HEALTH AND SAFETY CODE - HSC

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406] *(Division 104 added by Stats. 1995, Ch. 415, Sec. 6.)*

PART 3. PRODUCT SAFETY [108040 - 109052] *(Part 3 added by Stats. 1995, Ch. 415, Sec. 6.)*

CHAPTER 18. Chemicals in Medical Devices [109050 - 109052] *(Chapter 18 added by Stats. 2024, Ch. 562, Sec. 1.)*

109050. The Legislature finds and declares all of the following:

(a) Di(2-ethylhexyl) phthalate (DEHP) and other ortho-phthalates are toxic chemicals and can have negative impacts on human health as determined by the United States Food and Drug Administration, the United States Environmental Protection Agency, or the Office of Environmental Health Hazard Assessment within the California Environmental Protection Agency.

(b) They are used primarily to produce flexibility in plastics, mainly polyvinyl chloride (PVC).

(c) This includes DEHP, the most common ‘plasticizer’ used in medical devices, including intravenous solution containers (IV bags) and IV tubing.

(d) Over the course of its shelf life, DEHP leaches out of the plastic into the solution being held in the container.

(e) DEHP is classified as an endocrine-disrupting compound, meaning it can interfere with the hormonal system in humans and animals. It can mimic or block the actions of hormones, leading to adverse effects on reproductive health, development, and metabolism.

(f) Studies have suggested a potential link between DEHP exposure and certain types of cancer, including breast, liver, lung, and testicular cancer. The United States Environmental Protection Agency (EPA) has determined that DEHP is a probable human carcinogen, and it is included on the Proposition 65 list of chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.

(g) DEHP exposure has been associated with adverse effects on reproductive organs and fertility. It can disrupt normal reproductive development, reduce sperm quality, and affect hormone levels in both males and females.

(h) DEHP is metabolized in the liver and can accumulate in the body over time. Prolonged exposure to high levels of DEHP has been shown to cause liver and kidney damage in animal studies.

(i) Inhalation or ingestion of DEHP can cause respiratory irritation and allergic reactions in some individuals, particularly those with preexisting respiratory conditions or sensitivities.

(j) While some major hospital systems use IV bags made with alternatives to DEHP, approximately 70 percent of California hospitals are buying and using IV bags made with DEHP.

(k) DEHP dosed at varying concentrations in cell culture studies has been linked to potential multidrug resistance in breast cancer cells that may inhibit the effectiveness of breast cancer drugs.

(l) Triple-negative breast cancer cells dosed in culture with DEHP have been potentially linked to multidrug resistance, inhibiting the apoptosis mechanism induced by breast cancer drugs such as tamoxifen and increasing cell proliferation in vitro. One proposed mechanism is that DEHP may serve as a mitogenic factor for estrogen receptor-positive breast cancer cells, potentially making them multidrug resistant.

(Added by Stats. 2024, Ch. 562, Sec. 1. (AB 2300) Effective January 1, 2025.)

109051. For purposes of this chapter, the following terms have the following definitions:

(a) “DEHP” means Di(2-ethylhexyl) phthalate.

(b) “Intentionally added DEHP” means DEHP that a manufacturer has intentionally added to an intravenous solution container or intravenous tubing product that has a functional or technical effect on the product.

(c) “Intravenous solution containers” means a container used to house medicine, fluid, or nutrition therapy that is intravenously administered to patients in a hospital, outpatient, or other health care facility.

(d) “Intravenous tubing” means any tubing used to intravenously administer fluids, medication, or nutrients directly to an adult, child, or infant.

(e) “Ortho-phthalates” means a class of chemicals that are esters of ortho-phthalic acid, including all of the following:

(1) Benzyl-butyl phthalate (BBP) 85-68-7.

(2) Dibutyl phthalate (DBP) 84-74-2.

(3) Dicyclohexyl phthalate (DCHP) 84-61-7.

(4) Di-(2-ethylhexyl) phthalate (DEHP) 117-81-7.

(5) Diethyl phthalate (DEP) 84-66-2.

(6) Di-isobutyl phthalate (DIBP) 84-69-5.

(7) Di-isodecyl phthalate (DIDP) 26761-40-0.

(8) Di-isononyl phthalate (DINP) 28553-12-0.

(9) Di-n-hexyl phthalate (DnHP) 84-75-3.

(10) Di-n-octyl phthalate (DNOP) 117-84-0.

(11) Di-n-pentyl (DnPP) phthalate 131-18-0.

(12) Diisoheptyl phthalate (DIHP) 71888-89-6.

(f) “Unintentionally added DEHP” means DEHP in an intravenous solution container or intravenous tubing product that is not used for functional or technical effect on the product.

(Added by Stats. 2024, Ch. 562, Sec. 1. (AB 2300) Effective January 1, 2025.)

109052. (a) Commencing January 1, 2030, a person or entity shall not manufacture, sell, or distribute into commerce in the State of California intravenous solution containers made with intentionally added DEHP.

(b) Commencing January 1, 2035, a person or entity shall not manufacture, sell, or distribute into commerce in the State of California intravenous tubing made with intentionally added DEHP.

(c) A person or entity shall not replace DEHP, pursuant to this chapter, for revised or new products with other ortho-phthalates.

(d) An intravenous solution container or intravenous tubing product shall not have unintentionally added DEHP present at a quantity at or above 0.1 percent weight per weight (w/w).

(e) The following items, as described in Title 21 of the Code of Federal Regulations, are exempt from these provisions:

(1) Human blood collection and storage bags.

(2) Apheresis and cell therapy blood kits and bags, including integral tubing.

(f) A person or entity, due to pending United States Food and Drug Administration approval for the DEHP-free intravenous solution container or due to the manufacturer not having adequate equipment to manufacture the DEHP-free intravenous solution container, shall meet the requirement in subdivision (a) by January 1, 2032, if all of the following conditions are met:

(1) The person or entity notified its California customers, no later than July 1, 2025, that it has commenced development of the DEHP-free intravenous solution container to meet the requirements of this section.

(2) The person or entity provides notice to its customers and posts to its official internet website, no later than January 1, 2028, that it will not meet the deadline imposed pursuant to subdivision (a).

(Added by Stats. 2024, Ch. 562, Sec. 1. (AB 2300) Effective January 1, 2025.)