

s22

From: Recalls
Sent: Tuesday, 14 December 2021 5:10 PM
To: s22@edgewell.com; s22@Edgewell.com
Cc: Recalls; s22; s22; s22; s22
Subject: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636. [SEC=OFFICIAL]
Attachments: Porject 2561 - Notice of test compliance fail - Edgewell Sunscreen products. - Email 09-12-2021 110951 (5) s22.EML; uniform-recall-procedure-therapeutic-goods-urptg.pdf; urptg-example-consumer-level-media-advertisement.docx; Sponsor Consumer Level Communication Strategy.docx

Hello Ivan and Michelle,

Thank you for taking my call s22

Please find attached the correspondence sent to ap.others.australia@edgewell.com on Thu 9/12/2021. You have both mentioned verbally that you were unaware of this email notice and the email address above is not manned.

Please note – this is the main contact within the TGA TBS portal. I had also tried contacting Edgewell on the landline numbers provided on this system prior to calling your mobiles, all of which were either disconnected or routed to a battery manufacturing company. Sponsors are requested to verify that the relevant staff contact details given in the TGA TBS Portal are up to date as per the guidance below:
<https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators>

As noted within the attached “Notice of Compliance Test Failure” document, Benzene was detected in the listed medicines at levels above 2 mg/kg. There is also a number of additional requirements and DUE DATES stated within this document – it is recommended to address these requirements as soon as possible and to contact s22@health.gov.au if you have any concerns regarding the timing of addressing the requirements.

Based on the identified Benzene levels, a Consumer Level Recall for the 4 batches of product mentioned within the “Notice of Compliance Test Failure” Document is recommended. Attached is a copy of the Uniform Recall Procedure for Therapeutic Goods (URPTG). There is further information regarding Consumer Level Recalls inside this guidance document. Consumer level recall actions require a Communication Strategy, to help tailor notices for specific groups of consumers the impacted product may be sold to. Please find attached a template Communication Strategy document if required.

As discussed with Ivan over the phone, the Recalls section is aiming to have a consumer level recall action agreed and underway prior to the 24th December 2021.

Once you have read and understood the information provided in this email, please feel free to contact me on the number in my signature to discuss any next steps. I am happy to be involved with any teleconferences you may require with your National/International regulatory teams – However – As mentioned above, we are hoping to have an established action plan as soon as possible.

Please feel free to contact me to discuss any issues you may have.

Kind Regards,


s22

Recall Coordinator
Recalls Section
Manufacturing Quality Branch

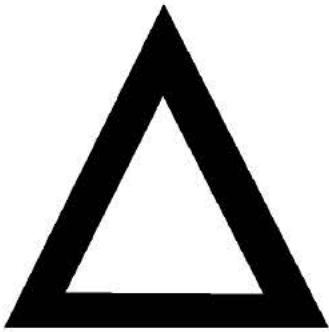
Phone: s22

Email: s22@health.gov.au

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



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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.

[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]