



February 10, 2021

Dr. Susan T. Mayne
Director, Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
Silver Spring, Maryland 20993

Re: Misbranded infant formula products marketed for children over 12 months old

Dear Dr. Mayne,

The Center for Science in the Public Interest (CSPI), the UConn Rudd Center for Food Policy & Obesity, and Dr. Jennifer Pomeranz, JD, MPH, Assistant Professor, New York University, write to urge the Food and Drug Administration (FDA) to take immediate enforcement action against the marketing of misbranded products that are labeled as infant formula but are marketed for use by children over 12 months, including the products highlighted in this letter (herein, referred to as “transition formulas”).

These products are misbranded under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FDA regulations, and their labeling may mislead consumers to believe that infant formula and/or infant formula-like products are necessary for children beyond infancy or that they provide benefits beyond what can be obtained from a healthy diet of ordinary foods.

This letter provides a brief background on this category of products, discusses the violations of FFDCA and the grounds for FDA enforcement action, and provides examples of five misbranded products.

I. BACKGROUND

“Transition formulas” refers to milk and soy-based beverages marketed for an age group that includes both infants (children up to 12 months old) and toddlers (children over 12 months, and up to 36 months old). These products typically meet FDA’s nutrient requirements for infant formula,¹ are labeled as “infant formula” and/or “toddler formula,” and bear the FDA’s infant formula nutrition label² as opposed to the Nutrition Facts label required for all FDA-regulated food and beverages other than infant formula (See Appendix A). Yet, contrary to the appropriate use of formula, these products are marketed for children who are over 12 months old.

¹ 21 C.F.R. 107.100

² 21 C.F.R. 107.10-107.30

Transition formula is a relatively new product category, and its sales have dramatically increased in recent years. Global sales of formulas marketed for children ages 13 to 36 months old increased by 53% from 2008 to 2013.³

Transition formulas, however, are *not* recommended by health authorities for children over 12 months old.⁴ Like infant formulas, these products are primarily composed of powdered milk, vegetable oil, corn syrup solids or other sources of added sugars, and added nutrients. While similar products are appropriate for infants, they are *not* appropriate for toddlers. These products contribute unnecessary added sugars to the diet and offer no unique nutritional value beyond what can be obtained through ordinary foods and beverages.⁵

According to a consensus statement from the Academy of Nutrition and Dietetics, the American Academy of Pediatric Dentistry, the American Academy of Pediatrics (AAP), and the American Heart Association (AHA), for children ages 1 to 5 years old, “toddler milk [defined as “Milk supplemented with nutrients and often containing added sugars...may be marketed as ‘transition formulas’”] is not recommended; nutrient needs should be met primarily through nutritionally adequate dietary patterns.”⁶ The only beverages recommended by these organizations for children ages 1 to 5 years are plain drinking water and plain, pasteurized milk.⁷

The potential for transition formulas to contribute added sugars to the diets of young children is particularly concerning. AAP,⁸ AHA,⁹ and the 2020-2025 Dietary Guidelines for Americans (DGA)¹⁰ recommend that added sugars should be avoided in the diets of children under 2 years of age.

In support of including this guidance in the DGA, the 2020 Dietary Guidelines Advisory Committee provided a threefold rationale. First, the committee found that the calories in added sugars are likely to displace calories from nutrient-dense foods in early childhood, increasing the risk of nutrient inadequacies. After conducting a systematic review, the DGAC also concluded that sugar-sweetened beverage consumption before 2 years of age is associated with increased risk of obesity later in childhood.¹¹ Finally, the DGAC noted the need to limit consumption of

3 Baker P, Smith J, Salmon L, et al. Global trends and patterns of commercial milk-based formula sales: is an unprecedented infant and young child feeding transition underway? *Public Health Nutrition*. 2016;19(4):2540-2550.

4 Lott M, et al. *Healthy Beverage Consumption in Early Childhood: Recommendations from Key National Health and Nutrition Organizations. Technical Scientific Report*. Healthy Eating Research. 2019.

5 *Id.*

6 *Id.*

7 *Id.*

8 Korioth T. Added sugar in kids' diets: How much is too much? *AAP News*. March 25, 2019. <https://www.aappublications.org/news/2019/03/25/sugarpp032519#:~:text=The%20AAP%20offers%20the%20following,under%202%20years%20of%20age>.

9 Vos MB, Kaar JL, Welsh JA, et al. Added sugars and cardiovascular disease risk in children: a scientific statement from the American Heart Association. *Circulation*. 2017;135:1017–1034.

10 U.S. Department of Agriculture and U.S. Department of Health and Human Services, Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov.

11 Dietary Guidelines Advisory Committee. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood. *Scientific Report of the Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services*. U.S. Department of Agriculture, Agricultural Research Service. 2020: 5. https://www.dietaryguidelines.gov/sites/default/files/2020-07/PartD_Ch5_ComplexFoods_first-print.pdf.

added sugars during a critical period for development of taste and flavor preferences. While additional research is needed to study the impact of consuming foods and beverages with added sugars on flavor preferences in early childhood, there is clear evidence that regular consumption of sugar-sweetened beverages in infancy and toddlerhood predicts greater consumption later in childhood.¹²

Even if caregivers are attentive to limiting added sugars in their children's diets, not all caregivers will recognize ingredients in transition formulas like "corn syrup solids" and "sucrose" as sources of added sugars. And since transition formulas typically bear FDA's infant formula label and not the Nutrition Facts label, their labels do not disclose the amount of carbohydrates that are total sugars and added sugars. Without knowing whether and how much added sugars are in products, caregivers have no way of meeting recommendations to avoid feeding added sugars to their toddlers.

In addition to potential health harms, transition formulas also have potential to cause economic harm to consumers. Transition formulas are considerably more expensive than cow's milk. The average cost per ounce of cow's milk was \$0.03 in 2019, while the cost of transition formula was at least triple (\$0.10-\$0.19)¹³ per prepared ounce of formula powder with water (Appendix B). Misconceptions that these products are healthy or even necessary for their children's growth and development may lead caregivers to purchase these expensive products in place of cow's milk. Labeling formula products only for the appropriate age group (*i.e.*, children under 12 months old) could protect caregivers from the economic harm of prolonging use of expensive formula products, which are neither necessary nor recommended for children over 12 months old.

II. PRODUCTS LABELED AS INFANT FORMULAS, BUT MARKETED FOR USE BY CHILDREN OVER 12 MONTHS, ARE MISBRANDED UNDER THE FFDCA

The FFDCA defines infant formula as "a food which purports to be or is represented for special dietary use *solely* as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk."¹⁴ An infant is defined under federal regulations as a person no more than 12 months old.¹⁵ Because infant formula may be marketed only for infants, infant formulas marketed for children over 12 months old are misbranded.

Furthermore, products marketed for children over 12 months old that do not bear the FDA's Nutrition Facts panel are misbranded. Any food product marketed for children over 12 months old must bear FDA's standard Nutrition Facts label and its requisite nutrient declarations. While infant formula is exempt from nutrition labeling requirements under 21 C.F.R. § 101.9, transition formulas marketed for children over 12 months old are not exempt. 21 C.F.R. § 101.9(j)(5)(i) states that:

12 Ziesmann A, et al. The Association between Early Childhood and Later Childhood Sugar-Containing Beverage Intake: A Prospective Cohort Study. *Nutrients*. 2019;11:2338.

13 This range excludes hypoallergenic varieties of transition formulas, made for young children with cow's milk allergies, which are even more expensive (\$0.38-\$0.48 per ounce) (*see* Appendix B).

14 FFDCA 201(z). Emphasis added.

15 21 C.F.R. § 105.3(e).

Foods, *other than infant formula*, represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age shall bear nutrition labeling. The nutrients declared for infants through 12 months of age and children 1 through 3 years of age shall include calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, dietary fiber, total sugars, added sugars, protein, and the following vitamins and minerals: Vitamin D, calcium, iron, and potassium.¹⁶

Transition formulas that are marketed to children over 12 months old (and therefore not subject to FDA's exemption of infant formulas), but that bear only the infant formula nutrition label, are misbranded because the infant formula nutrition label does not include information on saturated fat, trans fat, cholesterol, sodium, dietary fiber, total sugars, and added sugars.

III. FDA SHOULD TAKE IMMEDIATE ENFORCEMENT ACTION AGAINST THE MARKETING OF MISBRANDED TRANSITION FORMULA PRODUCTS

We have identified five products that are misbranded under FFDCA because they are marketed for children over 12 months old but do not bear the nutrient information required by FDA, and because they are labeled as “infant formula” but are also marketed for children over 12 months old.

Table 1. Misbranded “Transition Formula” Products

Parent Company	Brand	Product	Statement of Identity	Target Age on Label	Type of Nutrition Label (Infant formula vs. NFP)
Nestle	Gerber Good Start	Plant-based protein for toddlers	“Infant Formula with Iron”	9 to 24 months	Infant formula
Walmart	Parent’s Choice	Toddler Beginnings	“Infant Formula with Iron Milk-Based Powder”	9 to 18 months*	Infant formula
Mead Johnson & Company	Enfamil	Enfagrow Premium Toddler Transitions	“Infant & Toddler Formula”	9 to 18 months	Infant formula
Mead Johnson & Company	Enfamil	Puramino Hypoallergenic Infant Formula**	“Hypoallergenic Infant Formula amino acid-based powder with iron”	0 to 24 months	Infant formula
Mead Johnson & Company	Enfamil	Nutramigen Hypoallergenic Toddler Formula**	“Hypoallergenic Infant & Toddler Formula Powder with Iron”	9 to 36 months	Infant formula

NFP = Nutrition Facts Panel

*product label states “9 months & up”; marketing materials state “for babies 9-18 months”; see Appendix A

**specialty product marketed for children with cow’s milk allergies; FDA infant formula regulations still apply

16 21 C.F.R. § 101.9(j)(5)(i). Emphasis added.

All five of these products are formula products marketed for an age group that includes children over 12 months old, and none of these products are labeled with FDA's Nutrition Facts panel (Table 1). Instead, each of these products bears FDA's infant formula nutrition label which leaves out information on key nutrients that is required on the labels of products sold for children over 12 months old. Each of the products is therefore misbranded because it does not declare nutrition information required on such products under federal regulations.¹⁷

Three of these products (Gerber's "Plant-based protein for toddlers," Parent's Choice's "Toddler Beginnings," and Enfamil's "Puramino Hypoallergenic Infant Formula") are further misbranded because they are labeled as "infant formula" but are marketed for children more than 12 months old. FDA regulations define infant formula as a product represented *solely* as food for infants. Therefore, these products are either misbranded infant formula products that should only be marketed to infants, or a different type of food product misidentified as "infant formula."

The two remaining products, both from the brand Enfamil, are also misbranded because they are labeled with the statement of identity "infant and toddler formula," which is confusingly similar to "infant formula." This statement of identity does not adequately distinguish these products from infant formulas, including infant formulas from the same manufacturer. For example, Enfamil sells another product with nearly-identical branding as its "Hypoallergenic Infant & Toddler Formula Powder with Iron" but whose statement of identity is "Hypoallergenic Infant Formula Powder with Iron" (Appendix C). These products could be easily confused. The World Health Organization has described this practice of cross-branding breast-milk substitutes for infants and formulas intended for older children as a tactic used by the infant formula industry that "discourages breastfeeding and creates confusion about the use of infant formula" and a "clear...response to legislation that restricts marketing of formulas for infants."¹⁸

IV. CONCLUSION

We urge FDA to take swift enforcement action against the manufacturers of these misbranded products which present health and financial risks to young children and their families.

In addition to enforcement action, we also encourage FDA to establish new labeling requirements for beverages marketed for toddlers. In July 2020, we filed a citizen petition¹⁹ along with 27 other public health professionals and advocacy groups, that details specific updates to FDA's labeling regulations that we believe will help address consumer confusion regarding this product category. The petition requests that FDA require factual disclaimers to prevent consumer confusion between toddler beverages and infant formulas and amend 21 C.F.R. § 102 to establish a common or usual name for non-standardized beverages represented or purported to be for use by children 12 to 36 months old.

17 21 C.F.R. § 101.9(j)(5)(i)

18 World Health Organization, UNICEF. Cross-promotion of infant formula and toddler milks. 2019. <https://www.who.int/nutrition/publications/infantfeeding/information-note-cross-promotion-infant-formula.pdf?ua=1>. Accessed December 22, 2020.

19 Citizen Petition from Public Health Advocacy Institute, Inc. on behalf of 1,000 Days, et al. Docket Number FDA-2020-P-1718. July 29, 2020. <https://www.regulations.gov/document?D=FDA-2020-P-1718-0001>. Accessed December 19, 2020.

Thank you for considering these recommendations.

Sincerely,

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Appendix A

Principal Display Panels and Nutrition Labels for Five Misbranded Transition Formula Products

GERBER GOOD START: PLANT-BASED PROTEIN FOR TODDLERS



https://www.walmart.com/ip/Gerber-Good-Start-Soy-Infant-and-Toddler-Formula-Stage-3-24-oz/50280068?wmlspartner=wlp&selectedSellerId=0&&adid=2222222227038983426&wl0=&wl1=g&wl2=c&wl3=90380220872&wl4=aud-393207457166:pla-182540285552&wl5=9028088&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=50280068&veh=sem&gclid=EAIAIQobChMIydX4_aaK7QIVQeWzCh2F1wN0EAQYAyABEgJ4dPD_BwE

Accessed December 19, 2020

GERBER GOOD START: PLANT-BASED PROTEIN FOR TODDLERS (CONT.)



https://www.walmart.com/ip/Gerber-Good-Start-Soy-Infant-and-Toddler-Formula-Stage-3-24-oz/50280068?wmlspartner=wlp&selectedSellerId=0&&adid=2222222227038983426&wl0=&wl1=g&wl2=c&wl3=90380220872&wl4=aud-393207457166:pla-182540285552&wl5=9028088&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=50280068&veh=sem&gclid=EAIAiQobChMIydX4_aaK7QIVQeWzCh2F1wN0EAQYAyABEgJ4dPD_BwE

Accessed December 19, 2020

PARENT'S CHOICE: TODDLER BEGINNINGS



https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwivbsBRDsARIsADyISJ80efgUFQa-yT8Ho9lxRY2cJuAOkjvxaTyKJIKZEgyPglKFouSReU4aAkUnEALw_wcB

Accessed December 19, 2020

PARENT'S CHOICE: TODDLER BEGINNINGS (CONT.)

The screenshot shows the Walmart.com website interface. At the top, there are navigation icons (back, forward, search, etc.) and the URL: walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwvbsBRDsARIsADyISJ80efgUFQa-yT8Ho9lxRY2cJuAOkjvxaTyKJIKZEgyPgIKFouSReU4aAkUnEALw_wcB

The main header includes "Pickup & delivery" and "Walmart.com". Below the header is the Walmart logo and a search bar with the placeholder "Search Walmart.com". A yellow magnifying glass icon is on the right side of the search bar.

About This Item

We aim to show you accurate product information. Manufacturers, suppliers and others provide what you see here, and we have not verified it. [See our disclaimer](#)

Compare to the nutrition of Enfagrow Premium® Toddler Transitions™. Toddler Beginnings® Infant Formula Powder With Iron is for babies 9-18 months. It has calcium for growing bones and is suitable for children on a diet supplemented with baby cereals and baby foods. No preservatives, artificial sweeteners or colors. Made with ingredients that are not genetically engineered. Toddler Beginnings® Infant Formula has Triple Care™ to support brain, immunity, growth. Non-GMO: Ingredients not genetically engineered

[https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwvbsBRDsARIsADyISJ80efgUFQa-yT8Ho9lxRY2cJuAOkjvxaTyKJIKZEgyPgIKFouSReU4aAkUnEALw_wcB">https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwvbsBRDsARIsADyISJ80efgUFQa-yT8Ho9lxRY2cJuAOkjvxaTyKJIKZEgyPgIKFouSReU4aAkUnEALw_wcB](https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwvbsBRDsARIsADyISJ80efgUFQa-yT8Ho9lxRY2cJuAOkjvxaTyKJIKZEgyPgIKFouSReU4aAkUnEALw_wcB)

Accessed December 19, 2020

PARENT'S CHOICE: TODDLER BEGINNINGS (CONT.)

USE BEFORE DATE ON BOTTOM OF CAN.

INGREDIENTS: NONFAT MILK, VEGETABLE OILS (PALM OLEIN, SOY, COCONUT, HIGH OLEIC (SAFFLOWER OR SUNFLOWER) OIL), CORN SYRUP, LACTOSE, GALACTOOLIGOSACCHARIDES[‡], CALCIUM PHOSPHATE, **LESS THAN 1%**: MORTIERELLA ALPINA OIL*, CRYPTHECODINIUM COHNII OIL**, FRUCTOOLIGOSACCHARIDES[‡], LUTEIN, MIXED TOCOPHEROL CONCENTRATE, MONOGLYCERIDES, SOY LECITHIN, VITAMIN A PALMITATE, VITAMIN D (CHOLECALCIFEROL), VITAMIN E (*d*-ALPHA TOCOPHERYL ACETATE), VITAMIN K (PHYTONADIONE), ASCORBYL PALMITATE, BETA-CAROTENE, THIAMINE HYDROCHLORIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE, CYANOCOBALAMIN, NIACINAMIDE, FOLIC ACID, CALCIUM PANTOTHENATE, BIOTIN, ASCORBIC ACID, CHOLINE BITARTRATE, INOSITOL, CALCIUM CARBONATE, CALCIUM HYDROXIDE, CUPRIC SULFATE, FERROUS SULFATE, MANGANESE SULFATE, POTASSIUM HYDROXIDE, POTASSIUM BICARBONATE, POTASSIUM CHLORIDE, POTASSIUM PHOSPHATE, SODIUM CITRATE, SODIUM SELENITE, ZINC SULFATE, L-CARNITINE, TAURINE, NUCLEOTIDES (ADENOSINE-5'-MONOPHOSPHATE, CYTIDINE-5'-MONOPHOSPHATE, DISODIUM GUANOSINE-5'-MONOPHOSPHATE, DISODIUM URIDINE-5'-MONOPHOSPHATE).

CONTAINS MILK AND SOY INGREDIENTS.

DILUTED: EACH 5 FL OZ (150mL) CONTAINS 100 CALORIES

NUTRIENTS:	PER 100 CALORIES:	VITAMINS:	PER 100 CALORIES:
PROTEIN g	2.6	BIOTIN mcg	3
FAT g	5.3	VITAMIN C (ASCORBIC ACID) mg	12
CARBOHYDRATE g	10.8	CHOLINE mg	24
WATER g.....	131	INOSITOL mg	6
LINOLEIC ACID mg	800	MINERALS:	
VITAMINS:		CALCIUM mg.....	200
VITAMIN A IU	300	PHOSPHORUS mg.....	130
VITAMIN D IU	60	MAGNESIUM mg.....	8
VITAMIN E IU	2	IRON mg	1.5
VITAMIN K mcg	9	ZINC mg	1
THIAMINE (VITAMIN B ₁) mcg	80	MANGANESE mcg.....	15
RIBOFLAVIN (VITAMIN B ₂) mcg	140	COPPER mcg.....	75
VITAMIN B ₆ mcg	60	IODINE mcg.....	10
VITAMIN B ₁₂ mcg.....	0.3	SELENIUM mcg.....	2.8
NIACIN mcg	1000	SODIUM mg	36
FOLIC ACID (FOLACIN) mcg.....	16	POTASSIUM mg	130
PANTOTHENIC ACID mcg	500	CHLORIDE mg.....	80

https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwivbsBRDsARIAsAdyISJ80efgUFQa-yT8Ho9lxRY2cJuAOkjvxaTyKJIKZEgyPgIKFouSReU4aAkUnEALw_wcB

Accessed December 19, 2020

ENFAMIL: ENFAGROW PREMIUM TODDLER TRANSITIONS



https://www.amazon.com/Enfagrow-PREMIUM-Non-GMO-Toddler-Transitions/dp/B0039NMF9E/ref=sr_1_10?keywords=enfagrow&qid=1570643673&sr=8-10

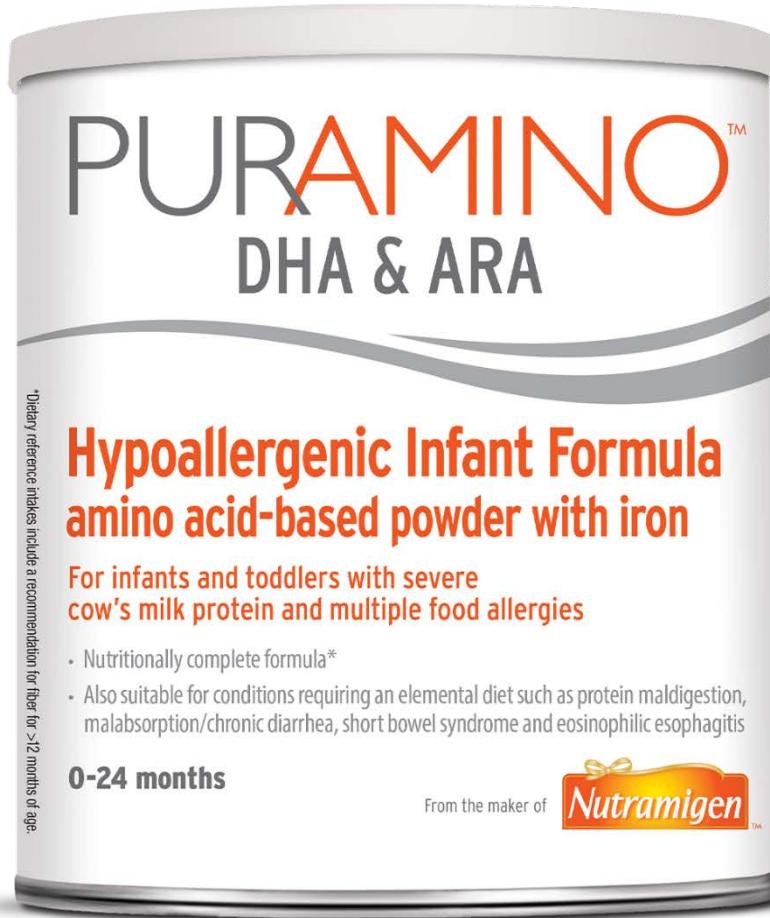
Accessed December 19, 2020

ENFAMIL: ENFAGROW PREMIUM TODDLER TRANSITIONS (CONT.)

NUTRIENTS / NUTRIENTES		
(Normal Dilution); per 100 Calories (5 fl oz)		
(Dilución Normal); por 100 Calorías (5 onzas líquidas)		
<hr/>		
PROTEIN / PROTEÍNA	g	2.6
FAT / GRASA	g	5.3
CARBOHYDRATE / CARBOHIDRATO	g	10.8
WATER / AGUA	g	132
LINOLEIC ACID / ÁCIDO LINOLEICO	mg	780
<hr/>		
VITAMINS / VITAMINAS		
A	IU / UI	300
D	IU / UI	60
E	IU / UI	2
K	mcg	9
THIAMIN / TIAMINA (B ₁)	mcg	80
RIBOFLAVIN / RIBOFLAVINA (B ₂)	mcg	140
B ₆	mcg	60
B ₁₂	mcg	0.3
NIACIN / NIACINA	mcg	1000
FOLIC ACID / ÁCIDO FÓLICO (FOLACIN / FOLACINA) ...	mcg	16
PANTOTHENIC ACID / ÁCIDO PANTOTÉNICO	mcg	500
BIOTIN / BIOTINA	mcg	3
C (ASCORBIC ACID / ÁCIDO ASCÓRBICO)	mg	12
CHOLINE / COLINA	mg	24
INOSITOL / INOSITOL	mg	6
<hr/>		
MINERALS / MINERALES		
CALCIUM / CALCIO	mg	200
PHOSPHORUS / FÓSFORO	mg	130
MAGNESIUM / MAGNESIO	mg8
IRON / HIERRO	mg	1.5
ZINC / CINC	mg	1
MANGANESE / MANGANESO	mcg	15
COPPER / COBRE	mcg	75
IODINE / YODO	mcg	10
SELENIUM / SELENIO	mcg	2.8
SODIUM / SODIO	mg	36
POTASSIUM / POTASIO	mg	130
CHLORIDE / CLORURO	mg	80

<https://www.walmart.com/ip/Enfagrow-Premium-Toddler-Transitions-Formula-Powder-20-oz-Can/14017993>. Accessed December 19, 2020.

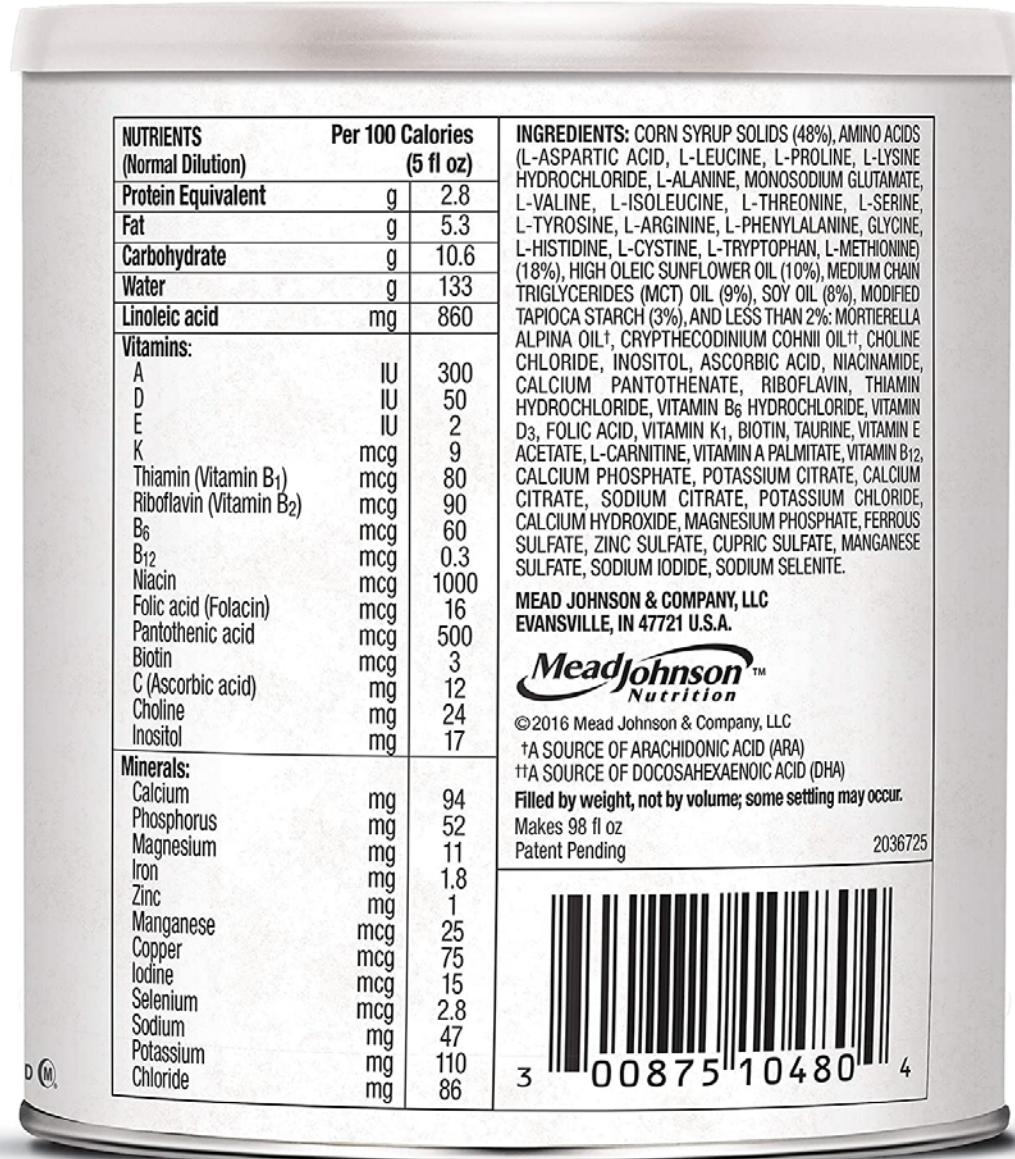
ENFAMIL: PURAMINO HYPOALLERGENIC INFANT FORMULA



<https://www.amazon.com/Puramino-Hypoallergenic-Formula-Powder-Allergies/dp/B00AQJPYN8>

Accessed December 19, 2020

ENFAMIL: PURAMINO HYPOALLERGENIC INFANT FORMULA (CONT.)



<https://www.amazon.com/Puramino-Hypoallergenic-Formula-Powder-Allergies/dp/B00AQJPYN8>

Accessed December 19, 2020

ENFAMIL: NUTRAMIGEN TODDLER HYPOALLERGENIC INFANT & TODDLER FORMULA WITH IRON



<https://www.walmart.com/ip/Enfamil-Nutramigen-Hypoallergenic-Toddler-Formula-with-Enflora-LGG-Lactose-Free-Powder-12-6-oz-Can/23872225>

Accessed December 19, 2020

ENFAMIL: NUTRAMIGEN TODDLER HYPOALLERGENIC INFANT & TODDLER FORMULA WITH IRON (CONT.)



<https://www.walmart.com/ip/Enfamil-Nutramigen-Hypoallergenic-Toddler-Formula-with-Enflora-LGG-Lactose-Free-Powder-12-6-oz-Can/23872225>

Accessed December 19, 2020

Appendix B

Price comparison of cow's milk and transition formula products

	Cow's milk ²⁰	Gerber Good Start: Plant-based protein for toddlers ²¹	Parent's Choice: Toddler Beginnings ²²	Enfamil: Enfagrow Premium Toddler Transitions ²³	Enfamil: PurAmino Hypoallergenic Infant Formula* ²⁴	Enfamil: Nutramigen Toddler* ²⁵
Grams per container	-	680	567	567	400	357
Price per container	\$3.45/gallon	\$17.48	\$11.83	\$18.98	\$42.92	\$28.86
Grams per 2 oz preparation	-	8.9	9.5	9.0	9.0	9.3
Price per prepared fluid ounce	\$0.03	\$0.11	\$0.10	\$0.15	\$0.48	\$0.38

*specialty product marketed for children with cow's milk allergies; FDA infant formula regulations still apply

20 U.S. Department of Agriculture. Retail Milk Prices Report. December 23, 2019.

<https://www.ams.usda.gov/sites/default/files/media/RetailMilkPrices2019.pdf>. Accessed December 19, 2020.

21 https://www.walmart.com/ip/Gerber-Good-Start-Soy-Infant-and-Toddler-Formula-Stage-3-24-oz/50280068?wmlspartner=wlp&selectedSellerId=0&&adid=2222222227038983426&wl0=&wl1=g&wl2=c&wl3=90380220872&wl4=aud-393207457166:pla-182540285552&wl5=9028088&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=50280068&veh=sem&gclid=EAIAIQobChMIydX4_aaK7QIVQeWzCh2F1wN0EAQYAyABEgJ4dPD_BwE. Accessed on December 19, 2020.

22 [https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwvbsBRDsARIsADyISJ80efgUFQavT8Ho9lxRY2cJuAOkjvxaTyKJKZEgyPglKFouSReU4aAkUnEALw_wcB">https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwvbsBRDsARIsADyISJ80efgUFQavT8Ho9lxRY2cJuAOkjvxaTyKJKZEgyPglKFouSReU4aAkUnEALw_wcB](https://www.walmart.com/ip/Parent-s-Choice-Toddler-Beginnings-Infant-Formula-with-Iron-20-oz/55522142?wmlspartner=wlp&selectedSellerId=0&adid=2222222227082720378&wl0=&wl1=g&wl2=c&wl3=195017225227&wl4=pla-311244932091&wl5=&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=online&wl12=55522142&veh=sem&gclid=Cj0KCQjwvbsBRDsARIsADyISJ80efgUFQavT8Ho9lxRY2cJuAOkjvxaTyKJKZEgyPglKFouSReU4aAkUnEALw_wcB). Accessed on December 19, 2020.

23 <https://www.walmart.com/ip/Enfagrow-Premium-Toddler-Transitions-Formula-Powder-20-oz-Can/14017993>. Accessed on December 19, 2020.

24 <https://www.walmart.com/ip/Puramino-DHA-and-ARA-Hypoallergenic-Formula-with-Iron-Powder-14-1-oz-Can/43330700>. Accessed on December 19, 2020.

25 https://www.walmart.com/ip/Enfamil-Nutramigen-Hypoallergenic-Toddler-Formula-with-Enflora-LGG-Lactose-Free-Powder-12-6-oz-Can/23872225?wmlspartner=wlp&selectedSellerId=0&wl13=2348&&adid=2222222227017588717&wl0=&wl1=g&wl2=c&wl3=40340822672&wl4=aud-393207457166:pla-78298637912&wl5=9010494&wl6=&wl7=&wl8=&wl9=pla&wl10=8175035&wl11=local&wl12=23872225&veh=sem&gclid=EAIAIQobChMI-93Fqfra7QIVSrzACh1pcAqFEAQYASABEgJQGvD_BwE. Accessed December 15, 2020

Appendix C



NUTRIENTS		INGREDIENTS	
(Normal Dilution); per 100 Calories (5 fl oz)		CORN SYRUP SOLIDS (47%), VEGETABLE OIL (PALM OLEIN, COCONUT, SOY, AND HIGH OLEIC SUNFLOWER OILS) (26%), CASEIN HYDROLYSATE (MILK) (17%), MODIFIED CORN STARCH (6%), AND LESS THAN 2%: MORTIERELLA ALPINA OIL, SCHIZOCHYTRIUM SP. OIL ¹ , LACTOBACILLUS RHAMNOUS ¹ , CALCIUM CHLORIDE, POTASSIUM CITRATE, SODIUM CITRATE, CALCIUM HYDROXIDE, MAGNESIUM OXIDE, FERROUS SULFATE, ZINC SULFATE, CUPRIC SULFATE, MANGANESE SULFATE, SODIUM IODIDE, SODIUM SELENITE, CHOLINE CHLORIDE, ASCORBIC ACID, NIACINAMIDE, CALCIUM PANTOTHENATE, VITAMIN D ₃ , THIAMIN HYDROCHLORIDE, RIBOFLAVIN, VITAMIN B ₆ HYDROCHLORIDE, FOLIC ACID, VITAMIN K ₁ , BIOTIN, VITAMIN B ₁₂ , INOSITOL, VITAMIN A PALMITATE, VITAMIN E ACETATE, L-CYSTINE, L-TYROSINE, L-TRYPTOPHAN, TAURINE, L-CARNITINE.	
PROTEIN	g 2.6		
FAT	g 5.3		
CARBOHYDRATE	g 10.3		
WATER	g 131		
LINOLEIC ACID	mg 780		
VITAMINS		MEAD JOHNSON & COMPANY, LLC, EVANSVILLE, IN 47721 U.S.A.	
A	IU 300		
D	IU 60		
E	IU 2		
K	mcg 90		
THIAMIN (B ₁)	mcg 80		
BIOTIN	mcg 90		
RIBOFLAVIN (B ₂)	mcg 60		
B ₆	mcg 0.3		
B ₁₂	mcg 1000		
FOLIC ACID (FOLACIN)	mcg 16		
PANTOTHENIC ACID	mcg 500		
BIOTIN	mcg 3		
C (ASCORBIC ACID)	mg 12		
CHOLINE	mg 24		
INOSITOL	mg 24		
MINERALS		*MODIFIED TO BE BETTER TOLERATED IN MILK-ALLERGIC BABIES	
CALCIUM	mg 94		
PHOSPHORUS	mg 52		
MAGNESIUM	mg 8		
IRON	mg 1.8		
ZINC	mg 1		
MANGANESE	mcg 25		
COPPER	mcg 75		
IODINE	mcg 15		
SELENIUM	mcg 2.8		
SODIUM	mg 47		
POTASSIUM	mg 110		
CHLORIDE	mg 86		
VITAMINS		This exclusive formula is available only from the Enfamil brand.	
A	IU 300		
D	IU 60		
E	IU 1.65		
K	mcg 13		
THIAMIN (B ₁)	mcg 180		
RIBOFLAVIN (B ₂)	mcg 180		
B ₆	mcg 154		
B ₁₂	mcg 0.3		
NIACIN	mcg 154		
FOLIC ACID (FOLACIN)	mcg 660		
PANTOTHENIC ACID	mcg 660		
BIOTIN	mcg 19		
C (ASCORBIC ACID)	mg 19		
CHOLINE	mg 24		
INOSITOL	mg 17		
MINERALS		MEAD JOHNSON & COMPANY, LLC, EVANSVILLE, IN 47721 U.S.A.	
CALCIUM	mg 130		
PHOSPHORUS	mg 72		
MAGNESIUM	mg 10		
IRON	mg 1.6		
ZINC	mg 1.1		
MANGANESE	mcg 50		
COPPER	mcg 50		
IODINE	mcg 17.6		
SELENIUM	mcg 2.5		
SODIUM	mg 37		
POTASSIUM	mg 122		
CHLORIDE	mg 80		

<https://www.walmart.com/ip/Nutramigen-Hypoallergenic-Infant-Formula-with-Enflora-LGG-Powder-12-6-oz-Can/14017994>

Accessed December 19, 2020



NUTRIENTS		INGREDIENTS	
(Normal Dilution); per 100 Calories (5 fl oz)		CORN SYRUP SOLIDS (55%), VEGETABLE OIL (PALM OLEIN, COCONUT, SOY, AND HIGH OLEIC SUNFLOWER OILS) (20%), CASEIN HYDROLYSATE (MILK) (14%), MODIFIED CORN STARCH (6%), AND LESS THAN 2%: MORTIERELLA ALPINA OIL, SCHIZOCHYTRIUM SP. OIL ¹ , LACTOBACILLUS RHAMNOUS ¹ , CALCIUM CHLORIDE, POTASSIUM CITRATE, SODIUM CITRATE, CALCIUM HYDROXIDE, MAGNESIUM OXIDE, FERROUS SULFATE, ZINC SULFATE, CUPRIC SULFATE, MANGANESE SULFATE, SODIUM IODIDE, SODIUM SELENITE, ASCORBIC ACID, NIACINAMIDE, CALCIUM PANTOTHENATE, VITAMIN B ₆ HYDROCHLORIDE, RIBOFLAVIN, VITAMIN D ₃ , THIAMIN HYDROCHLORIDE, FOLIC ACID, VITAMIN K ₁ , BIOTIN, VITAMIN B ₁₂ , INOSITOL, VITAMIN A PALMITATE, VITAMIN E ACETATE, L-CYSTINE, L-TYROSINE, L-TRYPTOPHAN, TAURINE, L-CARNITINE.	
PROTEIN	g 2.3		
FAT	g 4.3		
CARBOHYDRATE	g 12.8		
WATER	g 131		
LINOLEIC ACID	mg 640		
VITAMINS		*MODIFIED TO BE BETTER TOLERATED IN MILK-ALLERGIC BABIES	
A	IU 300		
D	IU 60		
E	IU 1.65		
K	mcg 13		
THIAMIN (B ₁)	mcg 180		
RIBOFLAVIN (B ₂)	mcg 180		
B ₆	mcg 154		
B ₁₂	mcg 0.3		
NIACIN	mcg 154		
FOLIC ACID (FOLACIN)	mcg 660		
PANTOTHENIC ACID	mcg 660		
BIOTIN	mcg 19		
C (ASCORBIC ACID)	mg 19		
CHOLINE	mg 24		
INOSITOL	mg 17		
MINERALS		MEAD JOHNSON & COMPANY, LLC, EVANSVILLE, IN 47721 U.S.A.	
CALCIUM	mg 130		
PHOSPHORUS	mg 72		
MAGNESIUM	mg 10		
IRON	mg 1.6		
ZINC	mg 1.1		
MANGANESE	mcg 50		
COPPER	mcg 50		
IODINE	mcg 17.6		
SELENIUM	mcg 2.5		
SODIUM	mg 37		
POTASSIUM	mg 122		
CHLORIDE	mg 80		

<https://www.walmart.com/ip/Enfamil-Nutramigen-Hypoallergenic-Toddler-Formula-with-Enflora-LGG-Lactose-Free-Powder-12-6-oz-Can/23872225>

Accessed December 19, 2020