

s22

From: Recalls
Sent: Thursday, 16 December 2021 5:17 PM
To: Nuich, Ivan; s22; s22
Cc: s22; s22; Clare, Belinda; s22; Lake, Mary; Tannhauser, Annie; Pamelard, Christophe; Becvar, Paola C.; Rizzi, Joseph; Recalls
Subject: Re: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636

Hello Ivan,

Thank you for the phone-call.

I acknowledge receipt of your email - and I will be in discussion with you and your recall team tomorrow.

s22

Recall Coordinator
Recalls Section
Therapeutic Goods Administration

From: Nuich, Ivan
Sent: Thursday, 16 December 2021 4:53 PM
To: s22; Recalls; s22
Cc: s22; s22; Clare, Belinda; s22; Lake, Mary; Tannhauser, Annie; Pamelard, Christophe; Becvar, Paola C.; Rizzi, Joseph
Subject: Recall of 4 batches of 'Banana Boat' Sunscreen Products - ARTGs 206508, 311003 and 342636

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

I refer to your Notice of Compliance Test Failure dated 9 December 2021, which came to Edgewell's attention on 14 December 2021. I also appreciate the subsequent conversations we have had with TGA's recalls and technical teams both yesterday and today.

Edgewell is prepared to undertake a voluntarily recall the 4 products identified in the TGA's Notice. Out of an abundance of caution, and as a responsible supplier of sunscreens in Australia, Edgewell is also prepared to conduct a broader recall in relation to these product lines, including any other batches that have already been supplied to Australian (and NZ) consumers in the last 3 years. As stated in our call with TGA's recalls and technical teams today, Edgewell is in the process of changing its manufacturer for these particular sunscreens and has no further stock on hand. Further information regarding the batches in question are listed below.

Whilst Edgewell is not intending to pursue a technical review under regulation 30 at this point in time, we would nevertheless appreciate sharing of the underlying testing data and results obtained by TGA. Our global team intends to undertake independent analysis of retention samples in parallel with the Australian recall to determine the full extent of this problem. In doing so, it will be helpful to understand and align with TGA's testing methodology. This will also help us ensure that our new range of sunscreens in this category, which will be manufactured in Australia, are fully compliant with the requirements for residual solvents.

As indicated by s22 on our call earlier today, we will proceed on the basis that the recall will be commenced next week, and look forward to working with TGA to align on the execution process.

I look forward to hearing from your recalls team regarding next steps.

Kind regards

Ivan Nuich

Ivan Nuich

RVP - OCEANIA

M s22 | 11 Talavera Road, Macquarie Park, NSW 2113, Australia



	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 Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+	Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+
ARTG	206508	311003	311003	342636
BATCH/EXP	21036AF	20295AF	20328BF	20358AF
EXPIRY	01/2024	09/2023	10/2023	11/2023
Confirmation of quarantine of stock from the affected batch that has not been distributed	No SOH	No SOH	No SOH	No SOH
The number of units of this batch in stock	No SOH	No SOH	No SOH	No SOH
The number of units of this batch distributed to date	65,000	27,000	14,000	49,000
A list of other batches of the same product that are currently held in stock and are within the expiry date	No SOH	No SOH	No SOH	No SOH
Confirm if any units have been exported	None	2,500	2,500	15,000
Evidence that other batches of the same product on the market are of acceptable quality, if available.	N/A	N/A	N/A	N/A