Enteral Nutrition Products, Nasogastric Feeding Tubes, Feeding Pumps and Sets – Environmental Considerations for the RFP/RFI Process

The environmental considerations for most products in this category are covered by the Standardized Environmental Questions for Medical Products; however there are some additional considerations for electronic products and enteral nutrition products that have been added.

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<th>Rationale</th>
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<td>1.</td>
<td>Does this product contain postconsumer recycled content (excluding steel)? (Yes/No) If yes, what percentage by weight?</td>
<td>Yes, highest %</td>
<td>Postconsumer recycled content material is a material or finished product that has served its intended use and has been diverted or recovered from waste destined for disposal, having completed its life as a consumer item. Basically, it is the material collected from recycling programs. It is calculated as a percentage of total weight of the product. Steel is excluded from consideration as it commonly contains recycled content. This does not include preconsumer (sometimes referred to as postindustrial) recycled content which are recovered materials obtained from manufacturers. Buying recycled-content products ensures that the materials collected in recycling programs will be used again in the manufacture of new products. According to EPA, recommending postconsumer recycled content levels for items will have the most positive impact on reducing the amount of solid waste requiring disposal. Purchasers should prefer products with the highest postconsumer recycled content that also meet other considerations. Use of postconsumer recycled content supports closing the loop in the recycling process, and, based on EPA’s ReCon Tool, helps avoid generating greenhouse gas emissions.</td>
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<td>2.</td>
<td>Is this product recyclable? (Yes/No)</td>
<td>Yes</td>
<td>Recyclable, according to the FTC Green Guides, means the product can be collected, separated, or otherwise recovered from the solid waste stream for reuse, or in the manufacture or assembly of another package or product, through an established recycling program. Any claims of recyclability indicates the supplier can demonstrate that at least 60% of the hospitals in the U.S., or in the product distribution area, have access to an established recycling program for this item, or there is an existing take-back program by the vendor of the manufacturer that has been in operation at Recyclable products, those that are recyclable in communities in the U.S., reduce materials going to the waste stream and their associated costs. Although FTC has not finalized definitions to prove this claim, we are utilizing the FTC draft definition for ‘substantial majority’ to mean at least 60% and adding what it means to the health care community to ensure the needs of facilities who strive to divert materials from their waste stream.</td>
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| 3. | **Does the product’s primary packaging contain postconsumer recycled content? (Yes/No)** If yes, what percentage? | Yes, highest %

The primary packaging surrounds the product. For example the paper wrap surrounding a roll of toilet paper is primary packaging. (Secondary packaging surrounds a group of products, such as the box containing rolls of toilet paper.) *Postconsumer recycled content material* is a material or finished product that has served its intended use and has been diverted or recovered from waste destined for disposal, having completed its life as a consumer item. Basically, it is the material collected from recycling programs. It is calculated as a percentage of the total weight of the product.

Buying recycled-content products ensures that the materials collected in recycling programs will be used again in the manufacture of new products. According to EPA, recommending postconsumer recycled content levels for items will have the most positive impact on reducing the amount of solid waste requiring disposal. Purchasers should prefer products with the highest postconsumer recycled content that also meet other considerations. Use of postconsumer recycled content is fundamental to closing the loop in the recycling process, using fewer natural resources, and based on EPA’s ReCon Tool, can reduce greenhouse gas emissions. There are exceptions to the use of postconsumer recycled content in sterile barrier packaging (ISO 11607-1).

| 4. | **Is this product packaged without polystyrene? (Yes/No)** | Yes

Polystyrene (CAS 9003-53-6) is a plastic polymer from the monomer styrene. It comes in many forms: sheet, expanded or extruded foam, or as oriented polystyrene. What is commonly known as Styrofoam™ refers only to the extruded form of polystyrene. Packaging refers to all materials (primary, secondary, etc) used to transport and protect a product from damage. *Alternatives* to polystyrene packaging are available.

Also referred to as ‘PS’ with the SPI (Society of the Plastics Industry) resin code 6, polystyrene is difficult for hospitals to recycle and there are alternatives. Polystyrene is made with styrene. The International Agency for Research on Cancer (IARC) classifies styrene as a possible carcinogen. Foam blowing agents (called hydrochlorofluorocarbons, HCFCs) used to make polystyrene foam are compounds that have an ozone depletion potential.

| 5. | **Is this product sold as a multi-use product or device (not single patient use)? (Yes/No)** | Yes, with exceptions

A multi-use product or device is sold as a product that can be used on more than one patient. In *Sec 201 [21 U.S.C. 321]*, the FDA defines the term "single-use device" to mean a device that is intended for one use, or on a single patient during a single procedure. This question does not include products that can be reprocessed.

Products that can be used more than once reduce waste (and associated costs) and conserve natural resources. There are case studies that demonstrate the cost and environmental benefits of multi-use devices. There are exceptions; not all medical products should be multi-use.
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<th>Question</th>
<th>Material Type</th>
<th>Potential Issues</th>
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<td>6.</td>
<td>Is this product free of intentionally added polyvinyl chloride (PVC)? (Yes/No)</td>
<td>Yes</td>
<td>Polyvinyl chloride (PVC) shall be defined as a plastic polymer used in a wide array of products. It is the third most widely produced plastic. Intentionally added means a substance is deliberately added in the production of the product. Production and incineration of PVC releases dioxins and other harmful chemicals. Dioxins are widely distributed throughout the environment in low concentrations and are persistent, bioaccumulative and toxic (PBT). Dioxins are potent toxicants with many health impacts even at low exposure levels.</td>
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<td>7.</td>
<td>Is this product free of intentionally added phthalates: DEHP, BBP, DnHP, DIDP, and DBP? (Yes/No) If no, please specify the phthalate(s)</td>
<td>Yes</td>
<td>Phthalates are esters of phthalic acid mainly used as plasticizers (substances added to plastics to increase their flexibility, transparency, durability, and longevity). They are used primarily to soften polyvinyl chloride (PVC). Di-2-ethyl hexyl phthalate (DEHP) CAS 117-81-7, Benzylbutylyphthalate (BBP) CAS 85-68-7, Di-n-hexyl phthalate (DnHP) CAS 84-75-3, Di-isodecyl phthalate (DIDP) CAS 68515-49-1 or 26761-40-0, Dibutyl phthalate (DBP) CAS 84-74-2 People can be exposed through the use of products containing these chemicals. In 2002, the FDA issued a Public Health Notification for PVC devices containing DEHP. DEHP is also listed as a carcinogen on the Prop 65 list. The National Research Council has also noted the importance of looking at cumulative exposure from multiple phthalates. These five phthalates are listed as reproductive toxicants by Prop 65.</td>
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<td>8.</td>
<td>Is this product free of intentionally added Bisphenol A (BPA) or BPA derived plastics (such as polycarbonate plastic and resins)? (Yes/No)</td>
<td>Yes</td>
<td>Bis(4-hydroxyphenyl)propane, or Bisphenol A (BPA), is an organic compound used to make polycarbonate plastic, epoxy resins and for other applications. Polycarbonate plastic is derived from BPA. Resin derived from BPA is used to line metal food containers and in thermal paper for impact printing purposes. Intentionally added means a substance is deliberately added in the production of the product. People can be exposed through the use of products containing these chemicals. BPA is one of the highest volume chemicals produced worldwide. Laboratory studies have shown widespread health effects, at least in part through endocrine disruption mechanisms. The National Toxicology Program has some concern for the effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures. Bisphenol A</td>
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<td>9.</td>
<td>Does this product contain less than 1000 ppm halogenated organic flame retardants by weight of homogenous material? (Yes/No)</td>
<td>Yes</td>
<td>Halogenated organic flame retardants are intended to inhibit ignition and the spread of flames. Halogenated chemicals are chemicals that contain bromine, chlorine, fluorine or iodine bonded to a carbon atom. Homogeneous means uniform composition throughout, such as individual types of plastics or paper. Homogenous material, as defined by RoHS, is a unit that cannot be mechanically disjointed into single materials, or any material that is not mechanically divisible (disassembled, cut or ground) into separate material constituents. Mechanically disjointed means the materials can be, in principle, separated by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes. A Guidance for suppliers on testing is available. Halogenated organic flame retardants and/or their breakdown products tend to be persistent bioaccumulative and toxic (PBT) in the environment. They are widely found in the environment and in humans with Americans having some of the highest levels of them in their bodies. Some halogenated organic flame retardants are carcinogenic. These compounds are used in foams (for furniture and mattresses), textiles, paints and coatings, electronics, and plastics in health care. Alternatives exist that reduce the concern for environmental and human health effects. The European Union has a ban on some brominated flame retardants. In Europe, the Restriction of Hazardous Substances Directive (RoHS) restricts the use of PBDE’s and PBB’s in electronic equipment. Examples include, but are not</td>
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<td><strong>10.</strong></td>
<td><strong>Is this product free of intentionally added mercury? (Yes/No)</strong></td>
<td><strong>Yes</strong></td>
<td><strong>Mercury is a naturally occurring element that is found in air, water and soil. It exists in several forms: elemental or metallic mercury, inorganic mercury compounds, and organic mercury compounds. Intentionally added means a substance is deliberately added in the production of the product.</strong></td>
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<td><strong>11.</strong></td>
<td><strong>Is this product free of intentionally added latex? (Yes/No)</strong></td>
<td><strong>Yes</strong></td>
<td><strong>Latex is natural rubber latex that comes from a liquid found in tropical rubber trees. Intentionally added means a substance is deliberately added in the production of the product.</strong></td>
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12. **Will this product be classified (on its own or when aggregated) as non-hazardous waste according to EPA’s RCRA when disposed? (under 40 CFR 261.31-33)?** (Yes/No)  
Yes  
**Hazardous wastes**: are those determined by EPA to be hazardous including those classified as hazardous and if products exhibit one of the four characteristics (defined in 40 CFR Part 261.21-24). Hazardous wastes are divided into **listed** wastes, **characteristic** wastes, **universal wastes**, and mixed wastes. Specific procedures determine how **waste is identified**, classified, listed, and delisted. The Resource Conservation and Control ACT (RCRA) mandates strict controls over disposal of hazardous waste. These listed wastes are divided into three categories: K-list, F-list, and the P and U-Lists. Characteristic wastes include wastes that exhibit ignitability, corrosivity, reactivity or toxicity. Universal wastes include batteries, pesticides, mercury-containing products and lamps. Examples include computer equipment, lead-containing products, and applicable cleaning chemicals. Purchasers should know when products may become hazardous waste at the end of product use so that facilities can comply with EPA and RCRA regulations regarding the handling of hazardous waste or to seek alternatives during the procurement process. Reducing hazardous waste generation lessens the environmental impact and the expenses associated with disposal. Suppliers should seek alternative technologies to the greatest extent possible. Many state regulations may be more stringent than federal requirements. Consult the [HERC State Hazardous Waste Locator](http://www.epa.gov/osw/hazard/wastetypes/index.htm) to find more information on an individual state’s hazardous waste regulations. For more information on EPA listed wastes: [http://www.epa.gov/osw/hazard/wastetypes/index.htm](http://www.epa.gov/osw/hazard/wastetypes/index.htm).

13. **Does this product contain carcinogens or reproductive toxicants, as listed under the California Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65, below Prop 65 Safe harbor levels?** (Yes/No)  
Yes  
California’s Prop 65, The [Safe Drinking Water and Toxic Enforcement Act](http://www.epa.gov/osw/hazard/wastetypes/index.htm), enacted in 1986, requires the state to publish a **list of chemicals** known to cause cancer or reproductive harm. Prop 65 applies to suppliers who sell products in the state if their products exceed safe harbor levels established in Prop 65. Safe harbor levels establish thresholds for no significant risk levels (NSRLs) for carcinogens and maximum allowable dose levels (MADLs) for chemicals that cause reproductive toxicity. The California Proposition 65 list is an authoritative government list of carcinogens and reproductive toxicants that health care facilities may wish to avoid. All suppliers who do business in California must comply with this law. As such, this law already applies to many suppliers in the health care sector. Since this list is updated at least once a year, suppliers must provide up-to-date information for procurement contracts.

**Electronics**

Please consider asking these questions for electronic products. Some of the questions above also apply.

**Additional Considerations**

14. **Is this product free of intentionally added antimony?** (Yes/No)  
Yes  
Antimony is a silvery-white metal that is found in the earth’s crust. Antimony ores are mined and then either changed to antimony metal or combined with oxygen to form antimony oxide.xi Antimony oxides (primarily antimony trioxide) are used as fire retardants for plastics, textiles, rubber, adhesives, pigments, and paper.xii According to EPA, acute (short-term) exposure to antimony by inhalation in humans results in effects on the skin and eyes. Respiratory effects, such as inflammation of the lungs, chronic bronchitis, and chronic
emphysema, are the primary effects noted from chronic (long-term) exposure to antimony in humans via inhalation. Human studies are inconclusive regarding antimony exposure and cancer, while animal studies have reported lung tumors in rats exposed to antimony trioxide via inhalation.

15. Is this product free of intentionally added heavy metals - lead, mercury, cadmium, and hexavalent chromium and is compliant with RoHS (Restriction on Hazardous Substances Directive)? (Yes/No) Yes

RoHS restricts mercury and cadmium at no more than 100ppm, and hexavalent chromium and lead at 1000ppm. Although RoHS applies to electronic products, all products should be free of intentionally added heavy metals to prevent exposure. Heavy metals are persistent bioaccumulative and toxic. Heavy metals may enter the human body through food, water, air, or absorption through the skin when they come in contact with humans in agriculture and in manufacturing, pharmaceutical, industrial, or residential settings. They may build up in biological systems and become a significant health hazard. Cadmium is an extremely toxic metal. Lead accounts for most of the cases of pediatric heavy metal poisoning (Roberts 1999).

Enteral Nutrition Products

Please consider asking these questions in the RFI/RFP for enteral nutrition products.

**Enteral Nutrition Considerations**

1. Is this product or any product ingredients USDA certified organic or Food Alliance Certified? (Yes/No) Yes

**Certified USDA Organic** - Product must meet the federal organic standards as determined by a USDA-approved certifying agency. Organic products are produced without synthetic pesticides, fertilizers, genetically modified organisms, antibiotics, or added hormones. **Food Alliance certification** ensures that farmers/producers use safe and fair working conditions, humane livestock handling practices, cannot use hormones or non-therapeutic antibiotics, cannot use or produce GMOs, reduce pesticide use, implement water and soil conservation and habitat protection practices. Ingredients may have been produced with synthetic pesticides and fertilizers, genetically modified organisms, antibiotics, or added hormones (organic certification would avoid this).

Grains/legumes, meat, dairy, eggs, and produce may have been produced utilizing unfair labor/working conditions. Animal welfare may not have been taken into consideration and high levels of toxic pesticides and fertilizers may have been used to produce these foods. Products with grains, corn, soy and canola may be genetically engineered. Farming practices may be wasteful or harmful to water, soil and habitat health (Food Alliance certification would avoid this).

These two certifications are slightly different yet we did not want one to cancel the other by asking two separate questions. While not impossible, generally no producer would ever have both certifications in part because they do have some overlap in what they cover.

2. Is this product produced without genetically modified Yes

This product was not made with ingredients from genetically engineered/modified (GE/GM) Processed foods that contain corn, soy, canola and their derivatives (e.g., oil, high fructose corn syrup, corn meal, soy
| ingredients? (Yes/No) | ingredients. | protein, etc) may have been produced from GMO seeds. Prefer products labeled "No genetically engineered ingredients." GMO containing foods or ingredients are not adequately assessed for their credible adverse effects on human or animal health, or on the environment in which they are produced. Also of concern is the threat posed by genetic engineering to environmentally sustainable food production and the threat to the economic livelihood of farmers pursing sustainable food production. See related fact sheet: [http://www.noharm.org/lib/downloads/food/Genetic_Engineered_Food_Stmnt.pdf](http://www.noharm.org/lib/downloads/food/Genetic_Engineered_Food_Stmnt.pdf) |

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7. Ibid
10. EPA: Information for Health Care Providers, [http://www.epa.gov/hg/healthcare.htm#facilities](http://www.epa.gov/hg/healthcare.htm#facilities), viewed August 30, 2011
12. Ibid