

THE TOXIC FREE MEDICAL DEVICES ACT

SUMMARY

Di(2-ethylhexyl)phthalate (DEHP) is a type of phthalate. Phthalates are a group of industrial chemicals that add elasticity and durability to some plastic, like PVC.

DEHP is commonly used to impart flexibility to IV bags and IV tubing. Some IV bags and tubing can contain up to 40% DEHP by weight. DEHP has been shown to leach out of the IV bags and tubing and into the medication and other fluids being infused into the bloodstream of patients.

DEHP is a toxic chemical known to the State of California to cause cancer and birth defects¹.

Safer alternatives to IV bags and tubing made with DEHP already exist and are being utilized by major hospitals and health care systems.

This bill would phase out the use of DEHP in IV bags and tubing and prohibit its substitution with other harmful ortho-phthalates.

BACKGROUND

The U.S. Department of Health and Human Services classified DEHP as reasonably anticipated to be a human carcinogen (a substance that can cause cancer)².

The U.S. Environmental Protection Agency has determined that DEHP is a probable human carcinogen².

The International Agency for Research on Cancer has classified DEHP as possible carcinogenic to humans².

California has prohibited the manufacture, sale, or distribution of children's toys and child care articles containing DEHP since 2009 (Ma, 2007)³. California has also banned DEHP from cosmetic products sold in the state (Muratsuchi, 2020)⁴. The United States permanently prohibited DEHP from kids toys in 2008⁵.

In 2012, Kaiser Permanente announced that it will no longer buy IV medical supplies that contain DEHP⁶.

¹ chrome-extension://efaidnbmnnnibpajpegglefindmkaj/https://www.p65warnings.ca.gov/sites/default/files/downloads/factsheets/dehp_fact_sheet.pdf

² https://www.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=377&toxoid=65#:-:text=The%20U.S.%20Department%20of%20Health,is%20a%20probable%20human%20carcinogen.

³ http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1101-1150/ab_1108_bill_20071014_chaptered.html

⁴ https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200AB2762

PROBLEM

DEHP is linked to a number of environmental and health concerns:

- DEHP has been linked to breast, liver, lung, and testicular cancer⁷.
- DEHP is an endocrine disrupting compound, meaning it can interfere with the hormonal system in humans, leading to adverse effects on reproductive health, development, and metabolism. It has been linked to decreased testosterone and sperm mobility in men⁷.
- DEHP exposure during pregnancy may lead to the preterm birth, delayed mental development, and altered timing of puberty in the child⁷.
- DEHP exposure may have potential neurological effects on neural development and behavior⁸.
- DEHP impacts the thyroid and immune system⁸.

Research indicates that DEHP promotes drug resistance and inhibits the effectiveness of breast cancer drugs; interferes with the ability of chemotherapies to fight breast cancer, and that patients with higher levels of DEHP in their system had higher rates of relapse and mortality⁹.

SOLUTION

AB 2300 will prohibit the manufacture, sale, or distribution of IV bags for all patients and IV tubing used for high-risk patients in California.

AB 2300 will prohibit manufactures from replacing DEHP in IV bags and IV tubing with any of the other 11 chemicals that make up the class of ortho-phthalates.

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SUPPORT

Breast Cancer Prevention Partners (Sponsor)
California Black Health Network (Co-Sponsor)

⁵ https://www.cpsc.gov/Newsroom/News-Releases/2018/CPSC-Prohibits-Certain-Phthalates-in-Childrens-Toys-and-Child-Care-Products

⁶ https://www.plasticstoday.com/plastics-processing/kaiser-permanente-bans-pvc-tubing-and-bags

⁷ https://www.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=377&toxoid=65#:-:text=The%20U.S.%20Department%20of%20Health,is%20a%20probable%20human%20carcinogen.

⁸ chrome-extension://efaidnbmnnnibpajpegglefindmkaj/https://www.opc.ca.gov/webmaster/ftp/project_pages/MarineDebris_OEHHA_ToxProfiles/DEHP%20Final.pdf

⁹ https://www.sciencedirect.com/science/article/pii/S0753332221011860