

JAN 17 2020

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# A BILL FOR AN ACT

RELATING TO PRODUCTS CONTAINING SUN PROTECTION FACTOR  
INGREDIENTS.

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

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

- 10           (1) Category I: generally recognized as safe and  
11                 effective for the claimed therapeutic indication;  
12           (2) Category II: not generally recognized as safe and  
13                 effective or unacceptable indications; or  
14           (3) Category III: insufficient data available to permit  
15                 final classification.



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

12           The legislature finds that a number of sunscreen drugs have  
13 recently been demonstrated to pose intolerable toxicologic  
14 threats, such as: environmental contamination in coastal  
15 waters, including significant harmful impacts on Hawaii's marine  
16 environment, coral reefs, and other residing ecosystems; birth  
17 defects in human populations caused by Hirschsprung's disease,  
18 preterm incubatory births, changes in secondary sex-ratios, and  
19 other issues; and developmental disorders in children. To  
20 preserve the State's marine ecosystems, the state banned the  
21 sale, offer of sale, and distribution in the State of any



1 sunscreen that contains oxybenzone or octinoxate, or both,  
 2 without a prescription issued by a licensed healthcare provider,  
 3 through the enactment of Act 104, Session Laws of Hawaii 2018.  
 4 The legislature finds that additional action must be taken to  
 5 further prevent any potential harmful impacts of sunscreens  
 6 containing other, non-category I active ingredients.

7       Accordingly, the purpose of this Act is to require,  
 8 beginning January 1, 2023, that only sunscreen products that  
 9 contain active ingredients classified by the United States Food  
 10 and Drug Administration as a category I, generally recognized as  
 11 safe and effective, ingredients, shall be sold, offered for  
 12 sale, or distributed for sale in the State.

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

16       "§328-       Sale and distribution of sunscreen; prohibition  
 17 of products containing certain ingredients. (a) Beginning  
 18 January 1, 2023, only sunscreen products that contain active  
 19 ingredients classified by the United States Food and Drug  
 20 Administration as a category I, generally recognized as safe and  
 21 effective, ingredient, shall be sold, offered for sale, or



1 distributed for sale in the State, without a prescription issued  
2 by a licensed healthcare provider.

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

10 (c) For purposes of this section:

11 "Licensed healthcare provider" means a physician or  
12 osteopathic physician licensed pursuant to chapter 453, or an  
13 advanced practice registered nurse licensed pursuant to chapter  
14 457.

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



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

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

9       "§342D-       Sale and distribution of sunscreen; prohibition  
10 of products containing certain ingredients. (a) Beginning  
11 January 1, 2023, only sunscreen products that contain active  
12 ingredients classified by the United States Food and Drug  
13 Administration as category I, generally recognized as safe and  
14 effective, ingredients, shall be sold, offered for sale, or  
15 distributed for sale in the State, without a prescription issued  
16 by a licensed healthcare provider.

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



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

3 (c) For purposes of this section:

4 "Licensed healthcare provider" means a physician or  
5 osteopathic physician licensed pursuant to chapter 453, or an  
6 advanced practice registered nurse licensed pursuant to chapter  
7 457.

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

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

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



# S.B. NO. **2778**

1 SECTION 5. New statutory material is underscored.

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

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INTRODUCED BY:

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# S.B. NO. 2778

**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.*

