)
 - Will consumers be asked to return goods to the place of purchase or to visit the [bananaboat website](http://www.bananaboat.com.au) to receive a refund? [Consumers are to visit the Banana Boat website \(www.bananaboat.com.au\)](#) or contact our Consumer Service team on Free Call **1800 761 186** for a refund. [Consumers are to then dispose of the product.](#)

Also attached is a copy of the Customer list.

Ivan and I would like to catch up with yourself to ensure we are delivering all the assets required for tomorrow. Would you be free at 2pm for a call?

Kind regards,

Belinda

Belinda Clare

SENIOR MARKETING MANAGER

O: s22@Edgewell.com | 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

Sent: Tuesday, 21 December 2021 11:02 AM

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

Subject: Updated customer letter and consumer actions - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hello Belinda,

Thank you for the information yesterday afternoon.

I have attached and made some changes to the customer letter for your perusal.

I have some questions below that may again shape the wording used in the customer letter:

- Is any of the stock within the control of distributors or is the stock only currently under the control of supermarkets, pharmacies etc (retailers)?
- What action are consumers being requested to make?
 - Supermarkets may have their own internal policies for refunding/returning goods – however smaller chain pharmacies etc may not have such a clear policy for returns.
 - Will consumers be asked to return goods to the place of purchase or to visit the bananaboat website to receive a refund?

After you review and return the attached customer letter w/ above questions, I will need a copy of the customer list. Once provided, I will send you a final agreement letter (pending no additional major issues) by COB TODAY, the content of which will state that the agreed customer letter can be sent out **TOMORROW 22/12/2021** to all customers. The TGA Web-statement is currently being reviewed by TGA Executives and once finalised, I will send you a copy of the final document that will be uploaded around midday **TOMORROW 22/12/2021** (pending no major issues) – this should allow time for your customer letter to be electronically distributed to the impacted customers.

Let me know if you have any concerns and I will await your response.

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 4:23 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,

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: s22 | 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 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: s22 | 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
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
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: 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
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: Clare, Belinda <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
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
- [\[bananaboat.com.au\]](http://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: s22 | 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 11:27 AM

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

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 \[bananaboat.com.au\]](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

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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>

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 |
|---------------|-------|--------|
|---------------|-------|--------|

- 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 \[tga.gov.au\]](#)) – 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

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au tga.gov.au

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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; s22@health.gov.au; s22@Edgewell.com>; s22@Edgewell.com>; Lake, Mary

s22 [redacted]@Edgewell.com>; Tannhauser, Annie s22 [redacted]@Edgewell.com>; Pamelard, Christophe s22 [redacted]@Edgewell.com>; Becvar, Paola C. s22 [redacted]@Edgewell.com>; Rizzi, Joseph s22 [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 s22 [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 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 [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

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



| | Banana Boat High Protection Sunscreen |
|---|---------------------------------------|
| ARTG | 206508 |
| BATCH/EXP | 210003 |
| EXPIRY | 01/2022 |
| 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 | 63 |
| 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 | No |
| Evidence that other batches of the same product on the market are of acceptable quality, if available. | |

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Australian Government
Department of Health
Therapeutic Goods Administration

In reply please quote: RC-2021-RN-02404-1

Managing Director
Edgewell Personal Care Australia Pty Ltd
RC-2021-RN-02404-1

Attention: Belinda Clare
31/03/2022

Dear Belinda,

Subject: Final Letter to Sponsor

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

- * 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 Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+.

Product Codes: X64126A0, X006412601, X301146300, X301146301, X301146302, X300961300 and X300961302.

All batches with expiry dates 31/01/2024 or earlier.

AUST L: 206508, 311003 and 342636.

Thank you for your final report regarding the recall action involving the above therapeutic good(s).

Copies of the close out reports have now been reviewed by the TGA's Recalls Section regarding the effectiveness of the recall action itself. This information will also be used as part of ongoing monitoring and compliance activities undertaken by the TGA.

This recall action is now considered to be completed in accordance with the requirements of the current Uniform Recall Procedure for Therapeutic Goods ([URPTG](#)) and has been closed on the recalls database.

As part of finalising this action, the TGA Recalls Section is requesting that Sponsors verify the staff contact details given in the TBS Portal are up to date as per the guidance given in this link: <https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators>

Please do not hesitate to contact me on the numbers below if you have any further concerns on this issue.

Yours sincerely,

S22
Recalls Section

Manufacturing Quality Branch

Phone: s22 [REDACTED]

Email: Recalls@health.gov.au

Therapeutic Goods Administration

PO Box 100

Woden ACT 2606

www.tga.gov.au



(Signed electronically)