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PVC & DEHP Defined

Poly Vinyl Chloride (PVC): A hard, brittle opaque material. When combined with another chemical called a 'plasticizer,' the PVC is formed into a wide range of consumer and medical products.

Di(2-ethylhexyl) phthalate (DEHP): The most commonly used plasticizer for products made with PVC. It is a clear, oily substance that does not chemically bond with the PVC—so it will 'leach' or migrate away from the PVC matrix over time if the surrounding environmental chemicals are similarly oily.

WHAT ARE PVC & DEHP?

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Common consumer products made with DEHP-plasticized PVC include imitation leather in car interiors, food packaging, cling film and many products used in construction such as plumbing pipes, carpeting, and window blinds. DEHP-plasticized PVC also has been used extensively for more than 40 years in various medical devices: IV containers, enteral bags, blood bags and their associated tubings; breathing masks and circuits; dialysis tubing; and Extra Corporeal Membrane Oxygenation (ECMO) circuits. Prior to use in patient care, most of these products required regulatory review and approval in each country where the product is marketed; as a result, DEHP-plasticized PVC has undergone among the most extensive testing and reviews of any material used in medical devices.

When used in blood storage bags, DEHP-plasticized PVC containers provide a significant improvement in product shelf life for blood components compared to glass containers. Non-DEHP plastic containers can provide a comparable shelf life, but at the cost of compromising other key product attributes. Studies suggest that DEHP may play a role in stabilizing the red blood cell membrane, hence prolonging blood shelf life.¹

Why are physicians and materials managers asking about non-DEHP and non-PVC products?

DEHP and PVC are two related chemicals in our environment that are getting attention, particularly with regard to medical products. Advocacy organizations, such as Health Care Without Harm (HCWH) and Hospital for a Healthy Environment (H2E), are calling for the phase-out of DEHP and PVC in health care

institutions. They are working with various customer, legislative, and regulatory groups at the local and national level to implement this phase out. As recently as July 2002, the Food and Drug Administration (FDA) issued a "Public Health Notification: PVC Devices Containing the Plasticizer DEHP" (<http://www.fda.gov/cdrh/safety/dehp.html>). In October 2003, the California Environmental Protection Agency (EPA) listed DEHP as a potential reproductive toxicant under their safe drinking water legislation referred to as Proposition 65.

Over the last 20 years, various studies have been conducted to understand the effects of DEHP-plasticized PVC on our bodies. With each new study our understanding evolves; sometimes the study results reinforce past conclusions and sometimes they refute them. As a result, there is a lot of confusion in the marketplace. The purpose of this customer tool is to provide you with information on DEHP and PVC: what has been thought in the past, what we know now, and what we still don't know.

PVC and DEHP and Human Health

Bio-contaminated medical waste may be incinerated to decontaminate it prior to disposal. When PVC is burned or incinerated under the wrong conditions another chemical, dioxin, is formed and released into the environment. Dioxin is a highly toxic chemical that is known to cause cancer in humans. Fortunately, the U.S. Environmental Protection Agency instituted regulations for medical waste incinerators in 1997. As a result of these regulations and the increased use of non-incineration technologies, dioxin emissions from medical waste disposal are estimated to contribute less than one percent of the total dioxin emissions in the U.S. While the overall concentration of this chemical in the environment has been significantly reduced, advocacy groups continue to be concerned about the potential for our bodies to encounter localized pockets of dioxin.

Numerous studies have been done on rodents to evaluate the effects of DEHP. Many of the early studies concluded that DEHP may cause liver cancer, so many organizations around the world put DEHP on their published lists of chemicals known to cause cancer. Subsequent studies



revealed that rodents metabolize DEHP very differently than humans. After thorough review of these studies, the conclusion reached by U.S. and international agencies, including the International Agency on Cancer Research² and the Superior Court of California³, is that DEHP does not pose a risk of liver cancer to humans.

While science has shown that DEHP does not cause liver cancer, other studies indicate that it may affect the development of reproductive organs in male rodents. In these studies, testicular damage and altered sperm production was observed in some, but not all, of the rodent species tested. At this time, scientists do not have a conclusive understanding of how developing rodent bodies and human bodies are similar or different when it comes to how DEHP may affect reproductive capability. Therefore, some organizations advocate total elimination under the philosophy that if DEHP might be harmful for some rodents under certain conditions, its use should be avoided in humans wherever possible.

However, some organizations take a risk management-based approach. They consider using alternatives to DEHP-plasticized PVC devices in certain procedures that could potentially expose developing males to high concentrations of DEHP. This is the approach recommended by the FDA in its Public Health Notification. After extensive review of studies available at the time, FDA focused its recommendations on some specific procedures when performed on

male neonates, pregnant women who are carrying male fetuses, and peripubertal males. The listed procedures of concern typically involve a medical device that is in contact with an ‘oily’ solution like blood or a fat emulsion, and include for example:

- Extra Corporeal Membrane Oxygenation (ECMO) in male neonates
- Massive blood (exchange) transfusions in neonates
- Total parenteral nutrition involving lipids in neonates
- Hemodialysis in peripubertal males and pregnant or lactating women
- Enteral nutrition in neonates

With regard to IV and dialysis solutions that are not ‘oily’ in nature, FDA states “there is little to no risk posed by patient exposure to the amount of DEHP released from PVC IV bags following infusion of crystalloid fluids (e.g., normal saline, D5W, Ringer’s Lactate.)”

Alternatives to DEHP-Plasticized PVC: Pros and Cons

Although DEHP-plasticized PVC has been studied and used in billions of patient days, according to the July, 2002 FDA Public Health Notification, there have been no reported adverse events associated with exposure to DEHP from the use of these products. The industry does, however, offer two alternative categories of materials:

- “Non-DEHP PVC” is plasticized using chemicals other than DEHP.

- “Polyolefins” is a category of plastic materials such as polypropylene, polyurethane, and polyethylene that are used in “non-PVC” products.

Products made with these materials also tend to be more costly due to fewer sources for medical-grade materials and/or the manufacturing process. The table below compares these materials to DEHP-plasticized PVC.

Get the Facts

Over the past decade the major medical device manufacturers have introduced bag and tubing products that utilize alternatives to DEHP-plasticized PVC for those applications of potential concern to customers. Some of the alternatives for bags are non-PVC as well as non-DEHP. Some of the alternatives for tubing utilize non-DEHP or non-PVC materials for the inner layer of the tubing that is in contact with the fluid.

1. Rock G. Tocchi M. Ganz PR. Tackaberry ES. *Incorporation of plasticizer into red cells during storage. Transfusion.* 24(6):493-8, 1984 Nov-Dec.

2. *International Agency for Research on Cancer (IARC), Volume 77 (15-22 February 2000)* <http://193.51.164.11/htdocs/announcements/vol77.htm>

3. *Superior Court of California Ruling on Baxter Healthcare Corporation v. California Office of Environmental Health Hazard Assessment, Superior Court of California, County of Sacramento, No. 99CS00868*

Feature	Comparison with DEHP-plasticized PVC	
	Non-DEHP PVC	Polyolefins
Clarity	Equivalent	Depends on specific materials and manufacturing processes used
Material flexibility	Equivalent in softness, pliability and strength	Stiffer, less pliable
Cost of Medical Grade Raw Materials	Slightly higher	Higher due to fewer sources of supply

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