

Nutrition Services
Public Health Nutrition

Infant Formulas

Ingredients and Indications

February 2026



Table of Contents

Contact and Acknowledgements	4
Documents For Health Professionals	5
Infant Formulas–Summary Sheet	5
Infant and Pediatric Formula Compendium	5
Definitions	5
Introduction	8
Canadian Regulations for Infant Formula	8
Health Canada Exemption Order	9
Caution Regarding Infant Formula Purchased Outside of Canada	9
Stage 1 and Stage 2 Infant Formulas	10
Stage 1 Infant Formulas	10
Stage 2 Infant Formulas.....	10
Stage 3 Beverages (Toddler Nutritional Supplements)	10
Indications for Type of Infant Formula	11
Dairy-based Infant Formulas ^{28,42–45}	11
Modified Cow’s Milk Formulas	12
Partially Hydrolyzed Protein Formulas	12
Lactose-Reduced Formulas.....	12
Lactose-Free Formulas.....	12
Soy Formulas	13
Formulas for Use Under Medical Supervision	14
Post-Discharge Preterm Formulas.....	14
Gastroesophageal Reflux (GER)–Infant Formulas for Spit-Up	14
Extensively Hydrolyzed Formulas.....	15
Amino Acid-Based Formulas.....	15
Indications for Certain Infant Formula Ingredients	16
Ascorbyl Palmitate, Mixed Tocopherols, and Citric Acid	17
Carrageenan	17

Nutrition Services, Public Health Nutrition
Infant Formulas – Ingredients and Indications

Choline	17
Corn Syrup Solids	17
Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA)	18
Inositol	18
L-Carnitine	18
Lutein	18
Lycopene	19
Maltodextrin (Dextrin)	19
Milk Fat Globule Membrane (MFGM)	19
Nucleotides	19
OPO (1,3-dioleoyl-2-palmitoylglycerol)	20
Palm Oil/Palm Olein	20
Prebiotics	20
Fructooligosaccharides (FOS)	20
Galactooligosaccharides (GOS).....	21
Human Milk Oligosaccharides (HMO)	21
Polydextrose (PXD).....	21
2'-Fucosyllactose (2'-FL)	21
Probiotics	22
Seed Oils	22
Skim Milk	22
Soy Lecithin	22
Taurine	23
Whey Protein Concentrates (WPC)	23
References	24

Contact and Acknowledgements

The purpose of the Infant Formulas–Ingredients and Indications is to provide health professionals with information on ingredients and indications for the use of infant formulas available at the retail level, and is intended for professional reference only when advising those who cannot or have made an informed decision not to breastfeed or to partially breastfeed.

This document was developed by the Public Health Nutrition Pillar 2 Working Group.



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Documents For Health Professionals

Infant Formulas–Summary Sheet

A summary sheet that lists infant formulas for retail sale in Canada by category is available for health professionals' use: [Infant Formulas – Summary Sheet](#).

Alberta Health Services (AHS) does not endorse or recommend one specific commercial infant formula over another unless it is intended to meet a specific clinical need.

Infant and Pediatric Formula Compendium

Infant formula nutrient composition, including sources of protein, fat and carbohydrate, is available for AHS healthcare professionals' use on Insite in the Infant & Pediatric Formula Compendium. For more information about infant formulas used in AHS, visit the Enteral Nutrition Insite page.

Definitions

Casein: the insoluble component of cow's milk protein, comprising 80% of the milk protein fraction.¹

Colic: recurrent and prolonged periods of infant crying, fussing, or irritability reported by caregivers that occur without an obvious cause and cannot be prevented or resolved by caregivers.² There is no evidence of infant failure to thrive, fever, or illness.² Symptoms start and stop in infants less than five months of age.² "Fussing" refers to intermittent distressed vocalization and has been defined as "[behaviour] that is not quite crying but not awake and content either." Infants often fluctuate between crying and fussing, so the two symptoms are difficult to distinguish in practice.²

Docosahexaenoic acid (DHA) and arachidonic acid (ARA): long-chain polyunsaturated fatty acids that have a role in brain and retina development.³ DHA is an omega-3 fatty acid.³ ARA is an omega-6 fatty acid.³

Food allergy: a medical condition where the immune system mistakenly treats something in a particular food (most often, the protein) as if it is dangerous. The body reacts to the allergen by triggering an allergic reaction.⁴

Nutrition Services, Public Health Nutrition

Infant Formulas – Ingredients and Indications

Galactosemia: a rare inborn metabolic disorder of carbohydrate metabolism characterized by the inability to metabolize galactose, resulting in life-threatening symptoms if galactose is not restricted from the diet.⁵ Dietary galactose is found mainly in breastmilk and dairy products in the form of lactose, a disaccharide formed by glucose and galactose.⁵

Gastroesophageal reflux: the passage of gastric contents into the esophagus, with or without regurgitation ("spitting up").³

Inclusive language terms: some clients may not identify with the term breastmilk and/or breastfeeding, and may instead identify with terms such as chestmilk or human milk, and/or chestfeeding, body feeding,⁶ or nursing. In all circumstances, care providers shall utilize client- and family-centred care to be responsive to the self-identified gender, pronouns, and terminology of the families they support.⁶

Infant formula: throughout the document, the words "infant formula" and "formula" refer to commercial infant formula. Infant formula is a substitute for human milk that is given to infants typically during the first year of life.⁷

Lactose intolerance: lactose malabsorption with associated gastrointestinal symptoms.⁸ Symptoms in infants, which generally occur within 30–60 minutes of ingesting lactose-containing foods, include diarrhea, perianal skin irritation, excoriation, and abdominal pain and distension.⁸ The four main clinical types of lactose intolerance are:⁸

- **developmental lactase deficiency:** observed in premature infants (less than 34 weeks gestation) due to temporary lactase deficiency, which improves with time.
- **congenital lactase deficiency:** a rare and severe autosomal recessive disorder caused by low or absent small intestinal lactase. Presents with severe watery diarrhea at the commencement of breastfeeding or lactose-containing infant formula.⁸
- **lactase non-persistence:** physiological gradual decline of lactase activity after weaning. Significant gastrointestinal symptoms generally do not occur before five years of age.⁸
- **secondary lactose intolerance:** May occur as a consequence of small bowel injury due to conditions such as viral gastroenteritis, celiac disease, or Crohn's disease. Infants with glucose-galactose malabsorption have normal lactase activity but present with osmotic diarrhea due to the inability to absorb glucose and galactose (derived from lactose).⁸

MCTs (medium-chain triglycerides): saturated fatty acids with carbon chain lengths of 6–10 atoms, which are more easily hydrolyzed, better absorbed, and more rapidly oxidized than long-chain triglycerides.⁹

Nutrition Services, Public Health Nutrition

Infant Formulas – Ingredients and Indications

Nucleotides: non-protein nitrogenous compounds which are precursors of nucleic acids and a component of coenzymes.¹⁰

Parent/caregiver: the term ‘parent’ will be used throughout this document to indicate parents, caregivers, or other persons caring for a child in the context of the family unit.

Partially hydrolyzed protein formula: infant formula in which the cow’s milk protein has been broken down into components or peptides that are smaller than the intact protein, but larger than the end products in extensively hydrolyzed protein formula.¹¹

Prebiotic: a substrate that is selectively utilized by host microorganisms, conferring a health benefit.¹²

Probiotics: live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.¹³

Regurgitation (spitting up): the passive movement of stomach contents into the pharynx or mouth.¹⁴

Whey: the soluble component of cow’s milk protein, comprising 20% of the milk protein fraction.¹

[Return to Table of Contents](#)

Introduction

This document provides information on ingredients and indications for the use of infant formulas available at the retail level and is intended for professional reference only when advising those who cannot or have made an informed decision not to breastfeed or to partially breastfeed.

This document was prepared with the full recognition that breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants.¹⁵ Exclusive breastfeeding for the first six months, and continued for up to two years or longer, is recommended for the healthy growth and development of infants and toddlers.³ and for the benefits to the individual who is lactating.¹⁶ As per the [AHS Breastfeeding Policy](#),¹⁷ health professionals must support parents/caregivers and their families to make informed feeding decisions.

If an infant is not fed breastmilk or is partially fed breastmilk, infant formula sold in Canada will meet the nutrition needs of infants and is the only recommended breastmilk substitute for infants.¹⁸ Infant formula is available in three formats: ready-to-serve, liquid concentrate that must be diluted with water, or powder that is to be mixed with water.⁷ Parents are advised to follow AHS guidelines for preparing infant formula and to follow the manufacturer's instructions (on the formula label) for the amount of infant formula and water to use. Health professionals should refer to the Nutrition Guideline: [Safe Preparation and Handling of Infant Formula](#).

Canadian Regulations for Infant Formula

Infant formula is regulated under the Food and Drug Regulations.¹⁹ Before an infant formula can be sold or advertised for sale in Canada, Health Canada assesses whether the infant formula is safe and nutritionally adequate to promote acceptable growth and development in infants.²⁰ All manufacturers, importers, and distributors of infant formula are responsible for ensuring their products comply with Canadian legislation.^{18,21}

Some infant formulas are eligible for some health insurance coverage or [Income Support programs](#) (e.g. extensively hydrolyzed casein formulas).

For more information on infant formula labelling, safety, and recalls, refer to [Health Canada Food and Nutrition](#).

Health Canada Exemption Order

Health Canada's [Exemption Order in Respect of Foods for a Special Dietary Purpose](#), December 2025, contains two parts. Part 1 includes a framework for importing and selling infant formula and human milk fortifiers to mitigate infant formula shortages, and Part 2 allows infant formulas and human milk fortifiers in the process of Health Canada's pre-market review to continue to be imported and sold in Canada until the review is completed. These products are listed on the [List of Transition Strategy Products](#).

Caution Regarding Infant Formula Purchased Outside of Canada

It is not recommended to purchase infant formula online from another country, as these products are not reviewed and approved by Health Canada. Therefore, it is not known if these infant formulas meet Canadian standards for safety and nutritional content. Other potential risks of purchasing infant formula online from another country include:

- There is no system in place to report infant formula recalls for formula purchased outside of Canada.
- Nutrient oxidation when infant formula powder is stored at high temperatures. Long-chain polyunsaturated fatty acids in powdered infant formula are sensitive to oxidation when stored at temperatures of 55°C and must be stored at proper temperatures to ensure their safety and quality.²²
- Labels and instructions that are written in an unfamiliar language create a risk if formula preparation and storage cannot be followed.

For more information:

- [Online Shopping: Product Safety | Health Canada](#)
- [Online shopping | Government of Canada](#)
- [Product Certification & Standards Development | CSA Group](#)

[Return to Table of Contents](#)

Stage 1 and Stage 2 Infant Formulas

Stage 1 and stage 2 infant formulas both function as partial or total replacements for breastmilk.²³

Stage 1 Infant Formulas

In Canada, term infant formulas are designed to be nutritionally adequate for term infants from birth to 12 months of age.²⁴ These formulas are typically labelled as stage 1, step 1, or simply with the number '1', and may also be referred to as 'starter' or 'routine' formulas.²⁵⁻²⁷

Stage 2 Infant Formulas

Infant formulas designed for infants six months of age or older are known as follow-up formulas²⁸ and are labelled as stage 2, step 2, or with a number '2'.²⁹⁻³¹ These formulas are similar to stage 1 infant formulas in terms of energy, fat, and carbohydrate, but contain higher amounts of calcium and phosphorus.^{26,27,29-32} Even though calcium and phosphorus needs increase in the second six months of life,³³ switching from a stage 1 to a stage 2 infant formula offers no advantage for infants receiving sufficient amounts of calcium and phosphorus from complementary foods.³⁴ Stage 2 formulas are not suitable for infants younger than six months of age.³⁵

Stage 3 Beverages (Toddler Nutritional Supplements)

Stage 3 beverages, also known as young child formulas or toddler drinks, are labelled as toddler nutritional supplements in Canada*.^{34,36-38} Products currently available in Canada include Enfagrow® A+, Go and Grow by Similac®, Good Grow™, NIDO®, and Else™ Toddler†.³⁶⁻⁴⁰ These products are not the same as stage 1 or stage 2 infant formulas and are inappropriate for infants under 12 months of age.³⁶⁻⁴⁰ They are marketed for young children aged 12 to 36 months as a substitute or supplement to cow's milk³⁶⁻⁴⁰ and are also considered breastmilk substitutes.⁴¹

After 9–12 months of age, toddlers should be eating a variety of complementary foods and can transition directly to 3.25% milk (whole milk), which serves as a partial or complete replacement for breastmilk.²⁸

* The Food and Drug Regulations define “nutritional supplement” as a food sold or represented as a supplement to a diet that may be inadequate in energy and essential nutrients. Refer to the [Regulations Amending the Food and Drug Regulations \(Human Milk Fortifiers\) | Canada Gazette](#) for more information.

† Stage 3 toddler supplements are not included in the companion document [Infant Formulas – Summary Sheet](#).

For most healthy young children older than 12 months, there is no indication for the use of infant formulas or toddler nutritional supplements if they are receiving sufficient amounts of vitamins and minerals through complementary foods.³⁴ Possible disadvantages of the use of toddler nutritional supplements are continued preference for liquid foods and subsequently reduced interest in complementary foods that require chewing.³⁴ The availability of such products may suggest to parents that these manufactured supplement beverages are a safer and healthier alternative for meeting a child’s nutritional requirements, rather than transitioning to family foods.³⁴ The use of toddler nutritional supplements instead of 3.25% cow’s milk may also create a financial burden on families.³⁴ In 2026, toddler nutritional supplements in Alberta cost at least six times[‡] as much per mL than 3.25% cow’s milk.

Since toddler nutritional supplements contain more iron and DHA than 3.25% milk, they may have benefits for some children not obtaining enough of these nutrients from food. If parents provide a toddler with a nutritional supplement due to nutrition concerns, it is recommended to consult a dietitian regarding these nutrition concerns.

Indications for Type of Infant Formula

Dairy-based Infant Formulas^{28,42-45}

Dairy-based infant formulas are designed to resemble the nutrient composition of human milk.¹⁰ This category includes both cow’s milk and goat’s milk-based infant formulas. While cow’s milk-based infant formulas make up most approved formulas in Canada, approved goat’s milk-based formulas are also safe and nutritionally complete. Standard formulas in this document and the [Infant Formulas – Summary Sheet](#) refer to those with intact milk protein⁴⁶ and unaltered lactose content. Dairy-based infant formulas are recommended for formula-fed healthy term infants until 9–12 months of age, regardless of their **risk** of allergy.⁴⁷ These formulas are not suitable for infants with milk protein allergy, galactosemia, or for those who cannot consume dairy-based products for religious³ or personal reasons.

Goat’s milk is not recommended as an alternative for infants with a cow’s milk allergy or history of lactose intolerance. Health marketing claims on goat’s milk (e.g. soothes fussiness, improves sleep, easier to digest, less allergenic) are not supported with strong evidence to being superior over cow’s milk formulas.^{42,45}

[‡] Calculations based on average prices from Walmart.ca, Superstore.ca and Saveonfoods.com for Enfagrow A+ 907g powder, reconstituted, and regular 3.25% cow’s milk, 4L (2026)

Modified Cow’s Milk Formulas

Partially Hydrolyzed Protein Formulas

Partially hydrolyzed protein infant formulas contain either partially hydrolyzed whey or a combination of partially hydrolyzed whey and casein protein.^{27,48-51} Some also have reduced lactose levels⁴⁸⁻⁵¹ (see Lactose-Reduced Formulas below for more information). Partially hydrolyzed protein formulas are considered safe and lead to appropriate infant growth.¹¹ However, there is little evidence to support any benefit of a partially hydrolyzed protein formula compared to standard cow’s milk protein formula³ despite the health benefits implied^{52,53} by these formula names (e.g., “soothe”, “comfort”, and “gentlease”) and claims (e.g., comfort proteins™, easy to digest,⁴⁹⁻⁵¹ tummy-friendly,^{49,50} for fussiness,^{48,49} tummy troubles,⁵⁰ or sensitive tummies⁴⁸). The reported benefits of using partially hydrolyzed formulas for reducing colic are inconsistent, and the quality of evidence is very low.⁵² Current evidence does **not** support feeding a partially hydrolyzed formula compared with exclusive breastfeeding or a standard cow’s milk formula for the prevention of allergic disease, whether or not an infant is at high risk or low risk of allergic disease.⁵⁴

Lactose-Reduced Formulas

Lactose-reduced formulas contain 18–70% of the lactose levels of routine dairy-based formulas: Good Start Soothe™: 70% lactose;⁴⁸ Enfamil A+® NeuroPro™ Gentlease®: 20% lactose;⁵⁰ Enfamil A+® Serenity: 50% lactose,⁵¹ and Similac Total Comfort®: 18% lactose.⁴⁹ There is no clear indication for the use of lactose-reduced formulas.

Lactose-Free Formulas

Glucose polymers, usually from corn syrup solids, replace lactose in lactose-free cow’s milk-based infant formulas.³ However, these formulas still contain a small amount of residual lactose and are therefore not suitable for infants with congenital lactase deficiency or galactosemia.³ Lactose-free infant formulas are also not suitable for infants with cow’s milk protein allergy³ and are thought to be ineffective in the dietary management of infant colic.⁸ During episodes of acute diarrhea, temporarily switching formula-fed infants to a lactose-free formula may reduce diarrhea duration.⁵⁵

[Return to Table of Contents](#)

Soy Formulas

There are limited indications for feeding soy formulas to term infants. These indications include the management of infants with galactosemia or primary lactase deficiency and infants who cannot consume dairy-based products for religious or personal reasons, such as a vegetarian lifestyle.^{3,56,57}

Note: The vitamin D in soy formula available in Canada is obtained from sheep's wool lanolin without causing harm to the animal. This may or may not be acceptable to some families following a vegan or plant-based diet, and is therefore important to share with them.⁵²

Soy infant formulas contain phytoestrogens called isoflavones,⁵⁶ which are non-steroidal chemicals that are structurally similar to estrogens.⁶⁰ Some studies found that most of the phytoestrogens present in soy infant formula are in a conjugated form, and therefore, are unable to exert hormonal effects.⁶¹ However, further research is warranted, and the use of soy infant formulas should be limited to the indications described above.

The use of soy infant formulas is not appropriate for infants:

- with soy protein allergy.
- with non-IgE-mediated cow's milk protein allergy (CMPA) due to the high rate of coincident soy allergies.⁵⁶ The use of soy formula is an acceptable alternative if a non-IgE-mediated CMPA can be satisfactorily ruled out, as the coincident soy allergy for IgE-mediated CMPA is much less frequent.^{3,56,57} It is usually safer and more appropriate to recommend an extensively hydrolyzed casein formula for infants with CMPA, especially in infants younger than six months of age.⁵⁶ Guidance from a physician is recommended to help determine when using a soy formula for children with CMPA is appropriate.⁶²
- born preterm. Soy formulas have high aluminum content, and aluminum toxicity may develop in preterm infants due to their reduced renal function.⁶¹ As aluminum competes with calcium for absorption, this may result in reduced skeletal mineralization (osteopenia).⁶¹ Serum phosphorus concentrations are lower and alkaline phosphatase concentrations are higher in preterm infants and infants with intrauterine growth restriction (IUGR) fed soy infant formula, compared to preterm infants fed cow's milk infant formula. Therefore, the degree of osteopenia is increased in infants with low birth weight receiving soy infant formulas.⁵⁷
- with congenital hypothyroidism. Infants with congenital hypothyroidism fed soy infant formula need close monitoring due to reported abnormal thyroid function. This does not appear to be a concern in infants with healthy thyroid function.⁶²

Formulas for Use Under Medical Supervision

Post-Discharge Preterm Formulas

Post-discharge preterm formulas have been specifically designed to meet the needs of preterm and low-birth-weight infants after discharge from the hospital and should only be used with the advice of a physician or dietitian. For more information on these infant formulas, refer to the Nutrition Guideline: [Post-discharge Preterm Formula](#).

Gastroesophageal Reflux (GER)–Infant Formulas for Spit-Up

Regurgitation (spitting up) is normal in infancy and only rarely leads to health problems such as growth faltering.³

Gastroesophageal reflux (GER) is relatively common in healthy-term infants, with regurgitation occurring daily in approximately 50% of infants three to four months of age.³ Education on feeding changes,⁶³ anticipatory guidance, and support are usually sufficient to manage healthy, thriving infants.

Formula that thickens in an infant’s stomach is intended for infants with mild GER and should be used only when recommended by a physician. Thickened infant formula does not decrease the frequency of reflux episodes but may decrease visible regurgitation, which may improve quality of life for parents.⁶⁴ This type of infant formula is not intended for infants who need a specialized thickened formula due to swallowing difficulties. It is not recommended to thicken infant formula with infant cereal³ as this may increase coughing during feeding, impair absorption of nutrients, lead to excessive weight gain, or increase gastrointestinal symptoms.⁶³

Extensively Hydrolyzed Formulas

Extensively hydrolyzed casein infant formulas contain protein from cow's milk that has been heat-treated and/or enzymatically hydrolyzed into short-chain peptides and amino acids.¹⁰ Casein was the protein source in extensively hydrolyzed formulas in Canada³ until 2022, when the importation of extensively hydrolyzed whey protein and extensively hydrolyzed rice protein formulas was allowed as part of Health Canada's interim policy to manage infant formula shortages.²¹ As of December 2025, the new [Transition Strategy](#) allows ongoing importation of these formulas into Canada.

A cow's milk-derived extensively hydrolyzed formula (casein or whey) is recommended as the first choice for formula-fed infants with:

- suspected cow's milk protein allergy who are on a diagnostic elimination diet.⁶⁵
- diagnosed cow's milk protein or soy protein allergies.^{3,65-68}
- specific malabsorption syndromes.^{3,67,68}

Extensively hydrolyzed formulas are not indicated for allergy prevention.⁴⁷ Refer to [Hydrolyzed Formulas and Allergy Prevention–Practice Change Notice](#) for more information.

Amino Acid-Based Formulas

Amino acid-based infant formulas, also known as elemental formulas, contain 100% free synthetic amino acids and have a lack of proteic residual allergenicity as they are not derived from cow's milk protein.^{10,69} Amino acid-based formulas are more expensive than extensively hydrolyzed formulas and have poor palatability when not started at a young age.

An amino acid-based formula is recommended as the first choice for formula-fed infants with:

- anaphylaxis to cow's milk protein⁶⁹
- cow's milk protein allergy associated with multiple food allergies⁶⁹ or faltering growth⁶⁵
- allergies who do not respond to extensively hydrolyzed formulas^{3,65}
- eosinophilic esophagitis who do not respond to extensive food-elimination diets or who are not yet eating complementary foods⁶⁹
- acute or chronic severe cow's milk protein-induced enterocolitis syndrome⁶⁹

[Return to Table of Contents](#)

Indications for Certain Infant Formula Ingredients

In general, Health Canada prohibits the use of food additives in infant foods, except for additives that stabilize the formula, prolong the shelf-life, and/or control the pH balance of the food. Health Canada has evaluated and approved the following food additives and preservatives as safe to add to infant formulas.^{70,71}

- [Ascorbyl palmitate, mixed tocopherols, citric acid](#)
- [Carrageenan](#)
- [Choline](#)
- [Corn syrup solids](#)
- [Docosahexaenoic acid \(DHA\) and arachidonic acid \(ARA\)](#)
- [Inositol](#)
- [L-carnitine](#)
- [Lutein](#)
- [Lycopene](#)
- [Maltodextrin \(dextrin\)](#)
- [Milk fat globule membrane \(MFGM\)](#)
- [Nucleotides](#)
- [OPO \(1,3-dioleoyl-2-palmitoylglycerol\)](#)
- [Palm oil/palm olein](#)
- [Prebiotics](#)
 - [Fructooligosaccharides \(FOS\)](#)
 - [Galactooligosaccharides \(GOS\)](#)
 - [Human milk oligosaccharides \(HMO\)](#)
 - [Polydextrose \(PXD\)](#)
 - [2'-fucosyllactose \(2'-FL\)](#)
- [Probiotics](#)
- [Seed oils](#)
- [Skim milk](#)
- [Soy lecithin](#)
- [Taurine](#)
- [Whey protein concentrates \(WPC\)](#)

Ascorbyl Palmitate, Mixed Tocopherols, and Citric Acid

Ascorbyl palmitate and mixed tocopherols are antioxidants added to formulas to help reduce fat oxidation (thus prolonging shelf life) and formula rancidity.⁷¹

Citric acid is added as a pH regulator and helps to prevent spoilage and prolong shelf life.^{76,77}

Carrageenan

Carrageenan is derived from red seaweed (Irish moss) and may be used in infant formula as a thickener, stabilizer and/or emulsifier. Carrageenan may be used to increase thickness (viscosity) in specialized infant formulas (e.g., anti-reflux or thickened formulas).^{72,73}

Choline

Choline is an essential nutrient naturally present in many foods, including meat, dairy, eggs, vegetables, whole grains, and human milk. All infant formulas approved for use in Canada are required to contain choline as it supports brain development, neuronal health, and lipid membranes.^{45,78–80}

Corn Syrup Solids

Corn syrup (liquid) and corn syrup solids (dry powder) come from corn starch, which is hydrolyzed using heat, acids, or enzymes into glucose polymers. These glucose polymers may be used as a replacement for carbohydrate in lactose-free infant formulas.⁸¹

High fructose corn syrup (HFCS) is not often used as an ingredient in infant formulas, and none are approved for use in Canada.⁸² It is a product that undergoes further conversion from corn starch to fructose, which is sweeter than corn syrup and corn syrup solids.

[Return to Table of Contents](#)

Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA)

DHA and ARA are found naturally in breastmilk and are essential for the maturation of the developing brain, retina, and other organs in newborn infants.⁸³ DHA and ARA can be synthesized from their precursors, alpha-linolenic acid and linoleic acid, respectively;⁸³ however, researchers have questioned if formulas containing only alpha-linolenic and linoleic acid are effective in meeting the full essential fatty acid requirements of infants.⁸³ Based on the most recent Cochrane review,⁸³ there are no consistent beneficial effects for term infants of DHA- and ARA-supplemented formula on visual acuity, neurodevelopmental or physical growth.⁸³ Even though some studies reported potential benefits, and formulas with added DHA and ARA are marketed as providing an advantage for infant development,⁸³ recommending formulas with added DHA and ARA presents a problem of inequity since these formulas currently cost more than the same infant formula without added DHA and ARA.⁵³ There is no strong evidence that these ingredients are needed in infant formula. Families can choose a formula with or without these ingredients.

Inositol

Inositol is a sugar alcohol naturally found in human milk and in the body. All infant formulas approved in Canada are required to contain inositol. It is added to support cell signalling, membrane synthesis, and brain development.^{45,84}

L-Carnitine

L-carnitine (also known as carnitine or propionyl-L-carnitine) is a naturally occurring compound made up of two amino acids (lysine and methionine). Humans make L-carnitine in the brain, kidneys, and liver for energy production through long-chain fatty acid breakdown. In Canada, all infant formulas are required to contain L-carnitine in amounts that meet the requirements of term infants.^{45,85,86}

Lutein

Lutein is a carotenoid (antioxidant) naturally occurring in various fruits and vegetables (e.g. carrots). Lutein is found in high concentrations in the eye and is added to infant formula as it may be beneficial in early infant brain and eye development.^{45,87,88} There is no strong evidence that this ingredient is needed in infant formula. Families can choose a formula with or without this ingredient.

Lycopene

Lycopene is a red carotenoid pigment (antioxidant) found naturally in fruits such as tomatoes. Although it is approved for use as a food colourant in Canada, it is not approved for other uses in foods, including infant formula. Lycopene may be present in infant formulas made outside Canada, as the World Health Organization has approved it as an optional ingredient. As such, international formulas allowed on [Health Canada's previous interim importation policy](#) and in the process of pre-market evaluation for ongoing approval in Canada may contain lycopene.⁸⁹⁻⁹³

Maltodextrin (Dextrin)

Maltodextrin is a carbohydrate made from edible starch, often derived from corn, rice, or potatoes. It is hydrolyzed using heat, acids and/or enzymes, followed by sugar removal to be used in infant formula as a carbohydrate source. It is used as a source of energy in infant formulas when lactose isn't the main carbohydrate source.^{81,94,95}

Milk Fat Globule Membrane (MFGM)

MFGM is a membrane made up of phospholipids and proteins that surround fat droplets within human milk. MFGM derived from cows' milk helps to keep essential fats evenly dispersed within infant formulas. They contain high amounts of short-chain fatty acids (linoleic) and polyunsaturated fatty acids (DHA), which may have potential benefits on immune function, brain development, and gut health.⁹⁶⁻¹⁰³ There is no strong evidence that this ingredient is needed in infant formula. Families can choose a formula with or without this ingredient.

Nucleotides

Nucleotides are conditionally essential nutrients, which means that they are not typically needed from the diet because humans possess the biological pathways to synthesize them. In certain conditions, such as rapid growth or illness, increased dietary intake of the nutrient may be needed to optimize tissue function.¹⁰⁴ Nucleotides are found in higher concentrations in breastmilk than in cow's milk,¹⁰⁵ and therefore some manufacturers add nucleotides to infant formula in an attempt to mimic the composition of breastmilk. Nucleotides have a role in modulating immune function, plasma fatty acid composition, and promoting intestinal development.¹⁰⁵ Some studies report an association between nucleotides in infant formulas and increased head growth and rate of early weight gain; however, the benefits of using an infant formula with added nucleotides are still inconclusive.¹⁰⁵ Families can choose a formula with or without this ingredient.

OPO (1,3-dioleoyl-2-palmitoylglycerol)

OPO is a naturally occurring fat (triglyceride) found in human milk. In infant formulas, OPO derived from cow's milk is added as a fat source to mimic human milk fat composition. Research suggests that OPO may help with infant growth, digestion, calcium absorption, bone development, and support healthy gut bacteria.¹⁰⁶⁻¹¹² There is no strong evidence that this ingredient is needed in infant formula. Families can choose a formula with or without this ingredient.

Palm Oil/Palm Olein

Palm oil (often called palm olein) is commonly used in infant formulas as a fat source. It is often included in combination with other vegetable and seed oils as part of the fat blend to provide a fatty acid profile that is closer to human milk. However, because the structure of palm oil differs from that in human milk, it has the potential to reduce calcium and fat absorption and may lead to harder stools. For this reason, some formulas use other fats to support better nutrient absorption and softer stools.¹¹³⁻¹¹⁶ Based on current evidence, health professionals can help families choose a formula with or without this ingredient.

Prebiotics

Prebiotics studied for use in infant formula are fructooligosaccharides (FOS), galactooligosaccharides (GOS), polydextrose (PDX), 2'-fucosyllactose (2'-FL) (a human milk oligosaccharide [HMO]), as well as combinations of these.¹¹⁷⁻¹²⁰ HMOs that are naturally present in breastmilk have been studied for their benefits to the immune system including anti-bacterial, anti-viral, and anti-inflammatory effects.¹²⁰ Evidence to support this claim in infant formulas continues to emerge.¹²¹ Families can choose a formula with or without this ingredient.

Fructooligosaccharides (FOS)

FOSs are non-digestible carbohydrates naturally found in fruits and vegetables such as bananas and onions. They are formed by linking two or more fructose (sugar) units together. FOS may be used in infant formula as a dietary fibre to help improve infant gut health and soften stools.^{81,122} There is no strong evidence that this ingredient is needed in infant formula. Families can choose a formula with or without this ingredient.

[Return to Table of Contents](#)

Galactooligosaccharides (GOS)

GOSs are non-digestible carbohydrates derived from cow's milk whey, designed to mimic the oligosaccharides occurring naturally in human milk. They are formed when enzymes link two galactose units (simple sugars from the breakdown of lactose) together. GOS may also act as a soluble fibre and may help promote soft stools in infants that are formula-fed.^{81,123} There is no strong evidence that this ingredient is needed in infant formula. Families can choose a formula with or without this ingredient.

Human Milk Oligosaccharides (HMO)

HMOs are complex non-digestible carbohydrates that are only naturally present in human milk. HMOs in infant formulas are synthetically manufactured to be structurally identical to those in human milk. HMOs have functional benefits such as anti-bacterial, anti-viral and anti-inflammatory effects and are the third most abundant solid component in human milk after lactose and lipids.^{124,125} There is no strong evidence that this ingredient is needed in infant formula. Families can choose a formula with or without this ingredient.

Polydextrose (PXD)

PXD is a non-digestible carbohydrate made up of glucose and sorbitol. Sorbitol naturally occurs in some fruits and is also derived from manipulating glucose. PXD may be used in infant formulas as a dietary fibre, given its non-digestible structure.⁸¹ Families can choose a formula with or without this ingredient.

2'-Fucosyllactose (2'-FL)

2'-FL are non-digestible carbohydrates naturally found in human milk. 2'-FL is one of the most abundant HMOs in human milk and is produced from microbial fermentation for commercial use. It is added to infant formulas to help to support immune function and gut health for infants.¹²⁶⁻¹²⁸ There is no strong evidence that this ingredient is needed in infant formula. Families can choose a formula with or without this ingredient.

Probiotics

Bifidobacterium lactis BB-12 (*B. lactis*),¹²⁹ *Lactobacillus* (formerly *Lactobacillus*) *rhamnosus* GG (LGG),⁶⁶ and *Lactobacillus reuteri* DSM 17938 (aka *Limosilactobacillus reuteri*) (*L. reuteri*)⁴⁸ are probiotics currently added to some infant formulas in Canada. Further studies with larger sample sizes testing dose, strain,¹³⁰ duration, and timing¹¹⁸ are required before it can be recommended that probiotic cultures be needed in infant formula.¹³¹ Because new evidence continues to emerge and available probiotic products frequently change, health professionals can consult probioticchart.ca for current evidence-based indications for using formulas with added probiotics. Families can choose a formula with or without this ingredient.

Seed Oils

Seed oils are oils extracted from the seeds of various fruits, nuts, vegetables, and grains. Seed oils such as soy, coconut, sunflower and/or safflower oils are often used in infant formulas to meet some or all of the fatty acid profile similar to human milk and provide roughly 50% of the total calories infants require.¹³²⁻¹³⁴

Skim Milk

Skim milk is whole cow's milk with the milk fat removed. Both whole milk and skim milk may be added to cow's milk infant formula. Skim milk may be added as a protein source to infant formulas.¹³⁵

Soy Lecithin

Soy lecithin is a food additive derived from soybean oil and is approved by Health Canada for use in infant formula as an emulsifier to stabilize mixtures of oil and water. Its purpose is to help disperse fats evenly in the formula. Soy lecithin is considered safe for most individuals with soy allergies, as it typically contains low levels of soy protein. However, highly sensitive individuals may still react and should consult their healthcare professionals.⁷³⁻⁷⁵

[Return to Table of Contents](#)

Taurine

Taurine is a conditionally essential free amino acid that can be produced in the body from cysteine, but the enzymes needed for this conversion are low in infants. Taurine is present in human milk in higher concentrations than cow's milk and, therefore, is added to many infant formulas to better meet this need. It has many benefits to humans, including aiding in brain and central nervous system development, retinal physiology, and platelet function. Synthetic taurine is added to infant formula to help support these functions.^{45,136-142}

Whey Protein Concentrates (WPC)

WPC are derived from cow's milk by removing non-protein components from whey. In infant formula, WPC serves as a source of high-quality protein, often used to mimic the composition of human milk. WPC are added to adjust the whey-to-casein ratio so it more closely resembles human milk, improves protein quality, and provides essential amino acids to support infant growth and development.^{24,45,143}

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