s22

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

Sent: Wednesday, 22 December 2021 5:18 PM

To: 'Clare, Belinda'; Nuich, Ivan; Pamelard, Christophe; \$22

Cc: \$22 ; \$22

Subject: RE: APPROVED - Consumer Press Advertisement - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

Hello Belinda,

The minor change and publishing date is approved.

Thank you for the email.

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

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From: Clare, Belinda \$22 @Edgewell.com>

Sent: Wednesday, 22 December 2021 5:08 PM

To: Recalls < Recalls @health.gov.au>; Nuich, Ivan \$22 @Edgewell.com>; Pamelard, Christophe \$22 @Edgewell.com>; \$22

@health.gov.au>; \$22 @health.gov.au>

Subject: RE: APPROVED - Consumer Press Advertisement - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Ні <mark>\$22</mark>

Thank you for this approval. We would like to move the print media to 29th December to avoid public holidays. Please let me know if you see an issue with this.

In addition to the print media we will post a social post on the Banana Boat Facebook page (Banana Boat Australia - Home | Facebook [facebook.com]) on the same schedule as the print media. I will send you a draft of the social post once available.

Please find attached the final consumer level media advertisement (one minor change - Customer Service to Consumer Service).

Once print media has been booked, I will send a confirmation email to Recalls@health.gov.au for confirmation.

Thank you again for your help.

Kind regards, Belinda

Belinda Clare

SENIOR MARKETING MANAGER

Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia @Edgewell.com W: Edgewell.com











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

Sent: Wednesday, 22 December 2021 4:46 PM

@Edgewell.com>; To: Clare, Belinda \$22 @Edgewell.com>; Pamelard, Christophe 222 @Edgewell.com>; Nuich, Ivan \$22

@health.gov.au>; @health.gov.au>

Subject: APPROVED - Consumer Press Advertisement - Banana Boat Aerosol Sunscreens - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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Hi Belinda,

Thank you for the information.

The below publishing schedule is approved – I have again attached the final approved consumer level media advertisement for reference.

As discussed over the phone - in addition to the Print Media below, a social media post on the Banana Boat Facebook page (Banana Boat Australia - Home | Facebook [facebook.com]) may also help consumers become aware of the issue. Please organise a social media posting to the effect of redirecting consumers to the Banana Boat Australia [bananaboat.com.au] main website to appropriately progress any refund and disposal of the impacted product.

Once the below print media has been booked, please send a confirmation email to Recalls@health.gov.au for confirmation.

Kind Regards,

Recall Coordinator Recalls Section Manufacturing Quality Branch

Phone:

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

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Please see below our proposed media schedule for print. If you are aligned we will proceed.

PRINT						
				Size		
Press						
PUBLISHER AND MARKET	SPECS	ONSALE	PUBLICATION	UNIT SIZE		
News - Sydney	188mm H x 137mm W	27-Dec	The Australian -	M6x3 -		
News - Sydney	188mm H x 129mm W	27-Dec	Daily Telegraph -	1/4 page -		
News - Melbourne	188mm H x 129mm W	27-Dec	Herald Sun -	1/4 page -		
News - Brisbane	188mm H x 129mm W	27-Dec	Courier Mail -	1/4 page -		
News - Adelaide	188mm H x 129mm W	27-Dec	Adelaide Advertiser -	1/4 page -		
News - Tasmania	188mm H x 129mm W	27-Dec	Mercury -	1/4 page -		
News - Darwin	188mm H x 129mm W	27-Dec	Northern Territory News -	1/4 page -		
Australian Community Media - Newcastle	92mm H x 129mm W	27-Dec	Newcastle Herald -	T22 -		
Australian Community Media - Canberra	92mm H x 129mm W	27-Dec	Canberra Times -	T22 -		
Nine Publishing - Sydney	92mm H x 260mm W	27-Dec	Sydney Morning Herald -	1/4 page -		
Nine Publishing - Melbourne	92mm H x 260mm W	27-Dec	The Age -	1/4 page -		
Seven West Media - Perth	124mm H x 88mm W	27-Dec	The West Australian -	M4x2 -		

Kind regards, Belinda

Belinda Clare

SENIOR MARKETING MANAGER

O: \$22 | Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia
E: \$22 | @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 \$22 @Edgewell.com>; Nuich, Ivan 3222 @Edgewell.com>; Pamelard, Christophe 322 @Edgewell.com>;

@health.gov.au>; @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/ [bananaboat.com.au/ [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]

Please confirm receipt of this email.

Kind Regards,

Recall Coordinator Recalls Section Manufacturing Quality Branch

Phone: \$22

Email: recalls@health.gov.au

Therapeutic Goods Administration Department of Health PO Box 100

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

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From: Clare, Belinda \$222 @Edgewell.com>

Sent: Tuesday, 21 December 2021 1:32 PM

To: Recalls @Recalls @Edgewell.com>;

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

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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 [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

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













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From: Recalls Sent: Tuesday, 21 December 2021 11:02 AM

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

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,

Recall Coordinator Recalls Section Manufacturing Quality Branch

Phone: 5222

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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@Edgewell.com> From: Clare, Belinda 222

Sent: Monday, 20 December 2021 4:23 PM

To: Recalls < Recalls@health.gov.au >; Nuich, Ivan @Edgewell.com >; Pamelard, Christophe Subject: RE: [DRAFT] TGA Web-statement - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL] @Edgewell.com>;

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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

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











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

Sent: Monday, 20 December 2021 3:46 PM @Edgewell.com>; Nuich, Ivan \$22 @Edgewell.com>; Pamelard, Christophe \$22 @Edgewell.com>; Subject: RE: [DRAFT] TGA Web-statement - Sunscreen Recall Action - RC-2021-RN-02404-1 [SEC=OFFICIAL]

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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,

Recall Coordinator Recalls Section

Manufacturing Quality Branch

Phone: 522

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 222 @Edgewell.com>

Sent: Monday, 20 December 2021 3:36 PM

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

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

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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

| Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia @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 @Edgewell.com>; Nuich, Ivan \$22 @Edgewell.com>; Pamelard, Christophe <\$22 @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,

Recall Coordinator

Recalls Section

Manufacturing Quality Branch

Phone: 5222

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' 222 @Edgewell.com>; Nuich, Ivan 22 @Edgewell.com>; Pamelard, Christophe 22 @Edgewell.com>;

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

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,

Recall Coordinator

Recalls Section

Manufacturing Quality Branch

Phone: \$22 Email: \$22 @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 @Edgewell.com>

Sent: Monday, 20 December 2021 11:47 AM

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

@Edgewell.com>; Pamelard, Christophe 22 @Edgewell.com>

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

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HIS22

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	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

O: 822 | Building C, Level 5, 11 Talavera Road, Macquarie Park, NSW 2113, Australia @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 222 @Edgewell.com>; Pamelard, Christophe

@Edgewell.com>; Clare, Belinda

@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 [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 [tga.gov.au]

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From: Recalls

Sent: Friday, 17 December 2021 2:39 PM

To: 'Nuich, İvan'

<a href="mailt

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)
 - o 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 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
 - o 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.

Recall Coordinator Recalls Section Manufacturing Quality Branch

Phone: \$22

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 <a href="mai

<u>@health.gov.au</u>>; Recalls < <u>Recalls@health.gov.au</u>>; s22
<u>@health.gov.au</u>>; a

Dhealth.gov.au>; @health.gov.au>: Lake, Mary < \$22 @Edgewell.com>: Tannhauser, Annie @Edgewell.com>: Pamelard, Christophe @Edgewell.com> DEdgewell.com>: Becvar. Paola C @Edgewell.com>: Rizzi, Joseph Subject: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636

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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.

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

I 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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