



Australian Government

Department of Health
Therapeutic Goods Administration

URGENT MEDICINE RECALL*

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2020-RN-01350-1

DATE AGREED: 22/12/2020

PRODUCT: Infants' Friend Oral Liquid Bottle 100mL

All batches within expiry, supplied since December 2018

Batch Numbers: 794916, 794917, 809093, 809094, 820794, 820795, 836054, 836055, 839135, 839136, 839139, 839140, 839137, 839138

ARTG 26678

SPONSOR: Infant's Friend Pty Ltd

PHONE: 1800 981 403 - Infants' Friend Customer Service

REASON: Infants' Friend Pty Ltd is recalling all batches within expiry of their Infants' Friend Oral Liquid 100mL.

The amount of the excipient trichloromethane (chloroform) contained within Infants' Friend Oral Liquid exceeds the Tolerable Daily Intake (TDI) at the recommended dose.

Following an investigation, it was concluded that the safety of Infants' Friend Oral Liquid was not acceptable due to the potential for infants to be exposed to intakes of chloroform that exceed a safe level. This conclusion took into consideration that the product label did not specify a maximum number of doses or duration of use, which may lead to prolonged use at high doses.

At high doses and/or following long-term use, chloroform is known to cause damage to the liver, kidneys and nervous system. However, intermittent, short-term use is not expected to be harmful.

**PROPOSED
CUSTOMER
ACTIONS:**

Wholesalers and Retailers:

All wholesalers and retailers are advised to inspect their stock immediately and quarantine affected stock on hand to prevent further use. If they have unsold or distributed stock, please relay this recall immediately and provide them with a copy of the customer letter and acknowledgement form (supplied to impacted facilities by the sponsor).

Retailers should utilise the return product services of their pharmaceutical wholesaler or grocery store chain. Once stock to be returned has been palletised and is ready for collection, wholesalers should email

recall@infantsfriend.com.au advising the number of pallets, collection address and any other collection instructions.

Consumers:

Consumers are advised that if they have a bottle of Infants' Friend Oral Liquid 100mL, to return it to the place of purchase for a refund or to call the customer service line to arrange the return of affected product and refund.

A TGA web statement will be published regarding this matter.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 44 wholesalers, with supply to supermarkets and retail pharmacies nationally

Product export status: N/A

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>