



21 February 2022

Distributed to:

Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:

Chief Executives
Directors of Clinical Governance

We recommend you also inform:

- Paediatricians
- Neonatologists
- Dietitians
- Pharmacy
- Relevant paediatric subspecialties (allergy, gastroenterology)
- Emergency Departments
- Family and Child Health

Deadline for completion of action

ASAP

Expert Reference Group

Content reviewed by:

Chief Paediatrician
Chief Health Officer
Expert Reference group, with representatives from:

- Paediatrics
- Neonatology
- Pharmacy

Clinical Excellence Commission

Tel: 02 9269 5500
Email: CEC-Recalls@health.nsw.gov.au

**Review date
February 2023**

Food Recall

Elecare, Similac and Alimentum infant formula products

Situation

Abbott Australasia Pty Ltd is conducting a precautionary recall of various powdered infant formula products including EleCare, Similac and Alimentum manufactured in the United States. The products are available nationally through prescription at pharmacies, hospitals and via direct mail order. The recall is due to potential microbial contamination (*Cronobacter* and *Salmonella*).

These are prescribed products for infants with specific allergies and medical conditions. NSW Health is aware this product may be in stock and is also available in the community.

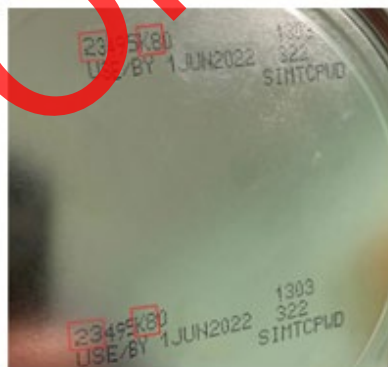
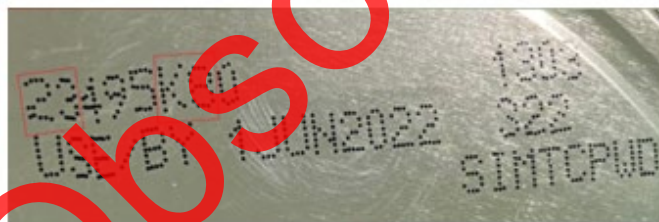
Infants or children may present to health services and emergency departments unwell if they have consumed affected formula

Background

Food products contaminated with *Cronobacter* or *Salmonella* may cause illness if consumed.

The recalled products can be identified by the 7 to 9 digit code and expiration date on the bottom of the package (see images). Products are included in the recall if they have all three items below:

- the first two digits of the code are 22 through 37 and
- the code on the container contains K8, SH, or Z2, and
- the expiration date is 1 APR 2022 (April 2022) or later.



Clinical Recommendations

- Cease feeding the affected product once an alternative has been sourced.
- **Be alert for clinical presentations related to this Food Recall and potential infection.** If an infant presents with signs of bacterial gastroenterological infection, isolate, collect faeces MC&S and blood for pathology. Forward positive results for *Salmonella* and *Cronobacter* to ICPMR Westmead for further identification and sequencing.
- **Treat patient according to clinical presentation and seek paediatric or neonatal advice as required.**



Clinical Alternatives

There are a number of alternative products to *EleCare*, for infants under 12 months, and infants over 12 months. See the Australasian Society of Clinical Immunology and Allergy Guide for Milk Substitutes in Cow's Milk Allergy : <https://www.allergy.org.au/hp/papers/guide-for-milk-substitutes-cows-milk-allergy>

Products potentially subject to recall	Suitable alternative product	Recommended supply*
Elecare® (Abbott) Elecare® LCP (Abbott) (Amino acid based formula for infants <12 months of age)	<ul style="list-style-type: none">• Neocate® Gold, LCP and SYNEO™ (Nutricia®)• Alfamino® (Nestlé®)	PBS listed (Authority prescription required)
Elecare® Vanilla (Abbott) (Amino acid based formula for children >12 months of age)	<ul style="list-style-type: none">• Neocate® Junior (Nutricia®)• Neocate® Junior Vanilla (Nutricia®)• Alfamino® Junior (Nestlé®)	PBS listed (Authority prescription required)

Elecare is PBS Authority listed for eosinophilic oesophagitis; cows' milk protein enteropathy; severe cows' milk protein enteropathy with failure to thrive; combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae; proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein; cows' milk anaphylaxis; cows' milk protein enteropathy; severe intestinal malabsorption including short bowel syndrome

EleCare LCP is PBS Authority listed for cows' milk protein enteropathy; combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae; proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein; cows' milk anaphylaxis; cows' milk protein enteropathy; severe intestinal malabsorption including short bowel syndrome

See www.pbs.gov.au for details of PBS Authority listings and where specialist PBS Authority prescriptions are required for PBS subsidy.

Required actions for the Local Health Districts/Networks

1. **Immediately upon receipt**, distribute this Safety Alert to all relevant wards/units and staff to ensure they are aware of the risk formula contamination and infection.
2. **Immediately** check for and quarantine stock. Contact your Clinical Product Manager.
3. **Within 24-28 hours**, acknowledge receipt of this Safety Alert and confirm if **affected or not** via email to CEC-Recalls@health.nsw.gov.au.
4. Escalate concerns that are not able to be managed locally to your Director Clinical Governance
5. Ensure any incidents relating to this Food Recall are notified in the Incident Information Management System (IMS+).