

Dr. Charles Gardner, Medical Officer of Health
Dr. Colin Lee, Associate Medical Officer of Health
Dr. Lisa Simon, Associate Medical Officer of Health

Shortage of Hypoallergenic Infant Formula

Attention: Hospitals, Family Health Teams, Midwives, Nurse Practitioners, Physicians, Pharmacies, Beausoleil First Nation, Moose Deer Point First Nation, Rama First Nation, Wahta First Nation, Licensed Child Care Providers, Ontario Health Central Region

Date: May 18, 2022

Health Canada has released a statement regarding a shortage of hypoallergenic infant formula on May 12, 2022, resulting from the temporary closure of Abbott's facility in Sturgis, Michigan. This closure is in addition to a recall in February 2022 of Abbott's Similac® Alimentum®. Consequently, the supply of extensively hydrolyzed formula (EHF) is impacted. Similac® Alimentum® is no longer available on the Canadian market and other EHF formulas recommended as alternatives (Pregestimil® and Nutramingen®) are currently out of stock, and the shortage is beginning to impact the availability of amino acid formulas recommended for severe or multiple allergies (Puramino® and Neocate®) (Health Canada, 2022).

As such, Health Canada is working to mitigate the effects of this shortage by facilitating importation of equivalent formulas from approved countries. In the meantime, a prudent approach is recommended by Health Canada to limit use of specialized products to babies who require them, and where possible, breastfeeding should be encouraged by following an allergen free diet with follow-up and advice from a Registered nutritionist or dietitian (Health Canada, 2022) and/or lactation consultant.

Given the circumstances, some families are looking for alternative sources of infant nutrition, and may benefit from the following recommendations and resources:

- Homemade formulas are not recommended:
 - [Safety of Homemade Infant Formulas in Canada - Canada.ca](#)
 - [Beware of Homemade Infant Formula – Canadian Paediatric Society \(cps.ca\)](#)
- Informal breastmilk sharing may have risks:
 - [Safety of Donor Human Milk in Canada - Canada.ca](#)
- (Re) lactation may be an option for some families through local breastfeeding support:
 - <https://www.simcoemuskokahealth.org/Topics/PregnancyandBefore/communityservices.aspx>
 - www.ontariobreastfeeds.ca

This is an evolving situation and as more information becomes available it will be shared on Simcoe Muskoka District Health Unit's (SMDHU) website.



Additional Information

The information included in this alert is available for patients on SMDHU's website, within the Hypoallergenic Infant Formula Shortage resource:

<https://www.simcoemuskokahealth.org/Promos/Hypoallergenic-Infant-Formula-Shortage>



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Food Directorate
251 Sir Frederick Banting Driveway
Tunney's Pasture, A.L. 2202E
Ottawa, ON K1A 0K9

May 12, 2022

Subject: Update regarding the shortage of hypoallergenic infant formula

Dear health care professionals,

As you are aware, a food [recall](#) warning was issued in February 2022 in relation to certain powdered infant formula products manufactured in Abbott's facility in Sturgis, Michigan. This facility is a key supplier for many countries including the USA and Canada. The Sturgis facility remains closed, and a reopening date has not been communicated. Abbott Laboratories is working with the United States Food and Drug Administration to establish the necessary corrective actions to ensure that production can resume.

The recall of Similac[®] Alimentum[®] infant formula and the extended closure of the Sturgis facility are affecting the availability of extensive hydrolyzed formulas (EHF) in Canada and abroad. The situation is evolving rapidly. Similac[®] Alimentum[®] is no longer available on the Canadian market, and other EHF formulas recommended as alternatives and authorized by Health Canada (Pregestimil[®] and Nutramigen[®]) are currently out of stock. This is in turn beginning to affect the availability of amino acid formulas recommended for severe or multiple allergies (Puramino[®] and Neocate[®]).

Health Canada is taking this situation very seriously and is actively working to mitigate the effects of this shortage. The Department published an [interim policy](#) to facilitate the importation of equivalent infant formula products that are approved in countries with similar regulatory standards to Canada and are safe to use. The interim policy includes a list of products suitable for importation that is updated regularly.

We are closely monitoring the availability of specialty formulas and working with manufacturers to facilitate production and importation of hypoallergenic products to adjust as quickly as possible to ongoing fluctuations in product availability. Expediting access to alternate products may result in changes in distribution methods. As such, some alternative products may only be available in pharmacies or online, especially those imported into Canada to mitigate the effects of the shortages.

A prudent approach is needed to mitigate the impact on families caring for vulnerable infants, including those with severe allergies or who are susceptible to anaphylactic reactions. The use of specialized products should be limited to babies who require them, and less specialized products should be used when the baby's situation allows it. Where possible, breastfeeding should be encouraged by following an allergen-free diet with follow-up and advice from a registered nutritionist or dietitian.

Health Canada is committed to maintaining ongoing communication with the healthcare community and the public as the situation evolves. Future updates will be provided on the same web page as the interim policy to facilitate the rapid dissemination of information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Karen McIntyre', written in a cursive style.

Karen McIntyre
Director General, Food Directorate
Health Products and Food Branch