

From: Recalls
 To: N. ch. I an.; Pamelard, Christo her; Care, Belinda s22
 Cc: Recalls
 Subject: Initial Information - Sunscreen Recall Act on - RC-2021-RN-02404-1 [SEC=OFFICIAL]
 Date: Friday, 17 December 2021, 2:38:47 PM
 Attachments: images01.png
 images02.png
 Consumer Press Advertisement.DOCX
 Sponsor Consumer Level Communication Strategy.docx

Hello Ivan

To help the progress of this recall I have outlined the information that we require to "agree" to the recall as below

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

Customer Name	State	Suburb
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- Consumer level communication strategy (template is provided as attached)
 - The template does not need to be used/fully completed – the information that I require is what s22 mentioned during the teleconference today. A proposed strategy for reaching as many consumers as possible – i.e. facebook posts, web-statements, consumer group notifications etc – the document attached provides some examples.
- Consumer Press Advertisement (template attached)
- TGA Web-statement
 - The TGA is currently drafting this document and will provide a DRAFT version for your comments early next week
 - The Web-statement will require an image of each of the products being recalled (similar to the [Neutrogena web-statement](#)) – 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 02 6289 4613
 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: 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 @Edgewell.com>; 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
 RVP OCEANIA

M s47F | 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

[Sponsor Name] Consumer-Level [Action]

[Product Name]

Consumer Level Communications Strategy

[Date]

SPONSOR KEY INFORMATION:

- The sponsor arranges and pays for consumer recall notices which are required for consumer level recalls unless they have complete and accurate distribution lists identifying the end-users.
- Prepare a communication strategy for your recall action, including draft consumer recall notices, which we will review and agree in consultation with you, or instruct in decisions relating to mandatory recalls.
- You should arrange for publication or broadcast of your notice in all forms of media agreed, within three to four business days after sending the customer letter as agreed with us, or as instructed in decisions relating to mandatory recalls.
- This document provides templated information for sponsors' consideration. Please provide additional information or delete non-applicable information where necessary. If you require help in completing this document, contact the TGA Recalls team on 02 6232 8935.
- Templates for customer letters or consumer media documents can be found at: <https://www.tga.gov.au/form/urptg-templates>

OVERVIEW & KEY MESSAGES

- [Description of Product(s)]
- [Description of Issue]
- [Description of Health Risks]
- [Description of Consumer Actions to be Taken]
- [Contact Information for Consumers]
- [Method of Product Recovery, Disposal or Correction]
- [Any Further Key Information]

[Sponsor Name] Consumer-Level [Action]
[Product Name]

Consumer Level Communications Strategy

[Date]

COMMUNICATIONS OBJECTIVES

The sponsor should tailor notices for specific groups of consumers. For example, it may be appropriate for the notices to be in other language(s) as well as English when the goods were sold to customers from specific non-English speaking backgrounds.

- [Statement of Objectives]
- [Estimated Outcome (Including Timeframe)]

COMMUNICATIONS ASSETS TO BE PRODUCED

Where the agreed communication strategy includes publication of your notice in print media daily newspapers, you should ensure the notice will be published:

- Once, in the daily print media newspapers (of each state and territory where the goods were possibly distributed); and
- Preferably in one of the first ten pages of the newspaper; and
- With a minimum size of double column width and 10 cm depth enclosed in a diagonally hatched border (refer to the example notice).

- [TGA Notification Letter]
- [Consumer Newspaper Advertisement]
- [Customer letter]
- [Sponsor/Manufacturer Website Post]
- [Social Media Posts]
- [Internal Communications]
- [Television or Radio]
- [Professional medical Colleges and Societies]
- [Community Forums and Focus Groups]
- [Peak Consumer Groups (Consumers' Health Forum, Australian Consumers' Association)]

[Sponsor Name] Consumer-Level [Action]

[Product Name]

Consumer Level Communications Strategy

[Date]

- [Patients Enrolled In Sponsor Developed Patient Support Programs]
- [Health Professionals and their Patients Enrolled in Sponsor Initiated Product Familiarisation Programs]
- [Industry Forums and Focus Groups]

KEY TIMINGS

[Date]

- [Action]
- [Action]

[Sponsor Name] Consumer-Level [Action]

[Product Name]

Consumer Level Communications Strategy

[Date]

COMMUNICATIONS STAKEHOLDER TIMEFRAME MATRIX:

STAKEHOLDER	What/Action	Media outlet/channel	Signature	DATE
EXTERNAL				
[Consumers]	[Media Advertisement]	[State and Territory Newspapers]	[Signature]	[Date Actionable]
INTERNAL				
[Internal Staff]	[Internal Quarantine Letter]	[Phone Call]	[Signature]	[Date Actionable]
GOV/INDUSTRY CONTACTS				
[ACCC]	[Letter Of Notification]	[Letter via Email]	[Signature]	[Date Actionable]



Consumer Press Advertising

Where the agreed communication strategy includes publication of your notice in daily print media newspapers, sponsors should ensure the notice will be published:

- Once, in the daily print media newspapers (of each State and Territory where the goods were possibly distributed); and
- Preferably in one of the first ten pages of the newspaper; and
- With a minimum size of double column width and 10cm depth enclosed in a diagonally hatched border as per the example attached on the following page.

VIC	SA	NSW	QLD	WA	TAS	ACT	NT
The Age	The Adelaide Advertiser	The Sydney Morning Herald	The Courier Mail	The West Australian	The Hobart Mercury	The Canberra Times	The Northern Territory News
The Herald Sun		The Daily Telegraph			The Launceston Examiner		

Use of Advertising Agencies or Consultants:

Sponsors may elect to utilise the services of professional advertising consultants, with some suggestions below. The TGA does not have any arrangements with the below companies.

<https://mmw3degrees.com.au/>

<https://hunterand.co/>

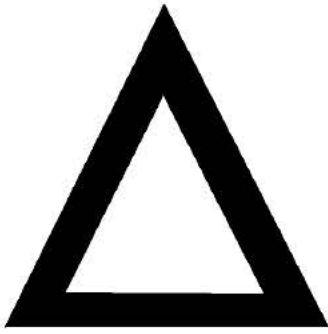
<https://www.mirumagency.com/en/home>

<https://fivebyfiveglobal.com/>

<https://www.omb.com/>

<http://www.72andsunny.com/>

<https://mccann.com.au/>



URGENT MEDICINE RECALL

<PRODUCT NAME> ELIXIR

120mg paracetamol per 5mL

100mL bottle

Batch number xxxxx, Expiry date: Oct 2017

AUST R xxxxx

<Company> Pty Ltd, Following consultation with the Therapeutic Goods Administration, is recalling batch xxxxx of <Product name> (which is an analgesic used to treat aches, pains and feverish conditions) because eucalyptus oil has been found in some bottles of this batch. No other batches of <Product name> Elixir are affected by this recall.

If you have a bottle of <Product name> Elixir from batch xxxxx, do not use it. Return it to the place of purchase for a refund or call our customer service line to arrange the return of affected product and refund.

CUSTOMER SERVICE 1800 xxx xxx

Ingestion of eucalyptus oil (other than in small amounts as in throat lozenges and inhalations etc.) may be harmful. As little as a few millilitres of eucalyptus oil may cause nausea, vomiting, dizziness, muscular weakness, delirium and convulsions. Anyone who is concerned in any way about the use of this product should consult their doctor.

<Company name> Pty Ltd sincerely regrets any inconvenience to their customers.