

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.