

WIC Formula Change 2007 Information for RDs and DNs

Responding to Concerns About Formula Tolerance When Changing Formulas

Find out more about symptoms – In most cases, concerns about formula tolerance will be due to normal physiological variations in infants or to problems with formula preparation or feeding practices. It is important to find out more about the symptoms the infant has been experiencing. The symptoms may be due to normal variations, or the infant may have a medical problem. A physician's documentation may be necessary in cases of severe symptoms of intolerance, such as projectile or recurrent vomiting, chronic diarrhea, or persistent dermatologic reactions.

- **Spitting up:** If it appears that the infant is experiencing normal spitting up and the formula preparation and feeding practices are appropriate, reassure the caregiver that the infant is fine. If the caregiver is still concerned or if the infant is experiencing significant problems, refer the infant to a health care provider.
- **Constipation or diarrhea:** A caregiver's concerns that her infant is constipated or has diarrhea are often found to be due to only slight variations in stool frequency or appearance. If the infant seems to be experiencing normal variation in his/her stools and the formula preparation and feeding practices are appropriate, reassure the caregiver that the infant is fine. If there appears to be a significant problem or if the caregiver is still concerned, refer the infant to a health care provider.
- **Skin problem:** A dermatologic symptom is unlikely to be related to a formula change. However, an infant with a persistent rash or skin problem should be referred to a health care provider who will determine whether a formula change is required.

Check formula preparation – Instructions on formula preparation and on checking expiration dates may alleviate symptoms. Be sure the caregiver dilutes the formula properly, keeps it refrigerated after mixing, discards any prepared formula after 24 hours, and discards any formula left in the bottle. Remember, preparation directions are on each can of formula, and Spanish instructions are found on the inside of the label.

Check feeding practices – Be sure the caregiver burps the baby often and does not make him/her finish the bottle. Minimal handling and upright positioning (hold the baby at a 45 to 65 degree angle) during and after feeding may reduce or eliminate the problem. The caregiver should always hold the baby during feeding and never prop the bottle.

Background Information

Facts about infant formula – The Infant Formula Act of 1980 (amended periodically) governs the manufacture of infant formulas, assuring their safety and nutrition. Under this Act, all infant formulas are required to meet minimum but not exceed maximum nutrient levels set by the FDA. These regulations came mainly from recommendations of the Committee on Nutrition of the American Academy of Pediatrics, and they represent the current scientific knowledge on nutrient needs of infants taking formula. The only exception to these regulations are for formulas intended for infants with unusual medical or dietary problems or congenital metabolic disorders.

The nutrient composition of available brands of milk-based and soy-based infant formulas meet the requirements of this Act. Table 1 summarizes the recommended nutrient levels of infant formulas for full-term infants. Tables 2 and 3 show nutrient levels for breastmilk and some milk-based and soy-based infant formulas. Note that the formulas are fairly comparable and, when consumed in adequate quantities, all meet an infant's need for growth. Table 4 shows nutrient content for several other formulas for specific needs.

Normal physiological variations in infants – All infants will at times regurgitate or spit up after feeding regardless of the type of feeding. Formula-fed infants may spit up more than breastfed infants. These are signs of severe vomiting requiring medical referral: vomiting large amounts or projectile (forceful) vomiting, especially if under 2 months old; vomiting fluid that is green or yellow or looks like coffee grounds or blood; difficulty breathing after vomiting or spitting up; refusing food and poor weight gain; or irritability and excessive crying.

Stool frequency is extremely variable in normal infants and may vary from none to seven per day. In general, as an infant matures frequency lessens. Breastfed infants may have more or less frequent stools than formula-fed infants. Constipation is not defined by infrequent stools but by consistency (dry, hard pellets). If stools are soft, the infant is not constipated.

The appearance (color and consistency) of stools varies with infants' age and diet. The earliest stools after birth consist of meconium, which is thick, sticky, and greenish-black. These are succeeded by transitional stools and then regular stools. Normal stool colors for infants are green, brown, yellow, orange, and combinations of these. As infants begin to eat solid foods, the types and amounts of food will affect both the frequency and appearance of the stools. Stools which are chalky white, tarry black, contain mucus, or contain bright red blood require medical referral. Diarrhea that irritates the skin or constipation that causes the infant to strain should also be referred to a health care provider.

Dermatological (skin) problems can be due to a variety of causes, most of which are unrelated to formula and would not be affected by a formula change.

Formula preparation – Incorrect formula preparation, particularly under-dilution of powder or concentrate, an unsanitary water supply, or out-of-date formula may cause symptoms which appear to be formula intolerance.

Feeding practices – Overfeeding or inadequate burping may result in excessive spitting up. Large amounts of juices, especially undiluted adult juices, may cause osmotic diarrhea. Constipation is often due to inadequate fluid intake.

**Table 1: Recommended Nutrient Levels for Infant Formulas
(Full-Term Infants)**

Nutrient (per 100 calories)	Minimum	Maximum
Protein (grams)	1.8	4.5
Fat (grams)	3.3 (30% of calories)	6.0 (54% of calories)
Essential Fatty Acids (% of calories)	2.7	--
Selected Vitamins		
A (IU)	250 (75 ug)	750 (225 ug)
D (IU)	40 (1 ug)	100 (2.5 ug)
C (mg)	8	--
B1 Thiamine (ug)	40	--
B2 Riboflavin (ug)	60	--
Niacin (ug)	250	--
Selected Minerals		
Calcium (mg)	60	--
Phosphorus (mg)	30	--
Magnesium (mg)	6	
Iron (mg)	0.15	3.0
Iodine (ug)	5	25
Sodium (mg)	20	60
Potassium (mg)	80	200
Chloride (mg)	55	150

Sources:

Pediatric Nutrition Handbook. American Academy of Pediatrics, 2004.

Federal Food, Drug, and Cosmetic Act, As amended through December 31, 2004, Requirements for Infant Formulas, Section 412.

**Table 2: Comparisons of Selected Modified
Cow's Milk-Based Infant Formulas**
(20 calories per ounce)

	Breastmilk	Enfamil LIPIL (Mead Johnson)	Similac Advance (Ross)	Store Brand (Wyeth)
Protein (grams per 100 milliliters)	0.9	1.5	1.4	1.5
Protein source	Human milk protein (whey 60%, casein 40%)	Whey, nonfat milk (whey 60%, casein 40%)	Nonfat milk, whey protein concentrate (whey 48%, casein 52%)	Nonfat milk, whey protein concentrate (whey 60%, casein 40%)
Fat (grams per 100 milliliters)	3.9	3.6	3.7	3.6
Fat source	Human milk fat	Palm olein, high-oleic sunflower, soy and coconut oils, DHA, ARA	High-oleic safflower, soy and coconut oils, DHA, ARA	Palm, high-oleic, coconut and soybean, safflower, or sunflower
Carbohydrate (grams per 100 milliliters)	6.7	7.3	7.3	7.2
Carbohydrate source	Lactose	Lactose	Lactose	Lactose
Osmolality (mOsm per kilogram water)	260-300	300	300	290

Sources:

Pediatric Nutrition Handbook. American Academy of Pediatrics, 2004.

Pediatric Formula Composition. Stanford University Medical Center, 2005.

Mead Johnson Nutritionals Product Labels. Mead Johnson Nutritionals, 2007.

**Table 3: Comparisons of Selected Modified Soy-Based Infant Formulas
(20 calories per ounce)**

	Enfamil ProSobee LIPIL (Mead Johnson)	Isomil Advance (Ross)	Store Brand (Wyeth)
Protein (grams per 100 milliliters)	1.7	1.7	1.8
Protein source	Soy protein isolate	Soy protein isolate	Soy protein isolate
Fat (grams per 100 milliliters)	3.6	3.7	3.6
Fat source	Palm olein, soy, coconut, and high-oleic sunflower oils, DHA, ARA	High-oleic safflower, soy, and coconut oils, DHA, ARA	Palm, high-oleic safflower or sunflower, coconut, and soy oils
Carbohydrate (grams per 100 milliliters)	7.2	7.0	6.9
Carbohydrate source	Corn syrup solids	Corn syrup solids, sucrose	Corn syrup solids, sucrose
Osmolality (mOsm per kilogram water)	200	200	228

Sources:

Pediatric Nutrition Handbook. American Academy of Pediatrics, 2004.

Pediatric Formula Composition. Stanford University Medical Center, 2005.

Mead Johnson Nutritionals Product Labels. Mead Johnson Nutritionals, 2007.

Table 4: Nutrient Content of Enfamil LactoFree LIPIIL, Similac Sensitive, Enfamil A.R. LIPIIL, Enfamil Gentlease LIPIIL, and Nestle Good Start (20 calories per ounce)

	Enfamil LactoFree LIPIIL	Similac Sensitive *	Enfamil A.R. LIPIIL	Enfamil Gentlease LIPIIL	Nestle Good Start *
Protein (grams per 100 milliliters)	1.4	1.4	1.7	1.5	1.5
Protein source	Milk protein isolate (whey 18%, casein 82%)	Milk protein isolate (whey 18%, casein 82%)	Nonfat milk (whey 18%, casein 82%)	Partially hydrolyzed nonfat milk, whey protein concentrate (whey 60%, casein 40%)	Partially hydrolyzed whey protein concentrate (whey 100%)
Fat (grams per 100 milliliters)	3.6	3.7	3.4	3.6	3.5
Fat source	Palm olein, soy, coconut, and high-oleic sunflower oils, DHA, ARA	High oleic safflower, soy, and coconut oils, DHA, ARA	Palm olein, soy, coconut, and high-oleic sunflower oils, DHA, ARA	Palm olein, soy, coconut, and high-oleic sunflower oils, DHA, ARA	Palm olein, soy, coconut, and high-oleic safflower oils
Carbohydrate (grams per 100 milliliters)	7.4	7.2	7.4	7.2	7.6
Carbohydrate source	Corn syrup solids	Maltodextrin, sucrose	Lactose, rice starch, maltodextrin	Corn syrup solids, lactose	Lactose, maltodextrin
Osmolality (mOsm per kilogram water)	200	200	230	220	260

*** For comparison purposes only**

Sources:

Pediatric Nutrition Handbook. American Academy of Pediatrics, 2004.
Pediatric Formula Composition. Stanford University Medical Center, 2005.
Mead Johnson Nutritionals Product Labels. Mead Johnson Nutritionals, 2007.

Additional Sources:

Textbook of Pediatrics, Nelson's 16th Edition. W.B. Saunders, 2000.
 Hyams JS et al., Effect of Infant Formula on Stool Characteristics of Young Infants. *Pediatrics* 95(1), 50-54.
 Parker S., Your Baby's Bowels: Color Changes. *WebMD*. www.webmd.com/content/Article/119/113533.htm (accessed 4/4/07).