

# Medical products: Guidance to achieve PVC/DEHP elimination for manufacturers



SAFER CHEMICALS » MEDICAL PRODUCTS

This document provides guidance for manufacturers wishing to meet Health Care Without Harm's safer medical products and devices criteria. Medical products must not contain **polyvinyl chloride (PVC)** or **diethylhexyl phthalate (DEHP)**.

For many years, Health Care Without Harm has [prioritized the elimination of PVC and DEHP in medical products](#) because of their toxicity and to increase the safety and sustainability of the health care sector.

## Guidance for manufacturers

The chart on the following page outlines key medical product categories that may contain PVC and DEHP. High priority categories that support Practice Greenhealth members in meeting the PVC and DEHP elimination goal and product categories eligible for the [Greenhealth Approved seal](#) are included.

Learn more about Health Care Without Harm's criteria to support the manufacturing and purchasing of medical products that meet [Safer medical product criteria](#).

## Chemical and material criteria details

**Polyvinyl chloride (PVC) and other chlorinated polymers:** The product does not contain polyvinyl chloride (PVC) or other chlorinated polymers.

**Definition:** PVC, or vinyl, is a synthetic thermoplastic material made by polymerizing vinyl chloride. The properties of the material depend on the additives, including plasticizers.

**Scope:** Very small components containing less than 1% of PVC by weight of the product are allowed. PVC tubing is not exempt.

**Rationale:** This plastic (PVC) is particularly problematic because of the toxicity of the monomers required to make the polymer and the generation and release of hazardous compounds during manufacture and disposal. PVC also generally requires more additives, many with their own toxic properties, when compared to other polymers. The diverse additives can also make PVC difficult to recycle.

**DEHP, or di(2-ethylhexyl)phthalate:** The product does not contain DEHP.

**Definition:** 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.

**Scope:** The de minimis level for DEHP in homogenous materials is 1000 ppm.

**Rationale:** 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.

Category	Examples and exclusions	Practice Greenhealth PVC/DEHP elimination goal	Greenhealth Approved seal eligible
Breast pumps and accessories	<b>Inclusions:</b> Breast pump mechanism, all component parts of the breast pump including kits, tubing, shields, and bottles, etc. <b>Exclusions:</b> Straw milk transfer items	X	X
Enteral nutrition products	<b>Inclusions:</b> Containers of nutritional formula and infant formula syringes <b>Exclusions:</b> Pumps	X	X
Enteral tubes	<b>Inclusions:</b> Nasogastric tubes, gastrostomy tubes (GT), percutaneous endoscopic gastrostomy (PEG) tubes, and dobhoff tubes	X	X
General urological	<b>Inclusions:</b> All items in urological kits, individual items or urologic sets (not the solutions), as well as their component parts, used for urinary catheterization or irrigation <b>Exclusions:</b> Urological stents	X	X
Parenteral infusion devices and sets*	<b>Inclusions:</b> Containers of formulations, tubing and syringes, used to access arteries and veins <b>Exclusions:</b> pumps; intraosseous, intrathecal, and intraperitoneal parenteral devices; catheters used to administer the formulation  *Not included in reporting for the Practice Greenhealth PVC/DEHP goal, but alternatives to PVC and DEHP materials exist in these products and devices. Catheters, solution containers, drains, cartridges, fluid bags (i.e. blood, IV), and blood filters.	X	X
Respiratory therapy*	<b>Inclusions:</b> Respiratory tubing (including tubing from a wall supply, respirator, or other devices), nasal cannulas, endotracheal tubes, tracheostomy tubes, ambu bags, nebulizers, and face masks including non-rebreather face masks <b>Exclusion:</b> Respiratory machines and other devices that plug in or have a battery  **Not included in reporting for the Practice Greenhealth PVC/DEHP goal, but alternatives to PVC and DEHP materials exist in these products and devices. Anesthesia breathing circuits	X	X
Vascular catheters	<b>Inclusions:</b> Arterial catheters, venous catheters	X	X
Gloves	<b>Inclusions:</b> Nitrile gloves	X	
NICU accessories	Armbands, eye shields, noise attenuators, and phototherapy diapers		X
Gynecological / obstetrical	Intrauterine pressure catheter system, vaginal irrigation bag, and disposable syringes		X
Single use disposable medical and surgical devices	Laparoscopic, arthroscopic, and endoscopic devices		X
Patient comfort products	Mattress overlays and covers, isolette pads, neonatal gel pillows, positioning devices, and compression devices		X
Patient support products	Patient ID bracelets and personal belonging bags		X
Other products	Floor Pads, shower Curtains, ECG electrodes, bodybags, and radiation aprons and shields		X