

ROOT CAUSE SUMMARY – RC-2021-RN-02404-1

On 9 December 2021, Edgewell Personal Care Australia Pty Ltd (**Edgewell**) was notified by the Therapeutic Goods Administration of Australia, that three Banana Boat branded products had been tested for the presence of benzene. Each lot tested was determined to have levels above 2.0ppm, the upper limit specified by ICH guideline Q3C (R8) on impurities: guideline for residual solvents (**Attachment 1**).

The products tested were the following:

- Banana Boat Simply Protect Kids – Very High Protection Sunscreen Spray – SPF 50+, AUST-L # 206508
- Banana Boat Dry Balance – Very High Protection Clear Sunscreen Spray – SPF 50+, AUST-L # 311003
- Banana Boat Ultra – Very High Protection Clear Sunscreen Spray – SPF 50+, AUST-L # 342636

On 22 December 2021, Edgewell voluntarily recalled the above- mentioned products. The associated 2-week, 6-week and Final Report for TGA Recall Reference Number: RC-2021-RN-02404-1 are included (**Attachment 2**).

In conducting its investigation into root cause, s22 an affiliate of Edgewell located in s22, identified the lots as having been manufactured by its contract manufacturer, s22 previously known as s22. s22 placed a distribution hold on all s22 manufactured products and issued requests for information to s22. s22 advised that its root cause investigation identified A-31 isobutane as the likely cause for the presence of benzene in its finished goods. s22 identified its impacted A-31 isobutane supplier as s22. s22 further inquired into Aeropres's investigation of benzene in its A-31 isobutane. Aeropres informed s22 that one of its feedstock suppliers to its s22 plant likely supplied s22 with A-31 isobutane containing residual benzene. s22 provided a copy of their internal investigation as support for the findings (**Attachment 3**).

Since May 2021, Edgewell has not manufactured any products containing A-31 isobutane at s22 and, following long-term manufacturing plans, has established s22 as its primary sunscreen supplier to the Australian market. s22 controls for the potential presence for benzene in the aerosols it makes through a combination of raw material testing by suppliers and process controls. Edgewell is confident that the implemented actions and controlled changes will prevent potential similar scenarios of contamination in the future.

Edgewell respectfully requests that the TGA treats this correspondence and its attachments that are marked "CONFIDENTIAL" as commercially sensitive and confidential. If any request under the *Freedom of Information Act 1982* (Cth) is received by the TGA regarding this matter, Edgewell requests that the TGA withholds this information, because it is necessary to protect the information, in circumstances where the disclosure of this information is likely to unreasonably prejudice Edgewell's commercial position.

Signature: s22

Date: 20 May 2022

Title: Director, Quality - North America CoMan/CoPack