

UPDATED: Disruption to supply of multiple antiseptic products



SAFETY NOTICE 011/25

Issue date:	21 May 2025
Content reviewed by:	Interagency Management Team (IMT) including Health Protection NSW and Infection Prevention and Control
Distributed to:	Chief Executives; Directors of Clinical Governance
KEY MESSAGE:	NSW Health facilities are informed of the current disruption to supply of antiseptic products impacted by the recent Therapeutic Goods Administration (TGA) recalls, quarantine notices, and cancellations from the Australian Register of Therapeutic Goods (ARTG), and the return to business-as-usual ordering processes from 26 May 2025 .
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	<ol style="list-style-type: none"> 1. Distribute this Safety Notice to all relevant clinicians and clinical departments where these antiseptic products are stored and/or used and include this information in relevant handovers and safety huddles. 2. Undertake a local risk assessment and incorporate the below recommendations to manage the disruption to supply of the affected products. 3. Ensure a system is in place to document actions taken in response to this Safety Notice. 4. Report incidents related to antiseptic products to the sponsor, <u>TGA</u> and in <u>ims+</u>.
We recommend you also inform:	<p>Directors, Managers and Staff of:</p> <ul style="list-style-type: none"> • Infectious Diseases and Microbiology • Infection Prevention and Control • Oncology/Haematology • Emergency Departments and Intensive Care Units • Neonatal and Paediatric Intensive Care Units • Operating Theatres • Burns Units • Public Health Units • All pathology providers and collection centres • All outpatient clinics and day centres • Medical Services • Nursing and Midwifery Services • Pharmacy Departments <p>Drug and Therapeutics, and Infection Prevention and Control Committees. Clinical Product Managers and clinicians who may use the identified products.</p>
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	November 2025

N SN: 011/25**What has been updated from SA:003/25?**

This Safety Notice replaces SA:003/25 – *UPDATED: Anticipated disruption to supply of multiple antiseptic products*, which has now been **rescinded**. Key changes in this Safety Notice include:

- Updated information regarding the availability of multiple antiseptic products in the context of recent TGA recalls, quarantine notices and product cancellations from the ARTG.
- Updated information regarding the procurement of chlorhexidine in 70% alcohol products (all strengths and formulations) and chlorhexidine gluconate 0.1% ampoules.
- Link to an updated factsheet providing information for NSW Health clinicians and procurement teams, including recommendations for managing the shortage of antiseptic products.

Situation

As a result of recent TGA recalls (**Table 1** in the Appendix), quarantine notices (**Table 2** in the Appendix), and product cancellations from the ARTG affecting 24 product lines from Reynard Health Supplies, there is an ongoing disruption to the supply of multiple antiseptic products.

Reynard Health Supplies have now re-registered their 24 previously cancelled antiseptic product lines, on the ARTG, after a change in manufacturing site. These products have different ARTG codes to the previously registered products, and have updated product codes from Reynard Health Supplies. Supply of these products are gradually becoming available and will continue to improve throughout June 2025.

Background

Antiseptic products have multiple uses, including skin preparation for aseptic procedures or prior to intravenous cannulation and routine blood collection (venepuncture), skin cleaning for wound and burn management, medical device cleaning (decontamination) and low-level disinfection, and disinfecting patient-use equipment between uses.

Assessment

As a result of Reynard Health Supplies re-registering their products on the ARTG and their gradual return to supply, commencing **26 May 2025** the supply of chlorhexidine in 70% alcohol products (all strengths and formulations) and chlorhexidine gluconate 0.1% ampoules will be released from centralised allocation and will no longer be managed under this model. **Weekly allocations will cease, and business as usual ordering can commence.**

NSW Health facilities should continue to ensure appropriate use of antiseptic products and refer to the CEC factsheet: [*Information for NSW Health clinicians – Clinical recommendations for managing the shortage of antiseptic products*](#) for advice on indications and clinical areas for which specific antiseptic agents should be prioritised, and associated safety considerations.

Specific attention should be given to the supply of chlorhexidine gluconate 0.5% and isopropyl alcohol 70% swab sticks as normal supply is not expected to resume until mid-June 2025. **Use of this product must be prioritised for preterm babies to conserve supply.** In the event of a complete disruption to supply, please refer to the CEC factsheet: [*Information for NSW Health clinicians – Clinical recommendations for managing the shortage of antiseptic products*](#) for alternative products available for use in this patient cohort.

N SN: 011/25

Recommendations

Previously recalled and quarantined products

- Ensure that all stock of the products subject to previous TGA recalls and quarantine notices (see **Table 1** and **Table 2** in the Appendix) have been inspected and quarantined to prevent further use.
 - For products subject to the **recall notice**, facilities are to dispose of all stock of affected products. For further information regarding the process for returning or disposing of stock, refer to the Customer Letter distributed by sponsors.
 - For products subject to **quarantine notices**, facilities are to clearly mark all stock as 'UNDER TGA QUARANTINE – NOT FOR PATIENT USE'. Note: these products are generally low use, and do not contain 70% alcohol.
 - All supply must be quarantined in a central location or location(s) within each facility.
 - The area supply is quarantined must be outside of the clinical area.
 - Liaise with Corporate Services for advice on quarantining large amounts of alcohol containing products (due to fire hazard, multiple quarantine locations may be required).

Managing supply of antiseptic products

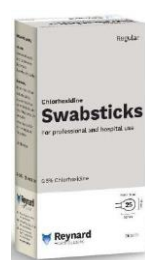


- LHDs/SHNs should continue to review antiseptic stock holdings, ensuring all locations of stock are identified. Identify all excess stock in wards/clinical areas and ensure mechanisms are in place to share stock both within and between facilities in your district/network.
- To assist with the management of the disruption to the supply of various antiseptic products, information has been provided in the following factsheets:
 - CEC factsheet: [Information for NSW Health clinicians – Clinical recommendations for managing the shortage of antiseptic products.](#)
 - Australian Commission on Safety and Quality in Health Care (ACSQHC) factsheet: [Appropriate and safe use of chlorhexidine in healthcare settings.](#)

The content within the above factsheets is subject to change as further information becomes available and the supply situation evolves. Refer to the **electronic versions** of these factsheets using the above hyperlinks for the most up-to-date information as printed versions are uncontrolled.
- LHDs/SHNs are to continue with established governance processes to ensure the judicious use of antiseptic products, and the appropriate distribution of alternative(s) to clinical areas based on individual product specifications, patient populations, and clinical indications to minimise risk to patient safety.

N SN: 011/25



APPENDIX – List of antiseptic products affected by the TGA recall and quarantine notices.

Table 1. Antiseptic products affected by the TGA recall (5 March 2025) – **not to be used.**

ARTG number	Sponsor	Product code	Product name	Product image
309237	Reynard Health Supplies	RHS477	0.5% Chlorhexidine Foam Swabstick	
		RHS478	0.5% Chlorhexidine Lge Foam Swabstick	
		RHS479	0.5% Chlorhexidine Prep Pads 6 cm x 6 cm	

Note: Batch numbers 240810, 221010, 210610, 20200610 and 20231113 are affected by the recall, however all batches of these products should not be used.

Table 2. Antiseptic products affected by the TGA quarantine notice (26 March 2025) that do not contain 70% alcohol – **not to be used.**

ARTG number	Sponsor	Product code	Product name	Product image
309237	Reynard Health Supplies	RHS421	2% Chlorhexidine Prep Pads 4.5 cm x 8.5 cm	
		RHS475	2% Chlorhexidine Regular Foam Swabstick	

Note: All batch numbers are affected.