HOUSE OF REPRESENTATIVES
THIRTIETH LEGISLATURE, 2020
STATE OF HAWAII

H.B. NO. 2248

A BILL FOR AN ACT

RELATING TO PRODUCTS CONTAINING SUN PROTECTION FACTOR INGREDIENTS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that sunscreens are considered by the United States Food and Drug Administration to be nonprescription, over-the-counter drugs that require specific testing to demonstrate that the sunscreen is generally recognized as safe and effective for its intended use before being sold to consumers. The Food and Drug Administration has published industry guidelines that outline the required testing for sunscreen. Each chemical found in a sunscreen product is categorized by the Food and Drug Administration as:

(1) Category I: generally recognized as safe and effective for the claimed therapeutic indication;

(2) Category II not generally recognized as safe and effective or unacceptable indications; or

(3) Category III: insufficient data available to permit final classification.

The legislature also finds that in February 2019, the Food and Drug Administration issued a proposed rule to update regulatory requirements for most sunscreen products in the United States. In the proposed rule, the Food and Drug Administration proposed that of the sixteen active ingredients currently marketed in sunscreen products, zinc oxide and titanium dioxide are the only two category I ingredients. Two ingredients are currently considered category II ingredients: aminobenzoic acid (PABA) and trolamine salicylate. The other twelve active ingredients currently marketed in sunscreen products are presently considered category III.

The legislature finds that a number of sunscreen drugs have recently been demonstrated to pose intolerable toxicologic threats, such as: environmental contamination in coastal waters, including significant harmful impacts on Hawaii's marine environment, coral reefs, and other residing ecosystems; birth defects such as Hirschsprung's disease, preterm incubatory births, changes in secondary sex-ratios, and increasing cell proliferation in cancer cells, increasing the risk for breast cancer, and other issues, and developmental disorders in children. To preserve the state's marine ecosystems, the state

banned the sale, offer of sale, and distribution of any sunscreen that contains oxybenzone or octinoxate, or both, without a prescription issued by a licensed healthcare provider, through the enactment of Act 104, Session Laws of Hawaii 2018. However, additional action must be taken to further prevent any potential harmful impacts of sunscreens containing other, non-category I active ingredients.

The purpose of this Act is to require that only sunscreen products that contain active ingredients classified by the United States Food and Drug Administration as a category I, generally recognized as safe and effective, ingredients, shall be sold, offered for sale, or distributed for sale in the state.

SECTION 2. Chapter 328, Hawaii Revised Statutes, is amended by adding a new section to part I to be appropriately designated and to read as follows:

"**§328- Sale and distribution of sunscreen; prohibition of products containing certain ingredients.** (a) Beginning January 1, 2023, only sunscreen products that contain active ingredients classified by the United States Food and Drug Administration as a category I, generally recognized as safe and effective, ingredient, shall be sold, offered for sale, or distributed for

sale in the state, without a prescription issued by a licensed healthcare provider.

(b) No county shall enact any ordinance or regulatory restriction to prohibit the sale, use, labeling, packaging, handling, distribution, or advertisement of sunscreens containing any active ingredient not classified by the United States Food and Drug Administration as a category I, generally recognized as safe and effective, ingredient, prior to January 1, 2023.

(c) For purposes of this section:

"Licensed healthcare provider" means a physician or osteopathic physician licensed pursuant to chapter 453, or an advanced practice registered nurse licensed pursuant to chapter 457.

"Prescription" means an order for medication, that is dispensed to or for an ultimate user. "Prescription" shall not include an order for medication that is dispensed for immediate administration to the ultimate user, such as a chart order to dispense a drug to a bed patient for immediate administration in a hospital. "Prescription" includes an order for a sunscreen.

"Sunscreen" means a product marketed or intended for

topical use to prevent sunburn containing any sun protection factor ingredient. Sunscreen does not include products marketed or intended for use as a cosmetic, as defined in section 328-1, for the face."

SECTION 3. Chapter 342D, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§342D- Sale and distribution of sunscreen; prohibition of products containing certain ingredients.** (a) Beginning January 1, 2023, only sunscreen products that contain active ingredients classified by the United States Food and Drug Administration as category I, generally recognized as safe and effective, ingredients, shall be sold, offered for sale, or distributed for sale in the State, without a prescription issued by a licensed healthcare provider.

(b) No county shall enact any ordinance or regulatory restriction to prohibit the sale, use, labeling, packaging, handling, distribution, or advertisement of sunscreens containing any active ingredient not classified by the United States Food and Drug Administration as a category I, generally

recognized as safe and effective, ingredient, prior to January 1, 2023.

(c) For purposes of this section:

"Licensed healthcare provider" means a physician or osteopathic physician licensed pursuant to chapter 453, or an advanced practice registered nurse licensed pursuant to chapter 457.

"Prescription" means an order for medication, that is dispensed to or for an ultimate user. "Prescription" shall not include an order for medication that is dispensed for immediate administration to the ultimate user, such as a chart order to dispense a drug to a bed patient for immediate administration in a hospital. "Prescription" includes an order for a sunscreen.

"Sunscreen" means a product marketed or intended for topical use to prevent sunburn containing any sun protection factor ingredient. Sunscreen does not include products marketed or intended for use as a cosmetic, as defined in section 328-1, for the face."

SECTION 4. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

SECTION 5. New statutory material is underscored.

SECTION 6. This Act shall take effect on July 1, 2020

INTRODUCED BY:

JAN 2 1 2020

H.B. NO. 2248

Report Title:
Hawaii Food, Drug, and Cosmetic Act Water Pollution; Sun Protection Factor Ingredients; Sunscreen; Sale; Distribution Prohibition

Description:
Requires that, beginning 1/1/2023, only sunscreen products containing active ingredients classified by the United States Food and Drug Administration as a category I, generally recognized as safe and effective, ingredient, shall be sold, offered for sale, or distributed for sale in the state.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.