

Non-DEHP Alternatives



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

July 12, 2000

Public Health Notification: PVC Devices Containing the Plasticizer DEHP

(You are encouraged to copy and distribute this information)

Dear Colleague:

This is to inform you that FDA's Center for Devices and Radiological Health completed its safety assessment of Di(2-ethylhexyl)phthalate (DEHP) released from polyvinyl chloride (PVC) medical devices in September, 2001, and to advise you of steps that you can take to reduce the risk of exposure in certain populations.

Devices Affected

PVC is a plastic polymer that is used in a wide array of products. Unplasticized PVC is hard and brittle at room temperature. A plasticizer (softener) is typically added to increase the flexibility of the polymer. DEHP is the plasticizer for most PVC medical devices.

Devices that may contain DEHP-plasticized PVC include:

- intravenous (IV) bags and tubing
- umbilical artery catheters
- blood bags and infusion tubing
- enteral nutrition feeding bags
- nasogastric tubes
- peritoneal dialysis bags and tubing
- tubing used in certain
- tubing

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DEHP-containing devices

Background and current issue

- Polyvinyl chloride (PVC) medical devices typically contain the plasticizer di(2-ethylhexyl)phthalate (DEHP)¹
 - Used since 1950, DEHP has become the industry standard²
 - There have been no reports of DEHP-related adverse events in humans¹
- Non-DEHP sets have long been available to help caregivers and patients avoid potential health risks caused by specific solutions known to extract DEHP
- A U.S. Food and Drug Administration (FDA) public health notification recommends the use of non-DEHP medical devices in select applications¹
- DEHP may be leached from a device into a solution, depending on:
 - Lipid content of infusion solution¹
 - Duration of solution contact with the material¹
 - Temperature¹

Our aim

Innovating I.V. therapy options

Committed to offering materials and designing products that meet the highest standards

- Hospira is one of the leading suppliers of infusion therapy products in the United States
- Longtime supplier of non-DEHP products for lipid infusions
 - Recently expanded broad medication delivery product line
 - Continual innovations of non-DEHP options
 - Addressing FDA recommendations and healthcare provider concerns
 - Providing new options for use with neonates

Dedicated to patient and caregiver safety

- Dependable resource for a range of safe I.V. therapy products and systems
 - Completely needlefree systems
 - Latex-free administration sets
- Providing safe I.V. therapy solutions and education through Needlestick Prevention Systems

Our non-DEHP devices

- *Continual innovation* in I.V. therapy product options, including plastic devices that contain trioctyl trimellitate (TOTM)
 - Used worldwide for decades in medical devices
 - Provides an alternative to DEHP
- *Comprehensive selection* of products for a variety of procedures.
 - I.V. sets for procedures and applications in neonates
 - Containers and tubing to infuse lipid products for total parenteral nutrition (TPN)
 - Glass bottles for lipid products
 - Polyethylene-lined sets for nitroglycerin and paclitaxel infusion
 - Custom configurations also available
- *Customer support* to fulfill caregiver needs
 - Continuing clinician education
 - Dedicated sales force
 - Reliable customer support
 - Online resources

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References:

1. Feigal DW Jr. FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP. US Food and Drug Administration Web site. July 12, 2002. Available at: <http://www.fda.gov/cdrh/safety/dehp.html>. Accessed September 22, 2004.
2. Koop CE, Juberg DR, Benedek EP, et al. Review and consensus statement. A scientific evaluation of health effects of two plasticizers used in medical devices and toys: a report from the American Council on Science and Health. *Medscape General Medicine*. 1999;1(1). Available at: <http://www.medscape.com/viewarticle/407990>. Accessed September 22, 2004.

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