DEHP in Plastic Medical Devices

What is DEHP and how is it used?
DEHP, also known as di-(2-ethylhexyl)phthalate, is a compound used as a plasticizer (softener) in many products made of polyvinyl chloride (PVC) plastic, including some medical devices. Among these are:

- IV bags and tubing
- Umbilical artery catheters
- Peritoneal dialysis bags and tubing
- Tubing used during Hemodialysis
- Blood bags and tubing
- Heart bypass machine tubing
- Nasogastric feeding tubes
- Respiratory tubing
- Enteral nutrition feeding bags

Why are there health concerns regarding DEHP?
Exposure to DEHP has produced a range of adverse effects in experimental animals, but those of greatest concern involve effects on the development of the testicles and the production of normal sperm in young animals.

Is there evidence that these effects occur in humans?
It is possible that the effects observed in animal studies could occur in humans. However, there are no human studies to date that show such effects. DEHP-containing devices have been used on newborn babies for many years without apparent ill effects, although studies have not been conducted which would rule out effects on humans.

If these effects occur in humans, which patients would be at most risk?
The FDA believes the greatest concern would be for very young male infants who are critically ill and have prolonged exposure to multiple devices containing DEHP. Also at risk would be the male fetus, through exposure of his mother, and peripubertal males. The National Toxicology Program, a component of the National Institutes of Health, has recently reached a similar conclusion. In contrast, there is little concern for adults receiving intravenous solutions or undergoing peritoneal dialysis.

What has been done to date to assess the potential risk?
We have examined the potential risks posed by patient exposure to DEHP by comparing the doses of this compound that patients may receive to a Tolerable Intake (TI) value for DEHP. A TI value is the dose of a compound that is not expected to produce adverse effects in exposed patients. For more information on how the safety assessment for DEHP was performed, as well as the potential risks of exposure to DEHP from various procedures, see the document "Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices".

What can be done to reduce the level of DEHP exposure?
We have issued a Public Health Notification to the medical community, identifying procedures that could result in exposure to relatively high levels of DEHP in sensitive patients (e.g., male neonates). We have recommended that devices made of alternative materials, or that are made of PVC that does not contain DEHP, be used for these procedures. If PVC devices containing DEHP must be used, we...
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We recommend that steps be taken to minimize the exposure, e.g., by using the freshest, coldest blood products available, or by using heparin-coated blood tubing.

We must emphasize that the risks of DEHP exposure are far less than the risks of forgoing critical procedures.

We will continue to make new information available on this website.

Link to: FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP²

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