



Dear Valued Partner,

At Nestlé, quality is our top priority for all our Brands, products and services. As our valued partner, we know you share our commitment to maintaining the quality of our HealthCare Nutrition products so that together, we can provide a high-quality experience for the customers and patients who use our products.

This document provides **Care and Handling Guidelines** on best practices Nestlé suggests for assuring product quality in transportation, storage and handling, including parameters for:

- 1) Transportation, including cold weather shipping rules for shelf stable enteral products
- 2) Warehouse Storage and Handling
- 3) Product Storage – Shelf Stable Products
- 4) Product Storage – Frozen Products
- 5) Product Dating Guidelines
- 6) Hang Time Guidelines for Open and Closed Enteral Feeding Systems (addresses preparation of enteral tube feeding formula for administration to a patient)

If you have any questions about these Care and Handling Guidelines, please contact Nestlé HealthCare Nutrition Customer Service at 1-877-463-7853.

Thank you for your attention to quality, and we look forward to providing an enhanced user experience together.

Sincerely,

Your Nestlé HealthCare Nutrition team

## 1. Transportation

### Pallet Height During Transportation of Liquid Nutritional Products

Because Nestlé HealthCare Nutrition’s packaging formats and label graphics are in transition, we are providing information for products identified by both “old” and “new” label graphics:

“Old” Label Graphics	“New” Label Graphics
<ul style="list-style-type: none"> <li>• Tetra Briks® = 1 pallet high</li> <li>• Cans = 2 pallets high</li> </ul>	<ul style="list-style-type: none"> <li>• Recommended pallet height = 5-6 feet</li> <li>• Tetra Briks®, Tetra Priskas® and ULTRAPAK® pouches = 1 pallet high</li> </ul>

### Small Parcel Damage Prevention

- All Liquid Nutritional products require over packing
- Use a shipper sized to best fit the product
- Ship cases in upright position
- Use packaging and filler (dunnage) to provide added protection and to fill in all voids for a snug fit. There should be no voids in the shipper.
- Maximum of 2 cases for each over pack
- Glass products (MCT Oil and Microlipid) require bubble wrap protection on all sides
- Banding should not be used

### Cold Weather Shipping Rules: Shelf Stable Enteral Products

The following rules and procedures apply in transporting liquid products in dry vans (for more than 72 hours) when temperatures are below 20 degrees F.

#### Loading/Transit Procedures

- All bills of lading should be marked: “Protect from Freezing below 20 degrees F.”
- Preloading should not occur more than 24 hours prior to the scheduled ship time.
- LTL/UPS Shipments that will carry over weekends need to be stored in heated terminals versus sitting on trailers.

**Note:** Truckload shipments exceeding 72-hour transit times need to be scheduled to insure that trailers are moving on a continuous basis.

#### Unloading Procedures

- It is recommended that all receipts of products exposed to freezing temperatures for more than 48 hours should be unloaded within 24 hours.

#### Inspection for Signs of Freezing

Inspect the inbound shipment for product condition (i.e. signs of freezing). Be sure to:

- Inspect product stored at the rear door of a truck.
- Inspect for swollen or leaking product and/or broken glass.

### **If Product Freezing/Damage Is Found**

- Immediately notify the carrier and Nestlé HealthCare Nutrition.
- File a carrier claim for the damaged product by contacting Nestlé HealthCare Nutrition Customer Service at 1-877-463-7853.

## **2. Warehouse Storage & Handling**

### **Pallet Stack Heights – Liquid Nutritional Products**

Because Nestle HealthCare Nutrition’s packaging formats and label graphics are in transition, we are providing information for products identified by both “old” and “new” label graphics:

<b>“Old” Label Graphics</b>	<b>“New” Label Graphics</b>
<ul style="list-style-type: none"> <li>• Tetra Briks® = 1 pallet high</li> <li>• Cans = 3 pallets high</li> </ul>	<ul style="list-style-type: none"> <li>• Tetra Briks® = 2 pallets high</li> <li>• Tetra Priskas®: = 2 pallets high</li> <li>• ULTRAPAK® Pouches = 1 pallet high</li> </ul>

## **3. Storage of Shelf Stable Enteral Products: Avoid Exposure to Excess Heat and Cold**

To provide optimum product quality, Nestlé HealthCare Nutrition shelf stable enteral products are to be stored unopened at room temperature (59°F – 86°F). Avoid exposure to excessive heat and freezing.

### **If Excessive Heat Occurs**

Exposure to heat extremes (>104°F for more than 24 hours) may result in:

- A decrease in the level of vitamin availability
- Nutrient content not meeting the label claim
- A darkening of the product

### **If Freezing Occurs**

Shelf-stable liquid enteral products should not be stored frozen, but the accidental freezing and subsequent thawing process will not affect nutrient content. Potential effects of freezing/thawing include:

- Issues with the consistency of the product and package integrity
- Fracturing of the emulsion, causing the product to separate

### **Steps for Assessing Product/Package Quality in the Event Excessive Heat/Freezing Occurs**

1. Bring product to room temperature.
2. Check all containers for leaks; insure packaging is intact. If the product container has leaked, or the condition of the label indicates exposure to excessive heat, cold or humidity, the product should not be used.

3. Take a sample container from the case. For ULTRAPAK® product, shake the product and visually inspect for signs of physical separation. For product in Tetra Pak® cartons, shake the product, open it and pour it into a container for visual inspection. If the shaken formula will not stay in suspension, the product should not be used.
4. Inspect the product for signs of coagulation. Coagulated or curdled product should not be used.
5. As with any food product, if there is an abnormal appearance, color, or odor, the product should not be shipped or consumed.

## 4. Storage and Usage of Frozen Products

### Special Guidelines for Products Stored Frozen and Served Thawed

Some frozen products are intended to be consumed after thawing, in which case there is a specific recommended time period for use after thawing. This time period is typically noted in a manner similar to the following:

*“Thaw Under Refrigeration (40°F or below). After thawing, keep refrigerated, use within 14 days after thawing.”*

As always, Federal, State, and/or local food codes take precedence when handling food products.

## 5. Product Dating Guidelines

### Definitions

Both the FDA and Nestlé HealthCare Nutrition, Inc. (“Nestlé”) use specific terminology to define when a product can or should be used. The FDA definitions for these terms include the following:

- Expiration Date. The calendar date on the packaging of a food that indicates the last date a food should be eaten or used. Foods that are purchased or used after the expiration date could contain spoilage bacteria or pathogens and may not be safe to eat.
- "Sell By" Date. A calendar date on the packaging of a food product that indicates the last day the product can be sold. The "sell by" date tells the retailer how long to display a product. It guides the rotation of shelf stock and allows time for the product to be stored and used at home. The date is quality driven, not a food safety concern.
- "Use By" Date. This is the last date a consumer is recommended to use a product while it is at peak quality. This date is recommended for best flavor or quality. It is not a "sell by" or food safety date.
- Nestlé Packaging. Nestlé product shippers and individual packages generally set forth these dates in one of two formats:
  - i. a date containing a Month, Day and Year; or
  - ii. a date containing a month and a year, in which case the determinative date, using the definitions described above, is the last day of the listed month.

## 6. Hang Time Guidelines for Using Open and Closed Systems

### Background

Many studies have looked at the bacterial contamination of enteral tube feeding formulas, but there is still a wide range of policies regarding the hang time of enteral formulas. Health care facilities are required to develop policies that reduce the potential for contamination.

The literature indicates that the incidence and degree of bacterial contamination is directly linked to the method of tube feeding preparation. Formulas which involve the greatest manual manipulation have been found to contain significantly more contamination than formulas that require minimal handling and manipulation.

Handling and manipulation includes all the steps required to prepare the tube feeding for administration to the patient:

1. Reconstituting a powdered formula in a commercial blender
2. Diluting a liquid, ready-to-use formula
3. Filling, emptying, and refilling the enteral administration container
4. Adding additional nutrients to the formula
5. Spiking the enteral feeding container<sup>1-9</sup>

### Closed System: ULTRAPAK® Container

The ULTRAPAK® Enteral Closed System is a prefilled, sterile, non-air dependent 1000 mL or 1500 mL container that may hang for up to 48 hours once spiked with an appropriate administration set. Closed system containers do not require mixing, dilution, or transfer to a bag for administration. The reduction in manipulation and handling that saves time and money also minimizes the risk of bacterial contamination.

To validate the 48-hour hang time of the ULTRAPAK® container, a study was conducted with intensive care patients comparing the contamination of the ULTRAPAK® system; a formula prepared from a powder and administered in an open system; and a ready-to-use formula decanted from a can into an open system.

As a result of these studies, Nestlé HealthCare Nutrition is able to recommend that when proper aseptic technique is followed **and** an administration set with a validated 48 hour time is used, each Nestlé HealthCare Nutrition Enteral Closed System (bottle or ULTRAPAK®) can safely hang for up to 48 hours to complete the administration of the container's contents, with minimal risk of contamination. While the closed systems have this extended hang time available, the actual amount of time a container is hanging is likely to be less than 48 hours.

It is important to refer to the specific guidelines established by the administration set manufacturer.

### Open Systems: Tetra Pak® cartons

An open system encompasses reconstituted powders or ready-to-use liquids decanted from a preparation container or from the original packaging (Tetra Pak® carton) into a feeding container. Higher degrees of contamination have been found in reconstituted formulas and in open systems allowed to hang for extended periods of time (greater than 21 hours).

The A.S.P.E.N. Enteral Nutrition Practice Recommendations provides the following hang time recommendations:<sup>10</sup>

- For a reconstituted powdered formula or a formula with additives, a 4-hour hang time is recommended.
- For a commercially sterile, liquid formulas decanted from a carton, an 8-hour hang time is recommended.

These hang time recommendations assume the formula is kept at room temperature and is subject to minimal handling and manipulation.

While the literature states a wide range of actual hang time recommendations, most agree that administration sets and bags used in an open system should be changed every 24 hours. This information also indicates that the bag and administration set should be flushed with water before adding additional formula.

### Summary

Nestlé HealthCare Nutrition follows the hang time guidelines based on best practices. Each health care facility should evaluate the appropriateness of these guidelines based on their patient population, staffing, and infection control policies and decide on the most appropriate procedure for their specific facility.

For any enteral tube feeding, whether in an ULTRAPAK<sup>®</sup> container or open system, care should be taken to visually inspect the formula at regular intervals for signs of contamination and to continuously monitor the patient for signs of feeding intolerance.

### References

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