



04.01.22

Edgewell Personal Care Week 2 Report

TGA Recall Reference Number: RC-2021-RN-02404-1

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 Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+

REQUIREMENT	RESPONSE	COMMENT
1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun.	YES	Approved letter has been dispatched to all the customers previously provided to the TGA.
2. Has a signed copy of the customer letter been provided to TGA Recalls?	YES	Supplied via email 22.12.21
3. Is the recall/corrective action progressing without major impediments?	YES	The recall is progressing as per the agreed timelines
4. Have the initial investigation findings changed the scope of the recall/correction	NO	
5. For any product exported from Australia, have the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia. Please list countries product has been exported to.	YES	New Zealand

Kind regards,

Ivan Nuich

Regional Vice President

Edgewell Personal Care



01.02.22

Edgewell Personal Care Week 6 Report

TGA Recall Reference Number: RC-2021-RN-02404-1

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 Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+

REQUIREMENT	RESPONSE	COMMENT
1. Have ALL the customers that you contacted responded to your requested recall/corrective action?	NO	92% of customers have responded. 2 customers have not responded and have been followed up by email twice (24/12/21 & 11/1/22) 1 customer no longer trading. Other customer has no stock on hand and has removed affected products from website.
2. Recall - Have ALL customers returned or destroyed their affected units;	Yes	All major customers stock has been returned. Tier 2 pharmacy stock has been removed from shelves and is to be picked up by 3PL by end February 2022.
3. Is the recall/corrective action progressing without major impediments?	Yes	

Kind regards,

Ivan Nuich

Regional Vice President

Edgewell Personal Care



21.03.22

Edgewell Personal Care Final Report

TGA Recall Reference Number: RC-2021-RN-02404-1

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 Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+

REQUIREMENT	RESPONSE	COMMENT
1. Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?;	NO	All affected stock has been isolated and destroyed except for s22 and s22 which have isolated all stock and a final pick up is arranged for week commencing 21/3/22. Once returned all stock will be destroyed. Destruction certificates will be provided on completion.
2. What was the root cause of the defect that led to the recall/corrective action?		Edgewell conducted a thorough investigation that included its contract manufacturer s22 the maker of the product impacted by the recall and raw material suppliers. The investigation found the root cause to be s22 use of contaminated A31 isobutane propellant during the manufacture of aerosol spray sunscreen products.
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?		Edgewell has ceased production of product manufactured with its contract manufacturer s22. Product made for the Australian market is now made at facilities where the raw materials are controlled for benzene levels through a combination of raw material testing by suppliers and process controls. This has been verified through testing of some finished product.
4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	NO	2 customers have not responded and have been followed up by email twice (24/12/21 & 11/1/22) 1 customer no longer trading. Other customer has no stock on hand and has removed affected products from website.

Kind regards,

s22

Ivan Nuich

Regional Vice President

Edgewell Personal Care