

Food Recall – Nestlé ALFAMINO infant formula products due to potential toxin



N SAFETY NOTICE 001/26

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| Issue date: | 8 th January 2026 |
| Content reviewed by: | Chief Health Officer, Ministry of Health, Sydney Children's Hospital Network, Health Protection NSW, Health System Support Group, HealthShare NSW, Clinical Excellence Commission, Paediatric specialists |
| Distributed to: | Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit |
| KEY MESSAGE: | <p>An Australia wide recall of 5 batches of Nestlé's ALFAMINO infant formula for babies with milk allergies has been issued due to potential presence of the toxin cereulide. Clinicians should be aware of the product recall and provide advice as required.</p> <p>If a patient presents with symptoms such as vomiting, diarrhoea or unusual lethargy, staff should confirm any use of Nestlé ALFAMINO and check the batch numbers.</p> |
| ACTION REQUIRED BY: | Pharmacy Departments, Paediatric teams, other Clinicians |
| REQUIRED ACTION: | <ol style="list-style-type: none"> 1. Immediately stop use of Nestlé ALFAMINO and check batch numbers for affected product/s. 2. Return all affected stock to pharmacy for quarantine and return to the supplier. 3. Be aware that the product may be in use by individual patients, independent of the hospital. 4. Refer consumers to the child's treating physician. Health Direct on 1800 022 222 can also provide appropriate support via the virtualKIDS service. 5. Escalate concerns that are not able to be managed locally to your Director, Clinical Governance. 6. Ensure any incidents related to this Food Recall are notified in the incident management system, ims+ |
| DEADLINE: | N/A |
| We recommend you also inform: | Directors, Managers and Staff of: Pharmacy, Paediatrics, Neonatology, Dietetics, relevant paediatric subspecialties (allergy and immunology, gastroenterology), Emergency Departments, Family and Child Health |
| Website: | https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html |
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Situation

Food Standards Australia New Zealand (FSANZ) is coordinating an Australia-wide recall of five batches of Nestlé ALFAMINO infant formula for babies with milk allergies due to the potential presence of the toxin cereulide.

Background

Nestlé ALFAMINO infant formula products are a specialist infant / paediatric enteral feeding formula and contain Human Milk Oligosaccharides (HMO's). These products are not available in supermarkets. They are a Pharmaceutical Benefits Scheme (PBS) listed item, available through hospitals, pharmacies and General Practitioners, and require a valid prescription to supply. However, a small number of affected products may have been purchased over the counter at pharmacies or online. Families may also supply their own feeding formulas, increasing the risk that some affected product may be available in NSW Health facilities.

This recall relates to selected batches of Nestlé's ALFAMINO products distributed across multiple regions. The issue was identified during routine quality testing which detected cereulide (produced by the microorganism *Bacillus cereus*), in an ingredient, prompting Nestlé to withdraw impacted batches as a precaution.

Unaffected batches remain suitable for use.

Assessment

Cereulide can cause gastrointestinal illness, and symptoms can appear between 30 minutes to 6 hours after exposure and typically resolve within 24 hours. There have been no reports of associated illness in Australia or internationally.

Although there are no reported incidents of illness or harm, affected batches must not be used.

Facilities may still hold stock in pharmacy, paediatrics, or NICU. Missing or unverified batch codes pose a risk of continued clinical use and potential patient harm.

Recommendations

- Immediately stop use of Nestlé's ALFAMINO products and check batch numbers for affected product – refer to the bottom of the tin for this information. Table 1 outlines the affected batch numbers.
- Quarantine any affected batches and arrange return to the supplier.
- Unaffected batches remain suitable for use.
- Escalate any suspected adverse events to your manager and via the Incident management System ims+.
- Be aware of, and review feeding requirements for patients being admitted who may use this product.

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- An alternative product (if required) is listed below
 - Please note that any recommendations would require review by relevant specialists (e.g., paediatrician, lactation CNC, dietitian).

Further information

Table 1: Recalled batches:

| Product | Use by date | Batch Numbers |
|-------------------------------|-------------|---------------|
| ALFAMINO (0-12months) 400g | 17.04.2027 | 51070017Y2 |
| | 18.04.2027 | 51080017Y1 |
| | 28.05.2027 | 51480017Y3 |
| | 29.05.2027 | 51490017Y1 |
| | 22.07.2027 | 52030017Y1 |

No other ALFAMINO batches or products in Australia or New Zealand are affected by this recall.

Unaffected batches remain suitable for use.

Approved alternative product:

HealthShare has identified a suitable alternative for patients with cow's milk allergies:

- *Nutricia Neocate Gold Amino Acid-Based Hypoallergenic Infant Formula 0+ Months, 400g*

Links

Further information about this recall is available from Food Standards Australia and New Zealand:

Product recall: <https://www.foodstandards.gov.au/food-recalls/recall-alert/nestle-alfamino-infant-formula-0-12-months-400g>

Media release: <https://www.foodstandards.gov.au/media/media-statement-recall-specialist-infant-formula-due-potential-toxin>

Nestlé's website: <https://www.nestle.com/ask-nestle/products-brands/answers/infant-formula-product-advisory>