CATEGORY RESOURCE GUIDE

Infant formula

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

EN0191 – Abbott Nutrition
EN0192 – Gerber Products Co.
EN0193 – Mead Johnson & Co.
FD9033 – Gerber Products & Co.

Distribution

Both direct and distributed through the following distribution channels:

Medical-surgical
Pharmacy
Food

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Questions? Contact supplyassurance@vizientinc.com, pharmacyquestions@vizientinc.com, novaplus@vizientinc.com.

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Making supply uncertainty a thing of the past, not the future

To help members maintain supply assurance for essential products, Vizient shares insights via **category resource guides** on vizientinc.com. These category-specific documents contain comprehensive manufacturing, logistics and utilization insights to help members source supplies with confidence. Category resource guides are one way we're building supply assurance together.

Manufacturing insights

Product overview

Infant formula is defined 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," according to The Federal Food, Drug, and Cosmetic Act (FFDCA) (FFDCA 201(z)). Infants are those not older than 12, according to the U.S. Food and Drug Administration (FDA) regulations (Title 21, Code of Federal Regulations 21 CFR 105.3(e)).

Infant formulas are liquids or reconstituted powders fed to infants and young children to serve as substitutes for human milk. Infant formulas have a special role in the diet because they are the only source of nutrients for some infants. All formulas are classified based on three parameters: caloric density, carbohydrate source and protein composition.

Cow's milk-based formulas account for about 80% of the formula sold. It is treated by heating and other methods to make the protein more digestible.

Women, Infants and Children (WIC) recipients who are families of low-income women, infants and children up to age 5 receive almost half of all U.S. formula. While WIC is a nationwide program designed to support these low-income families at nutritional risk, it is administered by states that usually negotiate with infant formula manufacturers to receive rebates for offering only one brand,

Infant formulas can have a maximum of nine nutrients from a list of 29 that have nutrient minimums as defined by the FDA (412(i) of the FFDCA and 21 CFR 107.100). An infant formula that does not meet these standards is considered "adulterated" unless there is an exemption. Exempt infant formula "is represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight, or who otherwise has an unusual medical or dietary problem" (FFDCA 412(h)(1).

All formulas marketed in the U.S. must meet federal nutrient requirements.

Selection factors

According to the American Academy of Family Physician, when choosing an infant formula, consider the following:

Class	Calories/oz.	Carbohydrate source	Protein source	Indication
Breast milk	20	Lactose	Human milk	Preferred for all infants
Term formula	20	Lactose	Cow's milk	Appropriate for most infants
Term formula with docosahexaenoic acid (DHA) and arachidonic acid (AA)	20	Lactose	Cow's milk	Marketed to promote eye and brain development
Preterm formula	24	Lactose	Cow's milk	Less than 34 weeks' gestation; weight less than 1,800 g (3 lb., 15 oz)
Enriched formula	22	Lactose	Cow's milk	34 to 36 weeks' gestation; weight 1,800 g (3 lb., 15 oz)
Soy formula	20	Corn-based	Soy	Congenital lactase deficiency, galactosemia
Lactose-free formula	20	Corn-based	Cow's milk	Congenital lactase deficiency; primary lactase deficiency, galactosemia, gastroenteritis in at-risk infants
Hypoallergenic formula	20	Corn or sucrose	Extensively hydrolyzed	Milk protein allergy
Nonallergenic formula	20	Corn or sucrose	Amino acids	Milk protein allergy
Anti-reflux formula	20	Lactose, thickened with rice starch	Cow's milk	Gastroesophageal reflux
Toddler formula	20	Lactose	Milk	Nine to 24 months of age

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FDA regulations require a "use by" date on each infant formula container. After this date, there is no guarantee that the infant formula will contain the nutrient amount detailed on the product label and otherwise offer acceptable quality. The manufacturer determines the sell by date with testing and other information.

Regulatory and approvals

In addition to laws and regulations governing foods, other statutory and regulatory requirements govern infant formula. These requirements for what is often the only nutrition source for a vulnerable population during a critical period of growth and development can be found in section 412 of the FFDCA and FDA implementing regulations in 21 CFR 106 and 107. Find the FFDCA and 21 CFR and view the FDA Federal Register Documents, Code of Federal Regulations and Food, Drug and Cosmetic Act.

The FDA and Health Canada requested review by The Committee on the Evaluation of the Addition of Ingredients New to Infant Formula that was charged with reviewing and developing infant formula safety and new ingredient recommendations for regulatory bodies, industry, and basic and clinical investigators The committee looked at preclinical and clinical studies and in-market monitoring, and any gaps in current safety regulations and guidelines.

The FD&C Act has primary two sections, 409 and 412, that apply to infant formulas. Health and Human Services is charged with ensuring safety for new food ingredients under Section 409. It considers ingredients like food additives and generally recognized as safe (GRAS) substances. To request a GRAS determination or premarket review of new ingredients in the U.S., manufacturers can file a Food Additive Petition with the FDA. GRAS eligibility is determined by use of the ingredient, rather than the ingredient itself.

The following regulations under section 412 have been implemented to ensure the formulas have the nutrients that allow infants to thrive:

- Infant Formula Quality Control Procedures (21 CFR §106)
- Records and Reports Regulations (21 CFR §106.100)
- Infant Formula Labeling Requirements (21 CFR §107.10–107.30)
- Exempt Infant Formulas (21 CFR §107.50)
- Nutrient Requirements for Infant Formulas (21 CFR §107.100)
- Infant Formula Recall Requirements (21 CFR §107.200–107.280)

The U.S. normally produces 98% of the infant formula it consumes, with the primary source of imports coming from trading partners in Mexico, Ireland and the Netherlands. However, in May 2022, in response to the infant formula shortage following supply chain issues, a voluntary recall and the closing of a plant that produces a large share of the country's formula, the FDA increased flexibilities regarding importation of certain infant formula products to increase its availability across the country while protecting the health of infants.

In November 2022, the FDA allowed the Danone (The Netherlands) Nutricia UCD Anamix Infant Formula (specialty formula for infants with urea cycle disorders) to be sold through home health care and durable medical equipment (DME) distributors, state and other government programs, and hospitals. The distribution of this formula has been targeted to metabolic clinics and patients and **not** available on retail shelves.

For more about infant formula information and ongoing FDA efforts to increase supply, please go here.

The FDA continues to dedicate resources to the infant formula industry by issuing draft guidance for information submitted to the agency when a new infant formula is brought to market; labeling guidance with respect to the statement of identity, nutrient content claims, health claims and qualified health claims, technical issues, warning statements, etc.; and improved microbiological safety.

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Complaints

Consumers or their healthcare providers can report in writing, by phone or via internet any complaint about infant formula to the FDA, including general issues, specific complaints or injuries incurred.

- Healthcare providers: Healthcare providers can report serious harm or illness from infant formula to the FDA MedWatch hotline at (800) FDA-1088 or by using Reporting by Health Professionals. The patient identity is kept confidential. MedWatch collects reports for FDA-regulated drugs, medical devices, medical foods, dietary supplements, infant formulas and other FDA-regulated products. For infectious diseases related to infant formula, healthcare providers can call the Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion at (800) 893-0485.
- Consumers: Consumers can also report what they believe are infant formula issues to the FDA at (800) FDA-1088 or using Reporting by Consumers. Consumers should report suspected infant formula issues even if they're not sure or they don't visit a healthcare professional about the problem.
- To notify manufacturers: You can also report issues directly to the manufacturers who provide toll-free numbers on the product labels.

Logistics insights

Product storage

According to the CDC:

- Prepared infant formula can spoil if it is left out at room temperature so it should be used within two hours of preparation and within one hour after feeding starts. Any formula not used within these timeframes should be stored in the refrigerator for use within 24 hours.
- Any infant formula left after a feeding should be discarded and the bottle cleaned and sanitized before the next feeding. Bacteria growth is possible when a baby's saliva combines with the formula.
- Unopened infant formula should be stored in a dry, cool indoor spot. Avoid leaving it in vehicles, garages and outdoor locations.
- Opened infant formula should also be stored with a tightly closed lid in a dry, cool location, not in a refrigerator.
- When you first open an infant formula container, write the date on the lid so you can ensure it's used within the suggested timeframe – usually one month, but check your product for the exact timeframe.
- The product should never be used after the container's use by date.

Utilization insights

Clinical contract support resources

Key Characteristics of Infants and Implications of the Recent Formula Shortage (2022)

This article discusses the implications of, options to and actions taken to address the formula shortage.

Infant Formula: 7 Steps to Prepare it Safely

Mayo Clinic offers preparation and storage tips to make sure formula is nutritious and safe.

Addressing the Infant Formula Shortage

See what the White House is doing to address the underlying issues that have contributed to the infant formula shortage.

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Building supply assurance

Conservation strategies

Because predicting the next supply shortage is impossible, it is important that healthcare providers not only adopt and implement care practice strategies to conserve critical products and supplies, but it is also equally important to sustain leading practices that will help ensure the availability of essential products post-recovery and into the future.

Healthcare providers and other leading organizations have identified and recommend the following actions:

- Assess and identify all hospital services.
- Identify and list critical products, supplies and resources required to sustain operation of those areas identified and ranked in the first step.
- Maintain the internal planning team document with accurate information. Review and update the document on a routine basis with current employee contact information. If a team member no longer works in the organization, identify the replacement and communicate the information to all stakeholders.
- Communicate practice changes and procedures frequently to staff and stakeholders.
- Hold regularly scheduled planning meetings in the absence of a supply chain shortage or event. This will help to ensure that identified processes and protocols remain relevant and any issues requiring revisions and/or updates are addressed in advance of a shortage or disaster.

If your organization has implemented conservation strategies for infant formula, or any other category, please share your information here. The information you share will be anonymous unless you grant Vizient permission to share.

Supply chain programs

Pediatric Program

Mead Johnson & Co. (EN0193) participates in the Vizient Pedatric Program. The Vizient Pediatric Program is a supply chain program focused on delivering savings, quality and choice from an industry-leading pediatric product portfolio. Additional information is available here.

Planning for disruptions

Best practice strategies

Unlike most other products, formula has virtually no close substitutes beyond breast milk. However, The American Academy of Pediatrics (AAP) recommends the following to consumers:

- Switching brands:
  - Slowly introduce the new formula by mixing small amounts with your regular formula, slowly increasing the new formula amount.
  - Call your pediatrician or other health healthcare provider if your baby shows any of the following signs of distress that may be related to intolerance to the new formula: vomiting, gas pains, crying or can't be calmed down when feeding, losing weight, has diarrhea, has blood or mucus in their poop, or is straining to poop
  - For comparable infant formula, you can refer to this list developed in response to a February 2022 formula shortage. The list from an organization of pediatric gastroenterologists called NASPGHAN might not include your baby's formula if it was not part of the shortage. Check with your pediatrician or other healthcare provider before switching.
- Check at doctor’s offices and reputable online distributors:
  - Be cautious about online buying formula that is not made in the U.S. It could be counterfeit.

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  - If you need hypoallergenic or medical specialty formula, it may be harder to find a substitute. Talk to your pediatrician or other healthcare provider about acceptable substitutes. Depending on which formula your baby needs, your doctor may be able to submit an urgent request for specialized formula to Abbott Nutrition, which is releasing some specialty and low-iron formulas on a case-by-case basis.
- Babies older than six months could temporarily use alternatives (e.g., cow's milk).
- Use donor milk from the milk bank.

Vizient offers the following best practices to help members manage disruptions. These suggestions are available to help you gain insight on how the industry is managing supply challenges.

If your inventory is low

Vizient is committed to bringing hospitals, manufacturers, distributors and the industry together to talk about this issue and any long-term implications. We feel continued dialogue about the issue by experts such as hospitals, manufacturers, distributors and industry will be crucial to ultimately arriving at a solution to a vexing issue. During critical supply periods, members should continue to order their normal levels of products in order to ensure continued availability for all institutions.

If you begin to experience a shortage:

- Evaluate your current supply.
- Contact your local supplier representative and report exactly how many days' supply you have left.
- If you are not getting a response from suppliers, contact Vizient so we can facilitate communication between member and supplier, provide whether you are ordering direct or through distribution (medical-surgical or pharmacy), and indicate supplier and distributor (if applicable) when you contact Vizient.
- We encourage you to continue the conversation within your organization, with your peers and with the manufacturers and distributors to identify ways to manage.
- Submit inquiries to disasterresponse@vizientinc.com.

Expedite supply resolution

- To expedite resolution for supply issues, contact your local supplier and provide the following information:
- The description and item number of the product that is experiencing a shortage
- Whether you are purchasing directly or through an Authorized Distributor
- Days' supply remaining in your inventory

If expanding your facility

We suggest members notify suppliers when expanding their facilities to assist in planning and anticipate increases in allocations. You should consider notifying your suppliers of at least three months ahead of the completion of your facility to ensure sufficient capacity.

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Building supply assurance together

Collaboration among suppliers, distributors, members and Vizient strengthens the assurance of supply for all stakeholders. Our wealth of experience, actionable data and predictive planning helps to strengthen supply assurance. Further, our work with stakeholders focuses on improving supply chain risk mitigation as we collaborate to enhance data, increase supply visibility and expand inventory access.

Four themes keep us centered and are the pillars of our supply chain assurance efforts: insights, access, enablement and advocacy. Learn more about our supply assurance strategy.

In the event of a supply disruption, Vizient will publish a product disruption brief to the Supply Assurance webpage. Curated by Vizient experts, these documents provide a summary of current conditions and strategies to manage product-level disruptions.

In addition to our disruption briefs, Vizient also compiles all known disruptions into the monthly Supply update executive summary which tracks all supply chain disruptors, including current market challenges, category-specific product updates and recovering markets.

Whether a supply disruption is the result of a natural or human-made disaster, it is imperative that members are informed. The Vizient Disaster Preparedness webpage was developed to help providers meet supply chain needs before, during and after an event. The Supply Update section of the guide is updated on a frequent and routine basis with communication from all awarded suppliers that have manufacturing facilities in areas impacted by a disaster. Additionally, a status update list of those manufacturers whose operations have been affected, as well as a list of impacted product(s) will be maintained and updated as that information is received from the supplier.

The importance of an internal planning team

Identifying an internal planning team is imperative to managing supply, mitigating risks and sustaining operations during a supply shortage. According to the Supply Chain Disaster Preparedness Manual developed by the CDC, internal teams should consist of representatives from supply chain, purchasing, emergency management, each clinical/care delivery area, inventory staff, receiving and distribution staff. Relative to medication and solutions, Vizient member feedback indicated the pharmacy department as an integral member to the internal team, as clinical/pharmacy practice changes may occur. Additional members may include the facilities safety manager, security, risk management, legal, marketing and communications and public relations.

A simple internal team planning document will help to identify, contact, and quickly convene relevant team members. See the sample below:

Name	Title	Department/role	Phone	Email

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Once an internal team is identified, additional considerations before beginning the development and implementation of a recovery plan include the following:

- The team's goals
- The responsibilities of each planning team member
- Other department/team members who may need to be involved
- Frequency of team meetings
- How the goal/mission will be accomplished
- How information will be documented and communicated to the broader audience
- Consideration of a current framework for success either within your facility or from a leading organization

Stakeholder communication

During supply chain product disruptions, it is vital that accurate and timely information is disseminated to internal and external stakeholders. The following actions should be considered in an effort to facilitate and ensure informed decisions:

- Designate the point person or persons who will be responsible for developing, disseminating and monitoring all communications coming from the internal planning team.
- The internal planning team should communicate key messages/information to stakeholders such as changes in policies and/or practice changes.
- Clearly communicate the roles and responsibilities of all staff based on the agreed upon recovery plan. If there are changes to the plan at any time, timely communication of those changes will help to increase risk mitigation and minimize interruption of patient care.
- Establish communication mechanisms for information exchange. Examples include but are not limited to regularly scheduled briefings and meetings, in-services, staff trainings, live/recorded webinars, memos and emails.
- Determine the frequency of reminders and updates regarding supply disruption status and anticipated resolution.
- Frequent updates and reminders after a supply disruption has been mitigated or eliminated help to ensure ongoing success and sustainability of best practices.

Supply management and logistics

A leading practice identified in managing recent shortages is a centralized management approach of impacted product codes. A key responsibility of the internal planning group is to identify all affected product codes and to determine the amount of supply on hand, expected and any allocation protocols implemented by the supply source. Once the current product status is determined, the following actions are recommended:

- Update and maintain an accurate inventory list. Each care area that utilizes any product code on the inventory list should identify a point person to collect on hand and usage levels on an agreed upon frequency. That information should be reported back to the internal planning team. Inventory can either be managed by care delivery areas or in a centralized manner.
- Identify space in the facility to store, manage and distribute product. Designate authorized personnel responsible for maintaining the inventory (expiration dates temperature, ventilation, utilization, equipment maintenance and repair, etc.).
- Develop and seek approval for the inventory management protocol and communicate this information to all stakeholders.
- Update and maintain accurate purchase order and allocation protocols from the contracted supplier and your group purchasing organization (GPO).
- Update and maintain accurate emergency contact information for all suppliers as well as internal stakeholders. This process should be done at least every six months.

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- Review the inventory management status on an agreed upon frequency with the internal planning group. Assess for barriers to its effectiveness, implement any changes necessary and communicate those changes to all stakeholders.

Planning for all levels of care and ancillary products

Feedback from lessons learned indicated the need to include all levels of care and ancillary products, if applicable, in the conservation plan. If your provider system has children's hospitals, ambulatory surgery centers, outpatient clinics, and/or long-term care facilities, utilization and logistics of products and supplies must be incorporated into the plan. Additionally, it is vital that ancillary products are considered when contemplating allocations and purchase orders. During the recent drugs and solutions shortages, as large volume solution bags went on back order, smaller volume bags, compounding products, and syringes also went on back order because of practice changes. Therefore, conservation planning should include actual and the additional ancillary products that may be required to sustain a clinical and/or operational practice change.

To learn more, please contact:
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As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver high-value care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.

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