Attachment 1

Australian Government

Department of Health
Therapeutic Goods Administration

File Reference: D21-3235278
Sent by email

The Regulatory Affairs Manager
Edgewell Personal Care Australia Pty Ltd
11 Talavera Road Level 5 Building C
Macquarie Park NSW 2113
Email: ap.others.australia@edgewell.com

Dear Sir/Madam,

## NOTICE OF COMPLIANCE TEST FAILURE

**Notice informing** Edgewell Personal Care Australia Pty Ltd **of the testing results 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+' **from the Australian Register of Therapeutic Goods** entry numbers 206508, 311003 and 342636, respectively**.**

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|---|---|
| **ARTG Number:** | 206508 |
| **Product Name:** | Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+ |
| **Batch Number:** | 21036AF |
| **Expiry date:** | 01/2024 |
| **TGA Sample Number:** | 2108002997 |

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|---|---|
| **ARTG Number:** | 311003 |
| **Product Name:** | Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+ |
| **Batch Number:** | 20295AF |
| **Expiry date:** | 09/2023 |
| **TGA Sample Number:** | 2108002964 |

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|---|---|
| **ARTG Number:** | 311003 |
| **Product Name:** | Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+ |
| **Batch Number:** | 20328BF |
| **Expiry date:** | 10/2023 |
| **TGA Sample Number:** | 2108002974 |

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|---|---|
| **ARTG Number:** | 342636 |
| **Product Name:** | Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+ |
| **Batch Number:** | 20358AF |
| **Expiry date:** | 11/2023 |

**TGA Sample Number:** 2108002965

I refer to the samples of the above mentioned medicines tested by the TGA's Laboratories as part of a problem investigation following a report published in May 2021 by the US based laboratory Valisure.

All medicines supplied in Australia must meet agreed specifications or, where appropriate, relevant pharmacopoeial specifications.

The samples were tested for compliance with the requirements for residual solvents as specified in the ICH guideline Q3C (R8) on impurities: guideline for residual solvents, which has been adopted by the BP and USP pharmacopoeia. In particular, the products were tested for the presence of the class 1 solvent benzene.

The enclosed Certificates of Responsible Analyst indicate that the above mentioned products do not comply with specifications outlined in the ICH guideline Q3C (R8) on impurities: guideline for residual solvents.

In particular:

- Benzene was detected in the listed medicines at levels above 2 mg/kg

**Action to be taken by you**

- You are requested to immediately quarantine stock from the affected batch that has not been distributed.
- Your comments on these laboratory test results are invited. Please provide comments on the test results to the undersigned at s22 [redacted] @health.gov.au .

You are requested to provide the following information by close of business **16 December 2021**:

- Confirmation of quarantine of stock from the affected batch that has not been distributed
- The number of units of this batch in stock
- The number of units of this batch distributed to date
- A list of other batches of the same product that are currently held in stock and are within the expiry date
- Confirm if any units have been exported
- Evidence that other batches of the same product on the market are of acceptable quality, if available.

You are also requested to provide by close of business **4 January 2022**:

- Any information you consider relevant to the TGA's consideration of the enclosed test results.

**Entitlement to Review**

Should you wish to provide evidence to dispute the findings of the Analyst under Regulation 30 of the Therapeutic Goods Regulations then this evidence should be submitted within 21 days of the date of this letter. If no evidence has been submitted (or foreshadowed) in this period, it will be assumed that your company does not intend to dispute the findings of the Analyst.
These findings have been referred to the Pharmacovigilance Branch who will be in contact shortly to discuss any further actions required.
Please reply by email **within 48 hours** to indicate your intentions regarding a review.

The written evidence accompanying your request for review must include a certificate from an analyst who has appropriate qualifications and experience setting out:

- A statement that the analyst has analysed a part of the same sample, or a similar sample from the same batch of the goods; and
- the results of that analysis; and
- details of the tests used in the analysis.

If you cannot meet the 21 day time frame, you should write as soon as possible to request an extension of time.

**Further Information**

Your early response in writing to this matter, and confirmation of receipt of this letter, is requested. If you have any queries regarding testing of this product, please do not hesitate to contact me directly on s22 or via email at s22 @health.gov.au .

Please note that these results will be published on the TGA website at http://www.tga.gov.au/ws-labs-index once the regulatory outcome of this matter is concluded.

Yours Sincerely

Signed and authorised by
s22
A/g Principal Chemist
Chemistry Section
Laboratories Branch
Email: s22 @health.gov.au

9 December 2021
Sent by email