

Date: 26 March 2025

## 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,

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.

<b>WHAT IS THE PROBLEM?</b>	<ul style="list-style-type: none"><li>The TGA has received reports of potential <i>Achromobacter</i> contamination. It has been determined a likely source of contamination is materials and products associated with the manufacturer <b>Baoying County Fukang Medical Appliance Co Ltd.</b></li><li>While the investigation into the potential contamination is ongoing, it has not been determined if the above products are affected. However, out of an abundance of caution, products from this manufacturer are to be quarantined until further notice.</li></ul>
<b>WHAT IS THE HAZARD/RISK?</b>	<ul style="list-style-type: none"><li>The TGA has limited information at present about the causal factors behind the infections and cannot confirm that it is due to these therapeutic goods. While the investigation is ongoing into the potential contamination, it has not been determined if the above products are affected.</li><li>If the products are confirmed to be contaminated with <i>Achromobacter</i> species, this can potentially result in serious infections, which may be life-threatening for patients with compromised immune systems.</li></ul>

## Reynard is reassurance.

<b>WHAT SHOULD YOU DO?</b>	<ul style="list-style-type: none"> <li>• Stop using and inspect your stock immediately. Quarantine any stock of the above products on hand to prevent further use, until further notice.</li> <li>• This problem is still being investigated by us and the TGA, and updates will be provided when available.</li> <li>• Complete the attached Customer Response Form immediately even if you do not have any affected stock and return it to <a href="mailto:enquiries@reynardhealth.com.au">enquiries@reynardhealth.com.au</a> so we can reconcile this Critical Quarantine.</li> <li>• Ensure relevant staff members are informed of this Class I Critical Quarantine.</li> <li>• 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.</li> <li>• Place this letter in a prominent position for at least one month.</li> </ul>
<b>HOW WILL THIS BE RESOLVED?</b>	<ul style="list-style-type: none"> <li>• No alternative stock is available currently. We will provide additional advice when alternative stock is expected to be available.</li> <li>• 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.</li> </ul>
<b>CONTACT INFORMATION</b>	<p>For questions regarding this letter, please contact:</p> <p>Zoran Radosavic</p> <ul style="list-style-type: none"> <li>• 1300 667 199</li> <li>• <a href="mailto:enquiries@reynardhealth.com.au">enquiries@reynardhealth.com.au</a></li> </ul>

Thank you for your assistance in helping us to manage this critical quarantine. 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	RHS421	Reynard Prep Pads 2% Chlorhexidine. 4.5cm x 8.5cm (100 swabs per pack, 10 packs per carton)
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	RHS475	Reynard Swabsticks 2% Chlorhexidine (25 per Box, 10 boxes per carton)
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 8.5cm (100 swabs per pack, 10 packs per carton)

## 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> <p><input type="checkbox"/> Has <b>NO</b> affected devices</p> <p><b>OR</b></p> <p><input type="checkbox"/> Has the affected device(s), listed in the table below.</p> <p><input type="checkbox"/> Will undertake quarantines of the affected devices</p> <p><input type="checkbox"/> Has contacted all known customers &amp; provided them with this letter.</p>			
Product Code	Batch	Quantity	Unit or box
EMAIL THIS FORM TO <a href="mailto:enquiries@reynardhealth.com.au">enquiries@reynardhealth.com.au</a>			