AVANOS

TECHNICAL BULLETIN

DEHP IN ON-Q*

BACKGROUND

DEHP (Di (2-ethylhexyl) phthalate, is a plasticizer which is primarily used in PVC (polyvinylchloride) products to make them soft and flexible. Flexible PVC is used in a variety of consumer products such as toys, cables, and building materials.

DEHP is also widely used as a plasticizer in many PVC medical devices/supplies. Examples of PVC medical products that contain DEHP are IV tubing and bags, blood bags, enteral nutrition feeding bags, nasogastric tubes, dialysis tubing, and tubing used in cardiopulmonary bypass procedures and ECMO procedures.

If present in the fluid path, DEHP may leach out of plastic medical devices into certain solutions that come in contact with the plastic. Generally, these are oily based solutions such as lipids, fat emulsions and enteral feeding solutions as well as blood and blood products. The majority of medications, including local anesthetics, do not have a leaching effect on DEHP.

The following Avanos elastomeric pumps, catheters and accessories contain some amount of DEHP in the fluid path:

- Elastomeric pump tubing – all models (no DEHP in the pumping chamber)
- ON-Q Soaker* and SilverSoaker* catheters
- Filling extension set

SAFETY CONCERNS

Both the European Commission and the U.S. Food and Drug Administration have published safety assessments of medical devices containing DEHP plasticized PVC. Essentially, the conclusion reached by both agencies is that exposure to DEHP is associated with a range of adverse effects in experimental animal studies. There is no conclusive scientific evidence to date that DEHP exposure has a harmful effect on humans; however, there is concern that children, particularly premature male neonates undergoing certain medical procedures, may be at a higher risk for reproductive toxicity due to DEHP exposure. Also potentially at risk is the male fetus, through maternal exposure and peripubertal males.

RISK FACTORS

Medical procedures used in these high risk groups, which may result in significant exposure were identified as follows:

- Exchange transfusion in neonates
- TPN in neonates
- Multiple procedures in sick neonates resulting in high cumulative exposure
- Hemodialysis in pregnant or lactating women and peripubertal males
- Enteral nutrition in neonates and adults
- Massive blood transfusions into trauma patients

Aside from the potential use of the elastomeric device in a neonatal patient undergoing multiple medical procedures (high cumulative exposure potential), none of the other procedures/infusions represent an intended use for the device and are contraindicated.

AVANOS PRODUCTS AND DEHP

In contrast, the delivery of crystalloid fluids (e.g. normal saline, D5W) and drugs stored in PVC bags that require a pharmaceutical vehicle for solubilization pose little or no risk of patient exposure to DEHP when drug label instructions are followed. The delivery of these infusions is the primary application for Avanos elastomeric pumps.

DEHP extraction studies were conducted using the Avanos elastomeric fixed flow rate device (Johnson, 2009). The test method used was in accordance with ISO 3826-1:2003. Based on the quantitation limit standard, the report concluded that there were "no detectable levels of DEHP present in the test article extracts" after seven days of extraction.

WHY ARE AVANOS PRODUCTS NOW LABELED FOR DEHP?

There has always been a statement in the IFU informing that the product contains DEHP. However, new regulations from the European Union (EU) now require that any CE marked product that has DEHP in the fluid pathway be labeled for DEHP and a human risk statement included in the DFU. In order for Avanos to sell products in the EU international market, this information is required.

NOTE: This is only an EU regulation. At this time, the FDA does not require labeling for DEHP.

CONCLUSION

- Selected Avanos products have always contained DEHP.
- DEHP label and IFU warning are required by the EU for CE marked products.
- Avanos products appear to pose little or no patient risk of DEHP exposure when used as intended.
- As a precaution, the risk and benefit of using medical devices with DEHP for pregnant women, breastfeeding mothers, infants and children should be evaluated prior to use.
- In addition, certain solutions may be incompatible with the PVC material used in the administration set. Consult drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

REFERENCES:

1. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062182.htm
2. USFDA (2001). Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices. Center for Devices and Radiological Health, U.S. Food and Drug Administration.
3. EUR 23384 (2008). European Union Risk Assessment Report on Bis(2-Ethylhexyl) Phthalate (DEHP), Volume 80, Eds. S. Pakalin, K. Aschberger, O.Cosgrove, B-O. Lund, A Paya-Perez and S. Vegro, Office for Offical Publicatoins of the European Communities, Luxembourg.Johnson, T.M. (2009).
4. Determination of extractable bis (2-ethylhexyl) phthalate (DEHP) in a polymer material per ISO 13485:2003. Unpublished study report 09T_50767_01, NAMSA, Northwood, Ohio, U.S.A. Study Sponsored by I-Flow*, LLC, U.S.A., a subsidiary of Kimberly-Clark Corporation (on file).

There are inherent risks in all medical devices. Please refer to the product labeling for **Indications**, **Cautions**, **Warnings** and **Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to **www.avanospainmanagement.com** and **www.avanosmedicaldevices.com** for additional product safety Technical Bulletins.

Please contact the Clinical Services Department at **800-444-2728** or **949-923-2400** if you have any questions regarding this information.

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