



Guidance to Achieve HH Safer Chemicals Challenge PVC and DEHP Elimination in Medical Devices

Version 3.0
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This document provides guidance for hospitals working to meet the requirements of the PVC and DEHP Elimination goal of the Healthier Hospitals Safer Chemicals Challenge, Version 3.0.

PVC and DEHP Elimination Goal for Hospitals

In order to meet the goal, hospitals must eliminate PVC and DEHP from at least two product categories.

Product categories include:

1. Breast Pumps and accessories
2. Enteral Nutrition Products
3. Enteral Tubes
4. General Urological
5. Gloves
6. Parenteral Infusion Devices and Sets
7. Respiratory Therapy Products
8. Vascular Catheters

Rationale: PVC requires highly toxic inputs during manufacture, and, in some cases, toxic additives to achieve key performance characteristics. It can also result in the formation of a variety of highly toxic chemicals during disposal by incineration. PVC can be difficult to recycle because it must be completely segregated from other plastics in the general waste stream. DEHP is a reproductive and developmental toxicant that can leach out of medical devices, threatening some patients exposed to the chemical. The FDA has recommended a reduction in exposure to DEHP, particularly for vulnerable patients. This goal requires devices to be both PVC- and DEHP-free.

Definitions

Polyvinyl chloride (PVC), or vinyl, is a synthetic thermoplastic material made by polymerizing vinyl chloride. The properties of the material depend on the additives, including plasticizers. PVC has a wide array of uses.

DEHP, or di(2-ethylhexyl)phthalate, is a softener often used in polyvinyl chloride (PVC) plastics. Unplasticized PVC is hard and brittle at room temperature. A plasticizer is typically added to increase the flexibility of the polymer. DEHP is the plasticizer used most often in PVC medical devices.

Exemptions and De Minimis Levels:

- PVC: Very small components containing less than 1% of PVC by weight of the product are allowed. PVC tubing is **not** exempt.
- DEHP: The de minimis level for DEHP in homogenous materials is 1000 ppm.

Notes:

- The goal is not intended to address the quality or constituents of solutions and formulations in the containers.
- The goal does not include secondary and tertiary packaging of the product.
- Search terms are provided to assist health systems with tracking their purchases in support of this goal.

Verification

Suppliers should provide to the health care purchaser, upon request:

- Laboratory testing data from an accredited lab, verifying compliance; or
- A formal declaration stating that the product supplied does not contain PVC or DEHP, as required by this guidance; the declaration must be written, signed, and dated by the manufacturer on the manufacturer's letterhead.

Scope of Products Covered

1. Breast Pumps and accessories

Scope: Breast pumps and accessories include the breast pump mechanism and all component parts of the breast pump, including kits, tubing, shields, bottles, etc.

Exclusions: straw milk transfer items

Departments that might use these products: Maternity ward, NICU, and PICU

Search terms - use search terms alone and in combination: breast, breast feeding, breast pump, tubing, breastshield, breast shield, breast shell. Note: Breastshields are also used by radiology departments and might come up in a search but should not be included.

2. Enteral Nutrition Products

Definition: Enteral means administration via any part of the gastrointestinal tract.

Scope: Enteral nutrition products include containers of nutritional formula, tubing, infant formula, and syringes.

Exclusions: pumps

Departments that might use these products: Used throughout the hospital

Search terms - use search terms alone and in combination: enteral, nutrition, nutrition container, nutrition tubing, nutrition syringe, feeding, feeding tube, feeding nutrition sets, formula, infant formula, feeding bag, tubing connector

3. Enteral Tubes

Definition: A tube that enters the intestinal tract.

Scope: Enteral tubes include, but are not limited to, nasogastric tubes, gastrostomy tubes (GT), percutaneous endoscopic gastrostomy (PEG) tubes, and Dobhoff tubes.

Departments that might use these products: Used throughout the hospital

Search terms - use search terms alone and in combination: nasogastric, NG tube, gastrostomy tubes (GT), percutaneous endoscopic gastrostomy (PEG) tubes, and Dobhoff tubes

4. General Urological

Definition: Urological products are those that relate to the urinary system.

Scope: General urological products include all items in urological kits, as well as individual items or urologic sets (not the solutions), as well as their component parts, used for urinary catheterization or irrigation.

Exclusions: urological stents

Departments that might use these products: Used throughout the hospital

Search terms - use search terms alone and in combination: urological, urinary, catheter, irrigation tray, collection bag, bedside drainage bag, leg bag, extension tubing, leg strap, catheter strap, surgical lubricant, irrigation syringe

5. Gloves

Scope: Gloves used in clinical care include general examination, surgical, general purpose, and protective gloves used in the preparation and administration of chemotherapy.

Exclusions: food service, housekeeping, facility maintenance, and landscaping gloves

Departments that might use these products: Used throughout the hospital

6. Parenteral Infusion Devices and Sets

Definition: The word “parenteral” means anything other than enteral, including, but not limited to, intravascular, intraosseous, intraperitoneal, and intrathecal. **However, the scope of this guidance is limited to products and their accessories that are used to access arteries and veins.**

Scope: Parenteral infusion devices and sets include containers of formulations, tubing, and syringes, used to access arteries and veins.

Exclusions: pumps; intraosseous, intrathecal, and intraperitoneal parenteral devices; catheters used to administer the formulation

Departments that might use these products: Used throughout the hospital

Search terms - use search terms alone and in combination: parenteral, nutrition, nutrition containers, tubing, syringe, primary infusion tubing, parenteral nutrition sets, parenteral formula, parenteral feeding bag, parenteral tubing connectors, TPN, PN

7. Respiratory Therapy Products

Definition: Products used in respiratory therapy.

Scope: Respiratory therapy products include respiratory tubing, including tubing from a wall supply, respirator, or other device; nasal cannulas, endotracheal tubes, tracheostomy tubes, ambu bags, nebulizers, and face masks including non-rebreather face masks.

Exclusions: Respiratory machines and other devices that plug in or have a battery, or any other device used in respiratory therapy that is not included in the scope above

Departments that might use these products: Used throughout the hospital

Search terms - use search terms alone and in combination: respiratory therapy, respiratory tubing, ventilator tubing, nasal cannulas, endotracheal tubes, tracheostomy tubes, ambu bags, nebulizers, face masks, non-rebreather face masks.

8. Vascular Catheters

Definition: A vascular catheter is a tubular medical device for insertion into an artery or vein, usually to permit the injection or withdrawal of fluid or to keep a passage open.

Scope: Vascular catheters include arterial and venous catheters.

Departments that might use these products: Used throughout the hospital

Search terms - use search terms alone and in combination: vascular catheter, arterial catheter, venous catheter, umbilical vessel catheter, diagnostic catheter, interventional vascular catheter, central venous catheter, central line