



Health  
Canada

Santé  
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Health Products  
and Food Branch

Direction générale des produits  
de santé et des aliments

Food Directorate  
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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<sup>®</sup> Alimentum<sup>®</sup> 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<sup>®</sup> Alimentum<sup>®</sup> is no longer available on the Canadian market, and other EHF formulas recommended as alternatives and authorized by Health Canada (Pregestimil<sup>®</sup> and Nutramigen<sup>®</sup>) 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<sup>®</sup> and Neocate<sup>®</sup>).

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