



Australian Government

Department of Health
Therapeutic Goods Administration

The Managing Director
Edgewell Personal Care Australia Pty Ltd
11 Talavera Road Level 5 Building C
Macquarie Park NSW 2113

TGA Reference: D22-5324844

Email: ap.others.australia@edgewell.com

Dear Sir/Madam

**Notice under s 31(2) of the *Therapeutic Goods Act 1989*
Requirement to provide information or documents**

**Re: Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+
 (AUST L 206508)**
**Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion
 Spray SPF 50+ (AUST L 311003)**
**Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50
 (AUST L 342636)**

I refer to the above mentioned products listed on the Australian Register of Therapeutic Goods (ARTG) in the name of Edgewell Personal Care Pty Ltd. The Therapeutic Goods Administration (TGA) may require information to assist in performing its regulatory functions, including assessing the safety and/or quality of listed medicines supplied in Australia, and compliance with legislative requirements applying to those listed medicines.

Background

The Therapeutic Goods Administration Laboratories Branch has recently tested samples of the above medicines listed on the ARTG in response to concerns about contamination of sunscreen products with the class 1 solvent benzene. The samples of the above mentioned products did not comply with relevant standards for residual solvents in medicines. The TGA is seeking information regarding to the root cause of this issue.

Relevant provision

Subsection 31(2) of the *Therapeutic Goods Act 1989* (Act) provides that the Secretary or a delegate may, by notice in writing given to a person:

- in relation to whom the goods are listed

- in relation to whom the goods were, at any time in the last five years, listed
- who is an applicant for the listing of goods

require the person to give the Secretary within such reasonable time specified in the notice, and in the form as is specified in the notice, information or documents relating to one or more of the matters set out in s 31(2) of the Act.

For your information, a copy of the Act (including the matters set out in s 31(2)) can be accessed from the Federal Register of Legislation (at <https://www.legislation.gov.au/Series/C2004A03952>).

Required information and documents

Under s 31(2) of the Act, as a delegate of the Secretary, I require you to provide the information and documents set out in this notice in the form set out in this notice.

You must provide the required information to the TGA by **5:00pm, 13 May 2022**. I am required to give a reasonable time for you to provide the requested information. I consider 7 working days to be a reasonable time period. This excludes public holidays in applicable states and/or territories.

Under s 31(2)(ca), (d), (f) and/or (g) of the Act A copy of the report that includes the following:

- a. your investigation into the root cause for the presence of benzene in batches of the above products;

How to reply to this notice

Your response should be addressed to the undersigned by reply email. Please note that TGA emails have a receipt limit of 20 megabytes per email.

The TGA will only be emailing this letter to your company. It is your responsibility to forward this correspondence to any agents or other parties acting on your behalf.

Please note that it is an offence under s 31(4) of the Act if you fail to comply with this notice without reasonable excuse.

The failure to reply to this notice by the due date may also result in other regulatory action such as proposal to cancel and/or cancellation of your medicine.

If you provide false or misleading material in response to this request you may be subject to criminal penalties under s 31(6) of the Act.

Review rights

Specified decisions under Part 3-2 of the Act that must be made by a delegate of the Secretary are subject to Ministerial review under s 60. Your rights for reconsideration of the decision to issue this notice are set out in **Attachment A**.

Please don't hesitate to contact the undersigned if you have any questions about this notice.

Yours sincerely

Signed and authorised by

s22

Delegate of the Secretary

Chemistry Section

Laboratories Branch

Email s22@health.gov.au

3 May 2022

ATTACHMENT A

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: **s22** @health.gov.au' and copied to 'decision.review@health.gov.au'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600**

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.