

BREASTFEEDING IS BEST (A)

This document was prepared with the full recognition that breastmilk is the normal and unequalled food for infants. Breastfeeding is a global priority in accordance with the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF).¹

COW'S MILK INFANT FORMULAS FOR HEALTHY TERM INFANTS

Alberta Health Services does not endorse or recommend specific commercial formula products. This information is intended for professional reference only when advising those who cannot or have chosen not to breastfeed or to partially breastfeed.

COW'S MILK STARTER FORMULAS (Iron Levels 4.0 – 12.2 mg/L) (B-D)

- ◆ Enfamil A+ (with DHA & ARA) (C)
- ◆ Enfamil Lower Iron
- ◆ Enfamil with Iron
- ◆ Good Start
- ◆ Good Start with Omega-3 & Omega-6 (C)
- ◆ Good Start Probiotic (with DHA & ARA) (C,D)
- ◆ Kirkland Omega + Infant Formula (C)
- ◆ Life Iron Fortified Infant Formula
- ◆ Life Lower Iron Infant Formula
- ◆ Life Omega 3 & 6 Infant Formula (C)
- ◆ Mom to Mom Sharing Wisdom (C)
- ◆ Parent's Choice Lower Iron Milk Based
- ◆ Parent's Choice Organic with Omega-3 & 6 (C,E)
- ◆ Parent's Choice with Iron
- ◆ Parent's Choice with Omega-3 & 6 (C)
- ◆ Parent's Choice with Probiotic (C,D)
- ◆ President's Choice Infant Formula
- ◆ President's Choice Infant Formula with Iron
- ◆ President's Choice Organics with Iron Plus Omega 3 & 6 Step 1 (C,E)
- ◆ President's Choice with Iron Plus Omega 3 & 6 (C)
- ◆ President's Choice with B.Lactis Probiotic and Iron plus Omega 3 and Omega 6 (C,D)
- ◆ Similac Advance Step 1 with Omega-3 and Omega-6 (C)
- ◆ Similac Iron Fortified Step 1 Regular
- ◆ Similac Lower Iron Step 1
- ◆ Similac Partially Broken Down Protein with Omega 3 and 6 * (C)

FOLLOW-UP (6+ months) ^G

- Cow's Milk**
- ◆ Enfamil 2 (formerly Enfapro)
 - ◆ Enfamil 2 A+ (formerly Enfapro A+) (C)
 - ◆ Follow-Up Transition (With Iron and Calcium)
 - ◆ Good Start 2
 - ◆ Good Start 2 Probiotic (with DHA & ARA) (C,D)
 - ◆ Good Start 2 with Omega-3 & Omega-6 (C)
 - ◆ Parent's Choice 2 with Omega-3 & 6 (C)
 - ◆ President's Choice with Iron & Added Calcium Plus Omega 3 & 6 (C)
 - ◆ Similac Go & Grow Step 2
 - ◆ Similac Go & Grow Step 2 with Omega-3 and Omega-6 (C)

INFANT FORMULAS FOR SPECIAL CONDITIONS

LACTOSE INTOLERANCE (H)

- Lactose-Free Formulas:**
- ◆ Enfamil Lactose Free A+ (C)
 - ◆ Kirkland Sensitive (C)
 - ◆ Parent's Choice Sensitive (C)
 - ◆ Similac Sensitive Lactose Free

- Low Lactose Formulas: ****
- ◆ Enfamil Gentlease A+ (with DHA & ARA) (C)
 - ◆ Parent's Choice Gentle with Omega-3 & 6 (C)

REFLUX (1)

- Formulas that become thickened:**
- ◆ Enfamil Thickened A+

HIGH RISK OF ALLERGY (J)

- Extensively Hydrolyzed Casein:**
- ◆ Alimentum
 - ◆ Nutramigen A+ (with DHA & ARA) (C)
 - ◆ Pregestimil A+ (with DHA & ARA) (C)

- Partially Hydrolyzed 100% Whey:**
- ◆ Good Start
 - ◆ Good Start Probiotic (with DHA & ARA) (C,D)
 - ◆ Good Start with Omega-3 & 6 (C)

COW'S MILK ALLERGY (K)

- Extensively Hydrolyzed Casein (J):**
- ◆ Alimentum
 - ◆ Enfamil Nutramigen A+ (with DHA & ARA) (C)
 - ◆ Enfamil Pregestimil A+ (with DHA & ARA) (C)

- Amino Acid-Based:**
- ◆ Neocate Infant DHA/ARA (C)
 - ◆ Puramino A+ (formerly Nutramigen AA)

Note: use only under medical direction if extensively hydrolyzed casein formulas are not tolerated.

Soy: Soy formula may be considered after 6 months of age for cow's milk allergy if tolerance to soy protein has been established under physician guidance.

VEGETARIAN, CULTURAL, GALACTOSEMIA (L)

0-12 months

- Soy(L):**
- ◆ Enfamil Soy A+ (with DHA & ARA) (C)
 - ◆ Good Start Alsoy with Omega-3 & Omega-6 (C)
 - ◆ President's Choice Organics Soy Plus Omega 3 & 6 Step 1 (C,E)
 - ◆ Similac Isomil
 - ◆ Similac Isomil with Omega-3 and Omega-6 (C)

6+ months

- Soy Follow-up (L):**
- ◆ Good Start Alsoy 2 with Omega 3&6 (C)
 - ◆ Similac Isomil Step 2

Note: For infants requiring soy formula, a soy follow-up formula should be offered by 12 months of age to help meet the child's calcium needs. Soy formula should be offered until 2 years of age at which time soy beverage may be used instead.

* Similac Partially Broken Down Protein with Omega 3 and 6 formula appears to be the same as Good Start, it was not added to High Risk of Allergy section as manufacturer does not recommend/ support the use of this formula for allergy prevention

** Current lactose reduced formulas contain only 20-25% of the lactose of the standard cow's milk based formulas.

Mead Johnson Nutrition. Enfamil® Gentlease™ A+® [product information on the Internet]. 2014 [cited 2015 March 18]. Available from: <http://www.meadjohnson.com/pediatrics/us-en/product-information/products/infants/enfamil-gentlease>
 Perrigo Nutritionals. [Product information online]. 2015 [cited 2015 March 18]. Available from: <http://www.perrigonutritionals.com/infant-formulas.aspx>

NOTES: COMMERCIALY PREPARED INFANT FORMULA FOR HEALTHY TERM INFANTS
A. Breastmilk is the normal and unequalled food for infants. (1)

B. All commercially available infant formulas contain adequate iron for the healthy term infant. Cow's milk-based infant formulas on the market currently contain added iron in the amounts of 4 to 13 mg/L. (2) For most healthy term infants there is no need to choose a formula with iron at the higher range. (3,4) Infant formula containing an amount at the higher end of the range may need to be recommended for infants at risk of iron deficiency. This includes infants with a birth weight of less than 3000 grams; those born to iron deficient mothers, mother with diabetes, or mothers who consumed excess alcohol during pregnancy; or those not fed according to current recommendations. (2)

C. DHA & ARA (Omega 3 & 6)

DHA (docosahexanoic acid) and ARA (arachidonic acid) are long-chain polyunsaturated fatty acids (LCPUFA) that have a role in brain and retina development. (5) DHA and ARA and their precursors are found naturally in breastmilk. (6)

All infant formulas contain linoleic acid and alpha-linolenic acid, essential fatty acids that are precursors to DHA and ARA. (2) The addition of DHA and ARA is not currently mandatory in Canada. (2) If they are present, these two fatty acids are often referred to as "omega 3 and omega 6", respectively, on formula labels. There are currently no Canadian federal guidelines that specify levels of DHA and ARA to be added. (7) These formulas currently have a higher cost than the same formula without added DHA & ARA. For term infants, the supplementation of infant formulas with LCPUFAs may provide possible benefits for visual and neurodevelopmental outcomes but results are inconsistent. (8) As there are potential benefits and no known adverse effects, parents may choose to provide a formula with DHA and ARA added based on selections available and their financial means. (8) However, at this time the evidence is not strong or consistent enough to make a public health recommendation for all infants to require formulas with added DHA and ARA. (9) The preferred source of nutrition for infants is breast milk, and the availability of infant formulas containing DHA and ARA does not change this recommendation. (8)

D. Formulas with Probiotics (Cow's Milk)

Probiotics are live microorganisms which, when consumed in adequate amounts, confer a health benefit on the host. (10) Probiotics can have potential health benefits for infants (12,13) if specific strains are consumed at proper doses. (11) More research is needed to determine the best dose, strain and duration for a specified use or disease. (14) *Bifidobacterium animalis* subsp. *lactis* (also known as *B. lactis* (15)) is currently the only probiotic bacterium available in infant formula in Canada. (16) Although current infant formula supplemented with probiotics is safe for healthy term infants, (17) further studies are required to confirm any specific health benefits of infant formula with *B. lactis* before it can be recommended that probiotic cultures (including *B. lactis*) are needed in infant formula. Caregivers may choose an infant formula with probiotics based on the selections available to them. More research regarding the safety of probiotics in vulnerable groups such as premature and low birth weight infants still needs to be undertaken. (18)

Some manufacturers are adding prebiotics (nondigestible food components that beneficially affect the host by selectively stimulating growth and/or activity of one or a limited number of probiotics) to infant formula. (19) Galacto-oligosaccharides (GOS) and polydextrose (PDX) are 2 prebiotics that are currently added to infant formulas in Canada. Further research is needed before it can be recommended that prebiotics are needed in infant formula. More research is needed to determine the optimal dose and duration of supplementation. Parents and caregivers may choose an infant formula with prebiotics based on the selections available to them.

E. Organic Infant Formulas

Infant formulas certified as organic in this document have received organic certification from a certification body that has been accredited by the Canadian Food Inspection Agency (CFIA). (20) The organic certification does not represent specific claims about the health, safety and nutrition of the organic product. (22) While organic infant formulas are safe and acceptable choices, current evidence does not identify any health advantages to choosing organic food products over non-organic food products. (22) Caregivers may choose an organic infant formula based on the selections available to them and their preference for this food production method.

F. Nucleotides

Nucleotides play key roles in many biological processes. At this time, nucleotides may be added to commercially available infant formulas, but their addition is not mandatory. Some studies have shown that nucleotide supplementation to infant formulas may have potential health benefits for an infant's immune and gastrointestinal systems. (23) However, the majority of supplemented formulas do not contain the supplementation levels most research studies have associated with potential health benefits. (23) More research is still needed to show that supplementing infant formulas with nucleotides consistently leads to health benefits, and to identify the optimal level of supplementation. Because of possible benefits and lack of adverse effects of nucleotide supplementation, caregivers may choose formulas with added nucleotides based on the selections available to them.

G. Follow-Up Formulas (Cow's Milk)

Cow's milk follow-up formulas are not suitable for infants younger than 6 months², or for infants with a cow's milk allergy, lactose intolerance, or galactosemia.

Follow-up or second-stage formulas, which are designed for infants 6 months of age and older who are consuming complementary foods, may be used for infants older than 6 months, (25) but no superiority to starter formulas has been established. (25,26) These follow-up formulas contain higher amounts of calcium and phosphorus than starter formulas because the requirements for calcium increase for the second 6 months of life. (26,27) However, infants should begin to consume solid foods at 6 months and therefore additional calcium and phosphorus requirements should be met without difficulty from standard (starter) infant formulas and food sources. (26) Pasteurized whole cow's milk may be introduced to infants 9-12 months of age who are consuming a variety of iron-rich solid foods, and continued throughout the second year of life. (25)

H. Lactose-Free Formulas (Cow's Milk)

Lactose-free formulas are not suitable for infants with congenital lactase deficiency, a rare disorder, or galactosemia as these formulas may contain residual galactose. (25) Lactose free formulas are also not suitable for infants with confirmed cow's milk protein allergy and are ineffective in the dietary management of infant colic. (25)

Lactose-free formula has previously been recommended for infants with diarrhea and gastroenteritis because of the possibility of small intestinal injury during such illness. Breastfeeding during acute diarrhea is still recommended and is well tolerated in spite of its higher lactose content compared to most cow's milk formulas. However, breastmilk is often provided as smaller, more frequent feedings than infant formula and this may decrease the lactose load delivered per feed, resulting in enhanced absorption. (28) The routine use of lactose free formula during acute diarrhea is not justified in most cases. (29) Enough lactose digestion and absorption are typically preserved in acute gastroenteritis that low lactose and lactose-free formulas do not have clinical advantages over lactose-containing formulas. (25,29) If dehydration has been treated, or if mild to moderate dehydration is present, lactose-free formulas are not indicated. (29) If severe dehydration, malnourishment, or severe enteropathy exists or when a lactose-containing formula worsens the condition (confirmed lactase deficiency), then the use of a lactose-free or low lactose formula by formula fed infants may be justified. **Error! Bookmark not defined.** (29)

I. Formulas that Become Thickened

Spitting up is normal in infancy and only rarely leads to health problems such as failure to thrive. Further assessment is warranted if spitting up persists or increases in severity. (2) Formula that thickens in an infant's stomach is intended for infants with mild gastroesophageal reflux, and should be used only upon recommendation by a physician. Thickened formula does not measurably decrease symptom frequency among infants with severe reflux. This formula is not intended for infants who require specialized thickened formula due to swallowing difficulties. It is not recommended to thicken infant formula with the addition of infant cereals. (2)

J. Allergy Prevention

Breastfeeding is the preferred method of infant feeding for infants at high risk of allergy. (30-32) There is no evidence to support giving hydrolyzed formula over exclusive breastmilk to prevent allergies. (30) For infants who are not breastfed or are partially breastfed and are at high risk of allergy (at least one first-degree relative with a confirmed allergy), some research shows an extensively hydrolyzed casein formula or a partially hydrolyzed 100% whey formula may reduce the risk of allergy (30, 31,33-36), if used for the first 6 months of life. (32, 37-39) More research is needed to conclude how these types of infant formulas compare to each other in terms of allergy prevention. (30,34,39,40) Evidence does not support using either an extensively or partially hydrolyzed protein formula after 6 months for allergy prevention. (32,37,38)

K. Allergy Treatment

A breastfeeding mother should be encouraged and supported to continue breastfeeding; she may need to avoid all milk products herself if baby reacts to the milk protein in the mother's diet. If this is the case, nutrition counselling is recommended. (41) For non-breastfed babies, extensively hydrolyzed cow's milk-based formulas are the first choice in the treatment of cow's milk protein allergy. (42) Extensively hydrolyzed formulas are not available everywhere, cost more, have a poor palatability, and some infants are still allergic to the cow's milk peptides present in the hydrolysate and may require an amino acid-based formula. (41) Soy infant formula may be a second option for infants older than 6 months provided a tolerance to soy has been established. (41)

L. Soy Formulas

Soy formulas have been shown to support normal growth and development in term infants. (43-45) No overt harm has been proven with the use of currently available soy-based infant formulas as the sole source of nutrition for infants with the exception of preterm infants, infants with congenital hypothyroidism (43) and infants with renal failure. (46) Caregivers of infants who require a soy formula should offer a soy follow-up formula by 12 months of age to help meet the child's calcium needs.

Soy Starter Formulas

Indications for the use of soy formula should be limited to:

- (a) infants with galactosemia. (43,44)
 - (b) infants who cannot consume dairy-based products for cultural, ethical or religious reasons, such as vegetarian lifestyle. (43,44)
- Note: The vitamin D in soy formula is from an animal source. This information is important to share with vegan families. (47)

Soy formula is not suitable for:

- (a) Soy protein allergy
- (b) Prevention of allergy in healthy term infants at high risk of allergy. Based on available evidence soy formulas cannot be recommended for the prevention of allergic disease. (48)
- (c) Preterm infants. Soy infant formulas have a high aluminum content and aluminum toxicity may develop in preterm infants due to their reduced renal function. As aluminum competes with calcium for absorption, this may result in reduced skeletal mineralization (osteopenia). (46) The serum phosphorus concentrations are lower, and alkaline phosphatase concentrations are higher in preterm infants and infants with intrauterine growth restriction (IUGR) fed soy protein-based formula, compared to preterm infants fed cow milk-based formula. Therefore, the degree of osteopenia is increased in infants with low birth weight receiving soy protein-based formulas. (44) For preterm infants, cow milk protein-based formulas designed especially for preterm infants are superior to soy protein-based formula.

Soy formula is not indicated for:

- (a) Colic. Soy formula has no proven value in the prevention or management of infantile colic. (44)
- (b) Congenital hypothyroidism. Infants with congenital hypothyroidism fed soy formula need close monitoring, due to reported abnormal thyroid function. This does not appear to be a concern in infants with healthy thyroid function. (43,49)

If a **cow's milk protein allergy (CMPA)** is suspected, physician diagnosis and direction is required. The use of soy-based formulas is contraindicated for non-IgE-mediated CMPA due to the high rate of coincident soy allergies. If a non-IgE mediated CMPA can be satisfactorily ruled out, then the use of soy formula is not contraindicated and is an acceptable alternative as the coincident soy allergy for IgE mediated CMPA is much less frequent; about 10-14%. Because it is often not possible or practical to distinguish IgE- from non-IgE-mediated allergy, it is safer and more appropriate to recommend a protein hydrolysate formula to treat all infants with cow's milk protein allergy, (43,47) especially in infants younger than 6 months of age. (43,50) Soy formulas may be considered for therapeutic use *after 6 months of age* (43,49-51); however tolerance to soy protein should first be established by a clinical challenge under physician guidance. (49) Infants with documented cow milk protein-induced enteropathy or enterocolitis frequently are sensitive to soy protein and should not be given isolated soy protein-based formulas. (44)

Soy formulas contain phytoestrogens called isoflavones. (43) Isoflavones are non-steroidal chemicals that are structurally similar to estrogens. (52) Some studies found that most of the phytoestrogens present in the plasma of soy infant formula are in a conjugated form and therefore are unable to exert hormonal effects. (46) A lack of sufficient evidence is available to suggest that soy formulas adversely affect endocrine function, development or reproduction in infants. (43,44) However, further research is warranted and indications for use of soy formulas should be limited at this time to infants with galactosemia or congenital lactase deficiency and infants who cannot consume dairy-based products for cultural, ethical or religious reasons, such as vegetarian lifestyle.

Soy Follow-Up Formulas

Follow-up or second-stage formulas are intended for infants 6 months of age and older who are consuming complementary foods. (25) Caregivers of infants who require a soy formula should offer a soy follow-up formula by 12 months of age to help meet the child's calcium needs. Infants who require soy formula should remain on a soy follow-up formula until 2 years of age when they can then transition to a fortified plant-based beverage, such as a soy beverage. Follow-up soy formulas, if consumed in recommended amounts (500 mL per day) may not contribute enough calcium to meet the calcium requirements of a 1-year old. (27) Therefore, other calcium-rich foods will also need to be emphasized and consultation with a Registered Dietitian may be beneficial.

- M. **Whole cow's milk** is an appropriate alternative for infants after 9-12 months of age who are consuming iron-rich complementary foods at most meals, and continues to be recommended for the second year of life. (42)
- N. When reconstituted, nutritional content of formula is very similar, when comparing the powder, liquid concentrate or ready-to-serve form. Powdered infant formula is not sterile. Caregivers should be advised to follow the manufacturer's instructions (on the formula can label) carefully when preparing infant formula.

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