# Infant Formulas for Healthy Term Infants – Summary Sheet

FOR PROFESSIONAL USE ONLY

This document was prepared with the full recognition that breastmilk is the normal and unequalled food for infants. This information is intended for professional reference only when advising those who cannot or have made an informed decision not to breastfeed or to partially breastfeed.

## Cow's Milk Infant Formulas for Healthy Term Infants

### Cow's Milk Starter Formulas

- Earth's Best Organic with DHA & ARA (5)
- Enfamil A+ with DHA & ARA (9)
- Enfamil Lower Iron
- Enfamil with Iron
- Good Start
- Good Start with Omega 3 & 6 + GOS
- Good Start Probiotic with DHA & ARA (10)
- Kirkland Omega +
- Parent's Choice Lower Iron Milk Based
- Parent's Choice with Iron
- Parent's Choice with Omega 3 & 6
- Parent's Choice Organic with Omega 3 & 6 (5)
- Parent's Choice with Probiotic (10)
- President's Choice Lower Iron
- President's Choice with Iron
- President's Choice with Iron Omega + (9)
- President's Choice Organics with Iron Plus Omega 3 & 6 Step 1 (5)
- President's Choice Probiotic and Iron plus Omega 3 & 6 (10)
- Similac Lower Iron Step 1 (7)
- Similac Iron Fortified Step 1 (7)
- Similac Advance Step 1 with Omega 3 & 6 (7,9)
- Simply Kids Lower Iron
- Simply Kids with Iron
- Simply Kids Omega+

### Cow's Milk Follow-Up Formulas (6+ months)

- Enfamil 2
- Enfamil 2 A+ (9)
- Follow-Up Transition (With Iron and Calcium)
- Good Start 2
- Good Start 2 with Omega 3 & 6 (9)
- Good Start 2 Probiotic (with DHA & ARA) (10)
- Parent's Choice 2 Growing Up
- President's Choice Omega + 2
- President's Choice with Iron & Calcium
- Similac Advance Step 2 with Omega 3 & 6 +GOS (7,9)

## Specialized Infant Formulas

### Lactose Intolerance

Lactose-Free Formulas:

- Enfamil Lactose Free A+
- Kirkland Sensitive
- Parent's Choice Sensitive
- Similac Sensitive Lactose Free (7)

Low Lactose Formulas:

- Enfamil Gentlease A+ with DHA ARA
- Parent's Choice Gentle with Omega-3 & 6
- President's Choice Gentle with Omega-3 & 6
- Similac Partially Broken Down Protein with Omega 3 & 6 (7)

### Reflux

Formulas that become thickened:

- Enfamil Thickened A+ (9)

### High Risk of Allergy

Extensively Hydrolyzed Casein Formulas:

- Alimentum
- Nutramigen A+ with DHA & ARA
- Nutramigen A+ with DHA & ARA & LGG (10)
- Pregestimil A+ with DHA & ARA

Partially Hydrolyzed 100% Whey Formulas:

- Good Start
- Good Start Probiotic with DHA & ARA (10)
- Good Start with Omega 3 & 6 & GOS (9)

### Cow's Milk Allergy

Extensively Hydrolyzed Casein Formulas:

- Alimentum
- Nutramigen A+ with DHA & ARA
- Nutramigen A+ with DHA & ARA & LGG (10)
- Pregestimil A+ with DHA & ARA (7)

Amino Acid-Based Formulas:

- Neocate Infant DHA/ARA (7)
- Puramino A+

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

### Vegetarian, Cultural, Galactosemia

Soy Starter Formulas (0–12 Months):

- Earth's Best Organic Soy with Omega 3 & 6 (5)
- Enfamil Soy A+ (with DHA & ARA)
- Good Start Alsoy with Omega 3 & 6
- Similac Isomil (7)
- Similac Isomil with Omega 3 & 6 (7)

Soy Follow-Up Formulas (6+ Months):

- Good Start Alsoy 2 with Omega 3 & 6
- Similac Isomil Step 2 (7)

*Soy formula may be used after 6 months of age for cow's milk allergy if tolerance to soy protein has been established.*

*Note: offer soy follow-up formula by 12 months of age and continue until 2 years of age at which time soy beverage may be offered*

(5) Organic, (7) No Palm Olein, (9) 4.0 g/L Prebiotics, (10) Probiotics

Nutrition Services, Alberta Health Services
2018 Version: Products current as of January 8, 2018. Recommendations in this document will evolve as new evidence is available and as product formulations change.

# Infant Formulas for Healthy Term Infants Summary Sheet – Overall Recommendations

Alberta Health Services is committed to the protection, promotion, and support for breastfeeding. Breastfeeding is the normal and unequalled method of feeding infants. Exclusive breastfeeding for the first 6 months, and continued for up to 2 years or longer, is recommended for the healthy growth and development of infants and toddlers.(1) This document is intended for professional reference only when advising those who cannot or have made an informed feeding decision not to breastfeed or to partially breastfeed.

The only recommended alternative to breastmilk for infants younger than nine months of age is commercial infant formula. When reconstituted, the nutrition content of powder, liquid concentrate or ready-to-feed infant formulas is very similar. Powdered infant formula is not sterile, but can be safely used for healthy full term infants when prepared and handled appropriately. (1) Liquid concentrate or ready-to-feed formulas are recommended for infants at greatest risk of infection (ie. pre-term, low-birth weight, immunocompromised, or less than 2 months of age). (1) Advise parents to follow AHS guidelines for preparing infant formula and to follow the manufacturer's instructions (on the formula can label) for the amount of infant formula and water to use.

## 1 Allergy Prevention

Breastfeeding is the normal method of infant feeding for infants at high risk of allergy. (2,3,4)
There is no evidence to support giving hydrolyzed formula over exclusive breastmilk to prevent allergies. (2) 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 diagnosed atopic disease such as atopic dermatitis, asthma, allergic rhinitis, or food allergy), there is limited evidence that feeding with a hydrolyzed formula (i.e. extensively hydrolyzed casein infant formula or a partially hydrolyzed 100% whey infant formula) as compared to a standard cow's milk formula, can help reduce the risk of allergic disease, particularly eczema (2,3,5,6,7,8) if used for the first 6 months of life. (4,9,10,11) More research is needed to conclude how these types of infant formulas compare to each other in terms of allergy prevention. (2,6,11,12,13,14) Evidence does not support using either an extensively or partially hydrolyzed protein formula after 6 months for allergy prevention. (4,9,10)

## 2 Allergy Treatment

Encourage and support a breastfeeding mother 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. (15) For non-breastfed babies, extensively hydrolyzed casein formulas are the first choice in the treatment of cow's milk protein allergy. (16) Some infants are still allergic to the cow's milk peptides present in the hydrolysate and may require an amino acid-based formula. (15) Soy infant formula may be a second option for infants older than 6 months provided a tolerance to soy has been established under physician guidance. (15)

## 3 DHA & ARA (Omega 3 & 6)

DHA (docosahexanoic acid) and ARA (arachidonic acid) are long-chain polyunsaturated fatty acids (LCPUFA) that are considered essential for maturation of the developing brain, retina and other organs in newborn infants. (17,18) DHA and ARA and their precursors are found naturally in breastmilk. (19)
All infant formulas contain linoleic acid and alpha-linolenic acid, essential fatty acids that are precursors to DHA and ARA. (18) The addition of DHA and ARA is not mandatory in Canada. (16) 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 guidelines that specify levels of DHA and ARA to be added. (20) These formulas currently cost more than the same formula without added DHA and ARA. For term infants, the supplementation of infant formulas with DHA and ARA may provide visual and neurodevelopmental benefits but results are inconsistent. (21) As there are potential benefits and no known adverse effects, parents may select to provide a formula with added DHA and ARA based on options available and their financial means. (21) 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. (18) 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. (21)

## 4 Iron

In Canada, commercial infant formulas contain levels of iron of 6.5 to 13 mg/L which is acceptable for most healthy term infants. (22) Formulas with iron at the lower levels should be sufficient for most healthy term infants. (23,24) It is prudent to recommend that infants at risk of iron deficiency consume infant formula with iron levels at the higher end of the range (eg.10 – 13mg/L). 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. (22)

## 5 Organic 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). (25) The organic certification does not represent specific claims about the health, safety and nutrition of the organic product. (26) 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. (27,28) Parents may select an organic infant formula based on the selections available to them and their preference for this food production method.

## 6 Nucleotides

Currently, nucleotides may be added to commercially available infant formulas, but are 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. (29) However, most supplemented formulas do not contain the supplementation levels most research studies have associated with potential health benefits (29) 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, Parents may select formulas with added nucleotides based on the selections available to them.

## 7 Palm Olein (PO)

Fat sources in commercial infant formulas vary and include a mix of soy, coconut, sunflower, and safflower oils. Palm olein (PO) (from fractionated palm oil) is added to some infant formula to create a fat profile with 23% palmitic acid and 34% oleic acid, the same ratio found in human milk. (30,31) However, due to structural differences, the added PO results in insoluble fatty acids that form poorly absorbed salts that are excreted in stool, causing stools to be firmer, greener in colour, and less frequent.(30,31)
No growth or weight gain differences have been observed in infants consuming formula containing PO. (32)

Not all infant formulas contain PO; parents may select infant formulas based on the options available. As the addition of PO to infant formulas may cause hard/ firm stools (33); it may be worthwhile for infants with hard stools to try an infant formula that does not have PO added.

## 8 Partially Hydrolyzed Protein, Lactose Reduced Formulas

These infant formulas have reduced lactose levels and contain partially hydrolyzed whey and casein proteins, (34,35) and are marketed as "Easy to Digest" or for infants with fussiness and gas. (34,35) There is insufficient evidence for a need for these infant formulas in reducing colic. (36) In addition, evidence does not support using a partially hydrolyzed infant formula, containing both casein and whey proteins, for allergy prevention. (37) Partially hydrolyzed protein, lactose-reduced infant formulas are considered safe and acceptable choices; however, based on current evidence, there is no clear indication for the use of these infant formulas for most healthy term infants. (38) The only time lactose reduced infant formulas may be justified is for situations of severe dehydration, malnourishment, severe enteropathy, or when lactose-containing formula worsens the condition, such as with confirmed lactase deficiency. (36) Current lactose reduced formulas contain only 20-25% of the lactose (about 1.5 – 1.8g) of the standard cow's milk based formulas. (35,39)

## 9 Formulas with Prebiotics

Prebiotics are nondigestible food components that selectively stimulate growth and/or activity of one or a limited number of bacterial species in the colon. (40) Galacto-oligosaccharides (GOS) and polydextrose (PDX) are 2 prebiotics that are added to infant formulas in Canada. More 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. Formula fed infants not yet introduced to complementary foods experiencing hard stools may benefit from consuming an infant formula supplemented with GOS (4g/L) or PDX/GOS blend (2 g/L PDX and 2 g/L GOS). (41,42,43) Parents may select an infant formula with prebiotics based on the options available.

## 10 Formulas with Probiotics

Probiotics are live microorganisms which, when consumed in adequate amounts, confer a health benefit on the host. (44) If specific strains are consumed at proper doses, probiotics can have potential health benefits (45) for infants (46,47) More research is needed to determine the best dose, strain and duration. (48) *Bifidobacterium animalis* subsp *lactis* (*B. lactis*) (49) and *Lactobacillus rhamnosus* GG (LGG) are 2 probiotics currently available in infant formulas. (50) Although current infant formula supplemented with probiotics is safe for healthy term infants, (46,51,) further studies are needed before it can be recommended that probiotic cultures are needed in infant formula. Parents may select an infant formula with probiotics based on the selections available to them. More research is needed regarding the safety of probiotics in vulnerable groups such as premature and low birth weight infants.

## 11 Follow-Up Formulas (Cow's Milk)

Cow's milk follow-up formulas are not suitable for infants younger than 6 months (52), or for infants with a cow's milk allergy, lactose intolerance, or galactosemia.

Follow-up or second stage infant formulas, which are designed for infants 6 months of age and older who are consuming complementary food, (53) do not offer any nutrition or healthy benefits over infant formula. (53,54) 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. (55) However, infants begin to consume solid foods at 6 months and therefore additional calcium and phosphorus requirements should be met without difficulty from starter infant formulas and food sources. (54Error! Bookmark not defined.) Pasteurized 3.25% 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. (53)

## 12 Soy Formulas

Soy formulas have been shown to support normal growth and development in term infants. (56,57,58) The patterns of growth, bone health, reproductive, endocrine, immune and neurological functions are similar to those observed in children fed cow's milk infant formula or human milk. (59) 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 (56) and infants with renal failure. (59) Advise parents of infants who require a soy formula to offer a soy follow-up formula by 12 months of age to help meet the child's calcium needs.

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

a) infants with galactosemia. (56,57)
b) infants who cannot consume dairy-based products for cultural, ethical or religious reasons, such as vegetarian lifestyle. (56,57)

Note: The vitamin D in soy formula is from an animal source. This information is important to share with vegan families. (60)

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. (61)
(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). (59) 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. (57)

(d) Congenial 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. (62)

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 an acceptable alternative as the coincident soy allergy for IgE mediated CMPA is much less frequent. From a public health standpoint, until a non-IgE-mediated response has not been ruled out, it is safer and more appropriate to recommend a protein hydrolysate formula to treat all infants with cow's milk protein allergy. (56,60) Soy formulas may be considered for therapeutic use *after* 6 months of age (56,62,63,64); however tolerance to soy protein should first be established under physician guidance. (62) Do not give isolated soy formulas to infants who have a documented cow milk protein-induced enteropathy or enterocolitis as frequently these infants are sensitive to soy protein. (57)

Soy formulas contain phytoestrogens called isoflavones. (56) which are non-steroidal chemicals that are structurally similar to estrogens. (65) 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. (59) A lack of evidence is available to suggest that soy formulas adversely affect endocrine function, development or reproduction in infants. (56,57) 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.

## 13 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. (53) When an infant needs to continue on a soy formula, a soy follow-up formula is recommended by 12 months of age to help meet calcium needs. A soy follow-up formula is advised until 2 years of age at which time a child 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. (55) Therefore, other calcium-rich foods will also need to be emphasized and consultation with a Registered Dietitian may be beneficial.

## 14 Lactose-Free Formulas (Cow's Milk)

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. (38) The use of lactose free formula during acute diarrhea is not justified in most cases. (38,66) 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. (38,53) If dehydration has been treated, or if mild to moderate dehydration is present, lactose-free formulas are not indicated. (38) 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. (38,66)

Lactose-free formulas are not suitable for infants with congenital lactase deficiency, a rare disorder, or galactosemia as these formulas may contain residual galactose. (53) 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. (53)

## 15 Formulas that Become Thickened

Regurgitation (spitting up) is normal in infancy and only rarely leads to health problems such. In infants, regurgitation reflects physiological immaturity, usually improves without any medical intervention, (67) becomes less frequent with time, and resolves in 90% of infants before 1 year of age. (68) Further assessment is warranted if spitting up persists or increases in severity. (16) Gastroesophageal reflux (GER), with or without regurgitation is relatively common in healthy term infants with regurgitation occurring daily in approximately 50% of infants three - four months of age. (16,69) 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 frequency of reflux episodes but may decrease visible regurgitation which may improve quality of life for caregivers. (6969) 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 (16) as this may increase coughing during feeding and may increase the energy density of the formula causing excessive energy intake. (6969)

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