

s22

**From:** Recalls <Recalls@health.gov.au>  
**Sent:** Tuesday, 21 December 2021 4:16 PM  
**To:** 'Clare, Belinda'; Nuich, Ivan; Pamelard, Christophe; s22  
**Cc:** s22; s22  
**Subject:** Sponsor Agreement Letter - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]  
**Attachments:** Agreement Letter - RC-2021-RN-02404-1.pdf; Edgewell-customer-acknowledgement-form - Email 21-12-2021 110208 (3) Clare, Belinda.DOCX; Edgewell-customers-letter - Email 20-12-2021 153626 (1) Clare Belinda 21.12.21.DOCX

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/> 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](mailto: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>

Please confirm receipt of this email.

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  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)



**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

---

**From:** Clare, Belinda s22 @Edgewell.com>  
**Sent:** Tuesday, 21 December 2021 1:32 PM  
**To:** Recalls <[Recalls@health.gov.au](mailto: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]

**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 ,  
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 to receive a refund? Consumers are to visit the Banana Boat website ([www.bananaboat.com.au](http://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 | Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia  
E: s22 @Edgewell.com W: [Edgewell.com](http://Edgewell.com)



From: Recalls

Sent: Tuesday, 21 December 2021 11:02 AM

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

Subject: Updated customer letter and consumer actions - Sunscreen Recall Action - RC-2021-RN-02404-1 [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 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](mailto:recalls@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)]

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

From: Clare, Belinda s22 @Edgewell.com>

Sent: Monday, 20 December 2021 4:23 PM

To: Recalls <[Recalls@health.gov.au](mailto: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]

**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,

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](http://Edgewell.com) [[nam04.safelinks.protection.outlook.com](mailto:nam04.safelinks.protection.outlook.com)]



From: Recalls <[Recalls@health.gov.au](mailto: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]

**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.**

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](mailto:recalls@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)]



**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

From: Clare, Belinda s22 @Edgewell.com>  
Sent: Monday, 20 December 2021 3:36 PM  
To: Recalls <[Recalls@health.gov.au](mailto: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]

**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 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](http://Edgewell.com) [[nam04.safelinks.protection.outlook.com](mailto:nam04.safelinks.protection.outlook.com)]

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]

**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 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](mailto:recalls@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)]



**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

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



**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

**From:** Clare, Belinda <s22@Edgewell.com>  
**Sent:** Monday, 20 December 2021 11:47 AM  
**To:** Recalls <[Recalls@health.gov.au](mailto:Recalls@health.gov.au)>; Nuich, Ivan <s22@Edgewell.com>; Pamelard, Christophe



s22 @Edgewell.com>; s22 s22  
**Subject:** TRIM: RE: Web-Statement Information - Sunscreen Recall Action - RC-2021-RN-02404-1 [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,  
 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)  
[\[bananaboat.com.au\]](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](http://Edgewell.com) [[nam04.safelinks.protection.outlook.com](mailto:nam04.safelinks.protection.outlook.com)]



**From:** Recalls <[Recalls@health.gov.au](mailto: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](mailto:Recalls@health.gov.au)>  
**Subject:** Web-Statement Information - Sunscreen Recall Action - RC-2021-RN-02404-1 [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.**

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 [redacted]@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)]

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

**From:** Recalls

**Sent:** Friday, 17 December 2021 2:39 PM

**To:** 'Nuich, Ivan' s22 [redacted]@Edgewell.com>; Pamelard, Christophe <s22 [redacted]@Edgewell.com>; Clare, Belinda <s22 [redacted]@Edgewell.com>; s22 [redacted]>

**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
---------------	-------	--------

- 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 [redacted] 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 [redacted]  
Recall Coordinator  
Recalls Section  
Manufacturing Quality Branch

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

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.



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

**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,

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



	Banana Boat High Protection Sunscreen
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	6
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.	

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this



communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

To Belinda Clare

Edgewell Personal Care Australia Pty Ltd

By Email: **s22** [@Edgewell.com](mailto:s22@Edgewell.com)

21/12/2021

Our Ref: RC-2021-RN-02404-1

**Sponsor Agreement Letter - 'Banana Boat' Sunscreen Sprays - Benzene Detection**

'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 notification of the above mentioned subject.

Pursuant to the current URPTG, this recall action has been classified as per the below summary:

<b>Hazard Classification:</b>	<b>Class II</b>
<b>Type of Recall:</b>	<b>Recall</b>
<b>Recall Level:</b>	<b>Consumer</b>
<b>Reason for Recall:</b>	<b>Therapeutic Goods Administration (TGA) laboratory testing has detected benzene in 4 batches of 'Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+', 'Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+' and 'Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+'.</b>  <b>Benzene is a Class 1 residual solvent, which should not be employed in the manufacture of drug substances, excipients, and drug products because of its unacceptable toxicity (it is a recognised carcinogen). Benzene is not an ingredient listed for inclusion within these products.</b>  <b>Out of an abundance of caution, Edgewell Personal Care are</b>



	<p>recalling all batches of these aerosol sunscreen products with expiry dates prior to 31/01/2024 from retail stores. Edgewell Personal Care are also asking consumers to stop using and appropriately discard the products.</p>
<b>Product Distribution:</b>	<b>Supermarkets, pharmacies and other retail stores nationally.</b>
<b>Customer Actions:</b>	<p><b>Wholesalers:</b></p> <ul style="list-style-type: none"> <li>* Inspect your stock immediately and quarantine affected stock to prevent further distribution.</li> <li>* Return affected stock on hand to the address provided with the completed Acknowledgement Form.</li> <li>* If the affected stock has been on-sold to other retail stores, forward the Recall Letter and the Recall Acknowledgement Form to that customer.</li> </ul> <p><b>Retailers:</b></p> <ul style="list-style-type: none"> <li>* Inspect your stock immediately and quarantine affected stock to prevent further distribution.</li> <li>* Retailers are to return all stock to Edgewell Personal Care (through normal supply chain channels) for refund.</li> <li>* For consumer requests - please direct all consumer requests for a refund to the Banana Boat website &lt;<a href="https://www.bananaboat.com.au/">https://www.bananaboat.com.au/</a>&gt;.</li> </ul> <p><b>Consumers:</b></p> <ul style="list-style-type: none"> <li>* Consumers should visit the Banana Boat website &lt;<a href="https://www.bananaboat.com.au/">https://www.bananaboat.com.au/</a>&gt; for information regarding refunds and disposal of the products.</li> </ul>

**Proposed recall action correspondence:**

- 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/> 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.

The above table information will be notified to the various state and territory [recall coordinators for therapeutic goods](#). Additionally, this information will be published in the public domain via the TGAs searchable database, [SARA](#). If you would prefer the recall summary information, which will be publicly

available, to include different contact details to that included in your customer letter, please advise us within the next 24 hours.

Both the recall notification and SARA publication will occur **on Wednesday 22/12/2021**.

Please note:

**1. Addressing of Recall Letters** - Recall correspondence is to be addressed in accordance with pages 49-50 of the [2019 URPTG](#). A sample is given of page 56. In particular, where hospitals are involved, letters should be addressed to the "Chief Pharmacist" for medicines and to the "Chief Executive Officer" for device recalls. More targeted letters are acceptable on a case-by-case basis.

**2. Dispatch of Recall Letters** – Recall Action letters are required to be dispatched to affected customers within 2 clear working days of receiving this agreement letter. Recall envelopes as described on page 54 of the [URPTG](#) must be used where mail distribution is the chosen method of communication. It is also acceptable to dispatch this notification electronically (facsimile or email) subject to the ability to confirm receipt. If the Recall Action letter is dispatched via email, the subject line must reflect the appropriate title of the letter submitted, e.g. URGENT MEDICINE RECALL/URGENT PRODUCT DEFECT CORRECTION, followed by the name of the affected product.

**Please advise the TGA if you are not able to initiate this Recall Action within 2 working days.**

**3. Recall Actions for Consumer Goods that are also Therapeutic Goods** – When a therapeutic good is also a consumer good, regardless of the level of action, the person carrying out the recall is required under the *Competition and Consumer Act 2010* (Schedule 2, Section 128 'Notification requirements for a voluntary recall of consumer goods') to provide the Minister for Consumer Safety, written notification within 2 days after commencing the Recall Action. This can be done via the instructions outlined in Attachment 1 which also contains the [URPTG](#) definition of a Consumer Therapeutic Good.

**4. Progress Reporting Requirements** - In accordance with the responsibilities of sponsors (Step 10) in the [URPTG](#), there is a requirement to submit a total of **three reports on the progress of the Recall Action as per the dates given in the table below. Typically these are at two weeks, six weeks and a 12 week close out report after the date of this correspondence.** An alternate timeframe or additional reports may be agreed on a case-by-case basis. Templates are given in Attachment 2 and this represents the minimum information expected, alternatively a suitable email will suffice. In the event all actions are completed prior to the specified dates given below, the report may be submitted earlier.

Report type:	2 week	6 week	Close out
Latest Due Date:	4 <sup>th</sup> January 2022	1 <sup>st</sup> February 2022	21 <sup>st</sup> March 2022

**5. TBS Update** – As part of conducting this recall action, Sponsors are requested to verify that the relevant 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>

Should you require any additional advice or further assistance with this recall, do not hesitate to contact me directly.

Yours sincerely,

s22

Recalls Section  
Manufacturing Quality Branch

Phone: s22

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



(Signed electronically)

## **Attachment 1:**

---

### **NOTIFICATION OF A CONSUMER GOOD RECALL ACTION TO THE ACCC**

---

Pursuant to subsection (7) of Section 128 of the *Competition and Consumer Act 2010*.

---

As per page 76 of the [2019 Uniform Recall Procedure for Therapeutic Goods \(URPTG\)](#), this recall action is to be reported to the ACCC, if the product involved is a *therapeutic good* and also a consumer good.

The definition of consumer goods from the Australian Consumer Law is “... *goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption...*”

To make a report to the ACCC for a recall of a good that is both a therapeutic good and a consumer good, complete and submit the webform on the ACCC website by clicking on the link below:

<https://www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall>

General information regarding ACCC recalls may be obtained here:

<https://www.productsafety.gov.au/recalls/guidance-for-suppliers/conducting-a-recall>

Should you need further assistance in determining whether or not your *therapeutic good* is also a *consumer good*, please contact the ACCC directly by:

- Emailing the ACCC Recalls inbox [Recalls@accc.gov.au](mailto:Recalls@accc.gov.au)

or

- Phoning the ACCC Recalls Hotline on: (02) 6243 1262

In the event you have doubt as to the status of your product in view of the above, **please do not report this action to the ACCC** unless the above determination has clearly been made and the product fits the definition of a *consumer good*.





**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Attachment 2: Reporting Requirements**

Reports should be submitted electronically to the Recalls Section via [recalls@health.gov.au](mailto:recalls@health.gov.au)

Please include the relevant TGA Recall reference number in the email subject line – e.g. RC-XXXX-RN-XXXXX-X

**2 WEEK REPORT REQUIREMENTS:**

<b>1. Has the recall/corrective action been initiated?</b> Confirm that the agreed action has begun. e.g. the approved letter has been dispatched to all the customers previously provided to the TGA.	<input type="checkbox"/> YES	<input type="checkbox"/> NO. Please explain:
<b>2. Has a signed copy of the customer letter been provided to TGA Recalls?</b>	<input type="checkbox"/> YES	<input type="checkbox"/> NO. Please ensure a signed copy of the letter is provided.
<b>3. Is the recall/corrective action progressing without major impediments?</b> e.g. The recall/corrective action is progressing as per the agreed timelines	<input type="checkbox"/> YES	<input type="checkbox"/> NO. Please explain:
<b>4. Have the initial investigation findings changed the scope of the recall/correction</b> e.g. Additional units or products have not been identified with the same defect	<input type="checkbox"/> NO	<input type="checkbox"/> YES. Please advise:
<b>5. For any product exported from Australia, have the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia.</b> <u>Please list countries product has been exported to.</u>	<input type="checkbox"/> YES <input type="checkbox"/> No exports	<input type="checkbox"/> NO. Please explain:

**6 WEEK REPORTING REQUIREMENTS:**

<p><b>1. Have ALL the customers that you contacted responded to your requested recall/corrective action?</b></p> <p>Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.</p>	<p><input type="checkbox"/> YES</p>	<p><input type="checkbox"/> NO. Please advise the % of customers that have responded .....%</p> <p>And;</p> <p><u>Detail attempts made to contact non-responding customers:</u></p>
<p><b>2. (a) Recall - Have ALL customers returned or destroyed their affected units; or</b></p> <p><b>(b) Correction - Have ALL customers with units requiring correction been identified?</b></p>	<p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> No goods left to recall or correct.</p>	<p><input type="checkbox"/> NO. Please advise when this is expected to occur:</p>
<p><b>3. Is the recall/corrective action progressing without major impediments?</b></p> <p>e.g. The recall/corrective action is progressing as per the agreed timelines</p>	<p><input type="checkbox"/> YES</p>	<p><input type="checkbox"/> NO. Please detail:</p>



**3 MONTH CLOSE OUT REPORTING REQUIREMENTS (or by the previously agreed time):**

<p><b>1. (a) Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?*; or</b></p> <p><b>1. (b) Correction - Have ALL units been corrected or have ALL customers been supplied with the correction?</b></p> <p><u>*A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.</u></p>	<p><input type="checkbox"/> YES</p>	<p><input type="checkbox"/> NO. Please explain &amp; advise when this is expected to occur:</p> <p>Please provide a list of non-responding customers:</p>
<p><b>2. What was the root cause of the defect that led to the recall/corrective action?</b></p>	<p>Please detail:</p>	
<p><b>3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?</b></p>	<p>Please detail:</p>	
<p><b>4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?</b></p>	<p><input type="checkbox"/> YES</p>	<p><input type="checkbox"/> NO. Please advise the % of customers that have responded .....%</p> <p>And;</p> <p><u>Detail attempts made to contact remaining customers</u></p>

# Customer acknowledgement form

Please complete this form *even if you do not have any affected stock*.

## URGENT MEDICINE RECALL

**TGA Recall Reference Number: RC-2021-RN-02404-1**

**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+**

On behalf of this organisation I acknowledge receipt of the Urgent Recall Notice date 22.12.21 relating to the above products.

### FROM:

<b>Organisation</b>	
<b>Position</b>	
<b>Name</b>	
<b>Email or fax no.</b>	
<b>Telephone no.</b>	
<b>Date</b>	
<b>Signature</b>	

**Affected Stock** [Recall and Product Defect Correction only]

If you have **no affected** stock, tick this box:

If you have affected stock, please complete the stock details table below.

<b>Product</b>	<b>Batch/Lot/Date</b>	<b>Quantity of stock received</b>	<b>Quantity of unused stock subject to recall (currently in quarantine)</b>
<b>Total affected product</b>			
<b>Other Relevant Details:</b>			



**Other organisations**

Has your organisation supplied potentially affected product to any other organisation?

- No
- Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

- Yes (please supply names and contact information of the organisations)


**Return completed forms by fax or email to:**

<b>Name</b>	
<b>Position</b>	
<b>Organisation</b>	
<b>Address</b>	
<b>Email</b>	
<b>Subject of email</b>	[Heading as noted above] of [Product details and description including batch/lot details]
<b>Fax no.</b>	
<b>Telephone no.</b>	



22.12.21

[Name and title of the recipient]

[Address]

Deleted: [Company's letterhead]

### URGENT MEDICINE RECALL

Formatted: Font: 16 pt

TGA Recall Reference Number: RC-2021-RN-02404-1

Formatted: Font: 10 pt

- 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+

Formatted: Not Highlight

Deleted: 01/2024  
05/2022

Formatted: Space After: 0 pt, Line spacing: single

Formatted: Space After: 0 pt, Line spacing: single

Product Name	Product Code	ARTG	Batch	Expiry
Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+	X64126A0/ X006412601	206508	<a href="#">21036AF</a>	<a href="#">01/2024</a>
			<a href="#">19171AF</a>	<a href="#">05/2022</a>
			<a href="#">19171AF</a>	<a href="#">05/2022</a>
			<a href="#">19224BF</a>	<a href="#">07/2022</a>
			<a href="#">20177AF</a>	<a href="#">05/2023</a>
Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+	X301146300/ X301146301/ X301146302	311003	<a href="#">19171AF</a>	<a href="#">09/2023</a>
			<a href="#">19019BF</a>	<a href="#">12/2021</a>
			<a href="#">19233FF</a>	<a href="#">07/2022</a>
			<a href="#">19233FF</a>	<a href="#">07/2022</a>
			<a href="#">20295AF</a>	<a href="#">09/2023</a>
Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+	X300961300/ X300961302/	342636	<a href="#">19171AF</a>	<a href="#">10/2023</a>
			<a href="#">19092AF</a>	<a href="#">03/2022</a>
			<a href="#">19129BF</a>	<a href="#">04/2022</a>
			<a href="#">20358AE</a>	<a href="#">11/2023</a>

Deleted: 21036AF  
19171AF

Deleted: /  
X006412600/

Deleted: 19019BF

Deleted: 19019BF

Deleted: 20295AF  
20328BF

Deleted: 09/2023  
10/2023

Deleted: 12/2021

Deleted: 12/2021

Formatted Table

Formatted: Space After: 0 pt, Line spacing: single

Deleted: /

Deleted: 19092AF

Deleted: 19092AF

Formatted: Space After: 0 pt, Line spacing: single

Deleted: 20358AF

Deleted: 11/2023

Deleted: 03/2022

Deleted: 03/2022

Deleted: the

Formatted: Superscript

Deleted: .

Deleted: /

Deleted: /

Deleted: is

Deleted: but is suspected to be a contaminant from raw materials used in the products' manufacture.

Deleted: but is sometimes used in medicine manufacturing processes.

Deleted: The TGA has limits on these types of solvents and be below a concentration of 2 parts per million (ppm) in medicines. This includes sunscreen products that are listed medicines in Australia.

Deleted: is

Edgewell Personal Care, after consultation with the Therapeutic Goods Administration (TGA), is conducting a consumer level recall of all batches of the above Banana Boat aerosol sunscreens with an expiry date of 31<sup>st</sup> January 2024 or earlier. We are contacting you as the potentially affected product may have been supplied to your organisation.

#### 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. It is not an ingredient in these products. The TGA is working with sponsors to investigate the source of benzene.

Product testing detected benzene at concentrations levels higher than the limit on four (4) batches supplied in Australia. Exposure to benzene in these sunscreen products at the levels detected, would not be expected to cause serious adverse health effects, but to reduce the risk to consumers, Edgewell Personal Care is recalling all batches of the affected product supplied within Australia.



If you have any concerns or questions about this issue please contact the Edgewell Personal Care Consumer Service team on Free Call **1800 761 186**.

This recall does not affect any other batches of Banana Boat or any other Edgewell Personal Care products. These above batches have been distributed to supermarkets, pharmacies and other retail since January 2019.

Deleted: [date].

### Action

Inspect your stock **immediately** and quarantine affected stock on hand to prevent further use.

Deleted: <batch numbers>

Complete the attached acknowledgement form immediately even if you do not have any affected stock and return it to **s22**  @Edgewell.com to reconcile this process.

Deleted: ¶

Deleted: email address;

Return affected stock on hand to the address below with the completed acknowledgement form.

Formatted: Line spacing: single

Deleted: inventory

**s22** 

Deleted: .

Deleted: ¶

Deleted: ¶

Deleted: ¶

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall immediately by providing a copy of this letter.

Deleted: ¶

Deleted: ¶  
Ensure relevant staff members are informed of this recall, including inwards goods staff, credit returns staff, relevant clinicians who may decide to monitor for adverse events, as applicable. ¶

Consumers should be directed to visit the Banana Boat website <<https://www.bananaboat.com.au/>> for information regarding refunds and disposal of the products.

Place this letter in a prominent position for at least one month.

### Replacement stock

No alternative stock is available currently. Alternative stock is expected to be available for order from Edgewell Personal Care February 2022.

For further information please contact your Edgewell Account Manager.

Edgewell Personal Care Pty Ltd sincerely regrets any inconvenience caused to your organisation.

Kind regards,

Ivan Nuich

Regional Vice President





Edgewell Personal Care

