

Date: 28 March 2025

UPDATED - CRITICAL QUARANTINE

Reynard Adhesive Removal Wipes, Reynard Alcohol Prep Pads, Reynard Alcohol/Chlorhexidine Swabsticks

Multiple products and product codes (see page 3)

Batch/Lot/Serial Number(s): All batches

ARTGs: 309541, 309236 and 309237 (all cancelled)

TGA Ref: RC-2025-RN-00344-1

Sponsor Ref: 627-REY0325

Dear Customer,

URGENT UPDATE 28/03 - The continuing investigation of this matter has now determined that the risk of contamination by most of the products listed in the table below is very low, and the critical quarantine can now be **LIFTED** for all product codes **except RHS421 and RHS475**. It is recommended that you remove all other product codes on page 3 from quarantine immediately **and allow their continued use**.

Product codes RHS421 and RHS475 should remain quarantined.

Reynard Health Supplies, following agreement with the Therapeutic Goods Administration (TGA), is conducting a Critical Quarantine of the below products. The potentially affected products have been supplied to your organisation.

<p>WHAT IS THE PROBLEM?</p>	<ul style="list-style-type: none"> The TGA received reports indicating <i>Achromobacter</i> Positive Blood Cultures. It was determined that a likely source of contamination was materials and products associated with the manufacturer, Baoying County Fukang Medical Appliance Co Ltd
<p>WHAT IS THE HAZARD/RISK?</p>	<ul style="list-style-type: none"> Following additional Whole Genome Sequencing testing on recent positive cultures, the TGA has determined that the risk of contamination for the majority of these products is very low, and they may <u>continue to be used</u>. This decision weighs up the risks posed by a supply disruption of these products given the additional testing results which has now reduced the perceived risk. However, the risk posed from product codes RHS421 and RHS475 is still being investigated, and they should remain in quarantine.

Reynard is reassurance.

<p>WHAT SHOULD YOU DO?</p>	<ul style="list-style-type: none"> • REMOVE FROM QUARANTINE all of the products on page 3, with the exception of product codes, RHS421 and RHS475. • Products removed from quarantine may continue to be used. • Complete the attached Customer Response Form immediately even if you do not have any affected stock and return it to enquiries@reynardhealth.com.au so we can reconcile this Critical Quarantine. • Ensure relevant staff members are informed of the UPDATE to this Class I Critical Quarantine. • If you have supplied or transferred any potentially affected product to another facility or organisation, provide that facility with a copy of this letter immediately. • Place this letter in a prominent position for at least one month.
<p>HOW WILL THIS BE RESOLVED?</p>	<ul style="list-style-type: none"> • No alternative stock is available currently. We will provide additional advice when alternative stock is expected to be available. • Following the investigation, you will be contacted to advise whether the quarantine can be lifted, and stock can be used, or if further action (such as a recall) will be required.
<p>NOTE</p>	<ul style="list-style-type: none"> • Please note that this is a <u>separate action</u> to the Consumer Level Recall of 3 different chlorhexidine products (RHS477, RHS478 and RHS479) supplied by Reynard Health Supplies. Those products must not be used and should be discarded as per the instructions in the recall notice RC-2025-RN-00160-1.
<p>CONTACT INFORMATION</p>	<p>For questions regarding this letter, please contact:</p> <p>Zoran Radosavic</p> <ul style="list-style-type: none"> • 1300 667 199 • enquiries@reynardhealth.com.au

Thank you for your assistance in helping us to manage this action. Reynard Health Supplies sincerely regrets any inconvenience caused to your organisation.



Rebecca Sutton
Product Quality Training and Systems Lead

ARTG	Product Code	Product Description
309236	RHS457	Reynard Adhesive Removal Wipes. 6cm x 6cm (100 sachets per box and 25 boxes per carton)
309237	RHS401	Reynard Prep Pads Medium 70% Alcohol & 2% Chlorhexidine. 6cm x 6cm (200 pads per box & 25 per carton)
309237	RHS408	Reynard Swabsticks 70% Alcohol & 2% Chlorhexidine (50 swabs per pack / 10 packs per carton)
309237	RHS408EP	Reynard Swabsticks Easy Peel Sachet 70% Alcohol & 2% Chlorhexidine (50 swabs per pack / 10 packs per carton)
309237	RHS408T	Reynard Swabsticks Triple Pack 70% Alcohol & 2% Chlorhexidine (25 Triple sachets per box & 10 boxes per carton)
309237	RHS408TR	Reynard Swabsticks Tinted 70% Alcohol & 2% Chlorhexidine (50 Swabsticks per pack & 10 packs per carton)
309237	<u>RHS421 (TO REMAIN QUARANTINED)</u>	<u>Reynard Prep Pads 2% Chlorhexidine. 4.5cm x 8.5cm (100 swabs per pack, 10 packs per carton)</u>
309237	RHS422	Reynard Prep Pads Large 70% Alcohol & 2% Chlorhexidine. 20cm x 16cm (100 pads per box, 10 boxes per carton)
309237	RHS422EP	Reynard Prep Pads Large 70% Alcohol & 2% Chlorhexidine (50 pads per box, 20 boxes per carton)
309237	RHS437	Reynard Prep Pads Premium 70% Alcohol 2% Chlorhexidine. 4.5cm x 8.5cm (100 swabs per pack, 10 packs per carton)
309237	RHS461	Reynard Prep Pads Small 70% Alcohol & 2% Chlorhexidine. 6cm x 3cm (200 pads per box & 25 per carton)
309237	RHS470	Reynard Swabsticks 70% Alcohol & 0.5% Chlorhexidine (25 per box, 10 boxes per carton)
309237	RHS470TR	Reynard Swabsticks Tinted 70% Alcohol & 0.5% Chlorhexidine (25 per box, 10 boxes per carton)
309237	RHS471	Reynard Swabsticks Large Tinted 70% Alcohol, 0.50% Chlorhexidine (25 per box and 10 boxes per carton)
309237	RHS472	Reynard Swabsticks Large Tinted 70% Alcohol, 2% Chlorhexidine (25 per box and 10 boxes per carton)
309237	RHS473	Reynard Swabsticks 70% Alcohol & 2% Chlorhexidine (25 per Box and 10 Boxes per carton)
309237	RHS474	Reynard Swabsticks Large 70% Alcohol, 2% Chlorhexidine (25 per box and 10 boxes per carton)
309237	<u>RHS475 (TO REMAIN QUARANTINED)</u>	<u>Reynard Swabsticks 2% Chlorhexidine (25 per Box, 10 boxes per carton)</u>
309541	RHS417	Reynard Prep Pads 70% Alcohol. 6cm x 6cm. STERILE (200 per pack, 25 packs per carton)
309541	RHS451G	Reynard Prep Pads 70% Alcohol. 6cm x 3cm. STERILE (200 per pack, 25 packs per carton)
309541	RHS438	70% Alcohol Prep Pads 4.5cm x 8.5xm (100 swabs per pack, 10 packs per carton)

Product codes RHS421 and RHS475 should remain in quarantine.

The quarantine is **LIFTED** for all other product codes listed above.

CUSTOMER RESPONSE FORM

RETURN TO:			
ATTN:	Reynard Health		
EMAIL:	enquiries@reynardhealth.com.au		
SUBJECT:	Critical Quarantine		
TGA Reference:	RC-2025-RN-00344-1		
ARTG:	309541, 309236 and 309237 (all cancelled)		
PLEASE COMPLETE THIS SECTION			
ORGANISATION:			
CONTACT NAME:			
POSITION:			
EMAIL:			
PHONE:			
SIGNATURE:		DATE:	
<p>I confirm receipt of the attached notification and confirm that this organisation:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Has NO affected devices <p>OR</p> <ul style="list-style-type: none"> <input type="checkbox"/> Has the affected device(s), listed in the table below. <input type="checkbox"/> Will undertake lifting of quarantines of the affected devices <input type="checkbox"/> Has contacted all known customers & provided them with this letter. 			
Product Code	Batch	Quantity	Unit or box
EMAIL THIS FORM TO enquiries@reynardhealth.com.au			