

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL

No. 484

Introduced by Senator Migden

February 18, 2005

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~~An act to amend Section 105180 of the Health and Safety Code, relating to health. An act to add Article 3.5 (commencing with Section 111791) to Chapter 7 of Part 5 of Division 104 of the Health and Safety Code, relating to cosmetics.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 484, as amended, Migden. ~~Occupational health—Cosmetics: chronic health effects.~~

~~Existing law requires the State Department of Health Services to maintain a program on occupational health and occupational disease prevention. Existing law further provides that in any situation where these activities may duplicate or overlap the activities of another state department or agency such as the Department of Industrial Relations or the Division of Occupational Safety and Health, the department shall avoid duplication.~~

~~This bill would make technical, nonsubstantive changes to this provision.~~

~~The existing Sherman Food, Drug, and Cosmetic Law requires the State Department of Health Services to regulate the packaging, labeling, and advertising of food, drugs, and cosmetics. The law prohibits a person from manufacturing, selling, delivering, holding, offering for sale, or receiving in commerce any cosmetic that is adulterated, and prohibits a person from adulterating any cosmetic. The law also prohibits a person from manufacturing or selling any cosmetic that is misbranded. A violation of these provisions is a crime.~~

~~This bill would establish the California Safe Cosmetics Act of 2005. The bill would, on or after January 1, 2007, require the manufacturer~~

*of any cosmetic product subject to regulation by the federal Food and Drug Administration that is sold in the state to, on a schedule determined by the department, provide the department with a list of its cosmetic products that are sold in the state and to identify by product any ingredient that contains a chemical identified as causing cancer or reproductive toxicity. Violation of this requirement would be a crime under existing law, thereby imposing a state-mandated local program.*

*The bill would authorize the department to conduct an investigation of cosmetic products that contain chemicals identified as causing cancer or reproductive toxicity or other ingredients of concern to the department. The bill would authorize the department to require manufacturers of products subject to investigation to submit relevant health effects data and studies and other information as requested by the department. The bill would require the department to establish reasonable deadlines for the submittal of that information and would make failure by a manufacturer to submit the information a crime, thereby imposing a state-mandated local program. The bill would require the department to submit the results of any investigation conducted to appropriate entities within the Division of Environmental and Occupational Disease Control. If the department determines that an ingredient in a cosmetic product is potentially toxic, the bill would require the department to immediately refer the results of its investigation to the Division of Occupational Safety and Health in the Department of Industrial Relations and would require the division, within 180 days after it receives the results, to develop and present one or more proposed occupational health standards to the Occupational Safety and Health Standards Board in the Department of Industrial Relations, unless the division affirmatively determines, in a written finding within 90 days, that a standard is not necessary to protect the health of an employee who has regular exposure to the hazard for the period of his or her working life.*

*The bill would require the department, as early as feasible within existing resources, to determine whether certain cosmetics have been adequately substantiated for safety, and if the cosmetic has, to determine if the cosmetic contains any ingredient that is not safe for the specific use indicated on the product's label. If the department finds that a product has been adequately substantiated for safety despite containing an unsafe ingredient, the bill would require the department to refer its findings to the Attorney General and the*

*federal Food and Drug Administration for possible enforcement action.*

*The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.*

*This bill would provide that no reimbursement is required by this act for a specified reason.*

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.  
State-mandated local program: ~~no~~-yes.

*The people of the State of California do enact as follows:*

1 ~~SECTION 1. Section 105180 of the Health and Safety Code~~  
2 ~~is amended to read:~~

3 *SECTION 1. The Legislature finds and declares all of the*  
4 *following:*

5 *(a) Independent testing in the United States and the European*  
6 *Union has determined that some cosmetic products contain*  
7 *substances known or suspected to cause cancer and reproductive*  
8 *toxicity that can harm the mother, fetus, and nursing children.*

9 *(b) Neither the federal Food and Drug Administration (FDA)*  
10 *nor the State Department of Health Services (DHS) require*  
11 *premarket safety testing, review, or approval of cosmetic*  
12 *products. According to the FDA, the regulatory requirements*  
13 *governing the sale of cosmetics are not as stringent as those that*  
14 *apply to other FDA-regulated products.*

15 *(c) Under the federal Food, Drug and Cosmetic Act (21 U.S.C.*  
16 *Sec. 301), cosmetics and their ingredients are not required to be*  
17 *approved before they are sold to the public and the FDA does not*  
18 *have the authority to require manufacturers to file health and*  
19 *safety data on cosmetic ingredients or to order a recall of a*  
20 *dangerous cosmetic product.*

21 *(d) Under the state Sherman Food, Drug, and Cosmetic Act,*  
22 *DHS has no authority to identify, review, or regulate ingredients*  
23 *in cosmetic products that may cause chronic health effects, such*  
24 *as cancer and reproductive toxicity.*

25 *(e) Cosmetic products are most heavily used by women of*  
26 *childbearing age, increasing the likelihood of exposing mothers,*

1 *fetuses, and nursing children to substances that can cause cancer*  
2 *and reproductive toxicity.*

3 *(f) Beauty care workers, including cosmetologists and*  
4 *manicurists, are most exposed to the potentially harmful effects*  
5 *of carcinogens and reproductive toxins in cosmetics.*  
6 *Cosmetologists and manicurists are dominated by women and*  
7 *minorities, particularly from Southeast Asia. In California, an*  
8 *estimated 80 percent of nail salons are operated by Vietnamese*  
9 *women.*

10 *(g) Federal law exempts chemicals used as fragrances or*  
11 *flavoring from being identified as ingredients on the labels of*  
12 *cosmetic products. Laboratory analyses of cosmetic products*  
13 *sold in California have found products that contain substances*  
14 *known to or likely to cause cancer or reproductive toxicity and*  
15 *not identified as an ingredient on the product's label. The law*  
16 *also does not require any ingredient labeling on cosmetic*  
17 *products sold for commercial use, thereby denying any*  
18 *information on ingredients to beauty care workers.*

19 *(h) The Division of Environmental and Occupational Disease*  
20 *Control in DHS conducts investigations of toxic materials in the*  
21 *workplace and analyzes data on workplace exposures to toxic*  
22 *materials. The Division of Occupational Safety and Health in the*  
23 *Department of Industrial Relations enforces occupational safety*  
24 *and health standards adopted by the Occupational Safety and*  
25 *Health Standards Board.*

26 *(i) Alternatives to substances that cause cancer or*  
27 *reproductive toxicity are readily available for use in cosmetic*  
28 *products. A number of manufacturers, including both small*  
29 *domestic producers and large multinational corporations, have*  
30 *eliminated substances that cause cancer or reproductive toxicity*  
31 *from their products.*

32 *(j) Given the presence of substances in cosmetic products that*  
33 *cause cancer and reproductive toxicity, the heavy use of these*  
34 *products by women of childbearing age, the significant exposure*  
35 *to these products in occupational settings such as nail and*  
36 *beauty salons, the adverse impacts of these substances on human*  
37 *health, the inadequate information about the presence of these*  
38 *substances in products or the extent of their impacts, and the*  
39 *availability of alternatives to the use of these substances, it is in*  
40 *the interest of the people of the State of California to take steps to*

1 *ensure that cosmetic products sold and used in the state can be*  
2 *used safely.*

3 *SEC. 2 Article 3.5 (commencing with Section 111791) is*  
4 *added to Chapter 7 of Part 5 of Division 104 of the Health and*  
5 *Safety Code, to read:*

6

7 *Article 3.5. Chronic Health Effects of Cosmetics*

8

9 *111791. This article shall be known, and may be cited, as the*  
10 *California Safe Cosmetics Act of 2005.*

11 *111791.5. For purposes of this article, the following terms*  
12 *have the following meanings:*

13 *(a) "Authoritative body" means any agency or formally*  
14 *organized program or group recognized pursuant to Section*  
15 *12306 of Title 22 of the California Code of Regulations as being*  
16 *authoritative for the purpose of identifying chemicals that cause*  
17 *cancer or reproductive toxicity.*

18 *(b) "Chemical identified as causing cancer or reproductive*  
19 *toxicity" means a chemical identified pursuant to Section*  
20 *25249.8 or identified by an authoritative body as any of the*  
21 *following:*

22 *(1) A substance listed as known or reasonably anticipated to*  
23 *be a human carcinogen in a National Toxicology Report on*  
24 *carcinogens.*

25 *(2) A substance given an overall carcinogenicity evaluation of*  
26 *Group 1, Group 2A, or Group 2B by the International Agency for*  
27 *Research on Cancer.*

28 *(3) A substance identified as a Group A, Group B1, or Group*  
29 *B2 carcinogen, or as a known or likely carcinogen by the United*  
30 *States Environmental Protection Agency.*

31 *(4) A substance identified as having some or clear evidence of*  
32 *adverse developmental, male reproductive, or female*  
33 *reproductive toxicity effects in a report by an expert panel of the*  
34 *National Toxicology Program's Center for the Evaluation of*  
35 *Risks to Human Reproduction.*

36 *111792. (a) On or after January 1, 2007, the manufacturer*  
37 *of any cosmetic product subject to regulation by the federal Food*  
38 *and Drug Administration that is sold in this state shall, on a*  
39 *schedule determined by the department, provide the department*  
40 *with a complete and accurate list of its cosmetic products that*

1 are sold in the state as of the date of submission and shall  
2 identify by product any ingredient that is a chemical identified as  
3 causing cancer or reproductive toxicity, including any chemical  
4 that meets either of the following conditions:

5 (1) A chemical contained in the product for purposes of  
6 fragrance or flavoring.

7 (2) A chemical identified by the phrase “and other  
8 ingredients” and determined to be a trade secret pursuant to the  
9 procedure established in Part 20 and Section 720.8 of Part 720  
10 of Title 21 of the Code of Federal Regulations. Any ingredient  
11 identified pursuant to this paragraph shall be considered to be a  
12 trade secret and shall be treated by the office in a manner  
13 consistent with the requirements of Part 20 and Part 720 of Title  
14 21 of the Code of Federal Regulations. Any ingredients  
15 considered to be a trade secret shall not be subject to the  
16 California Public Records Act (Chapter 3.5 (commencing with  
17 Section 6250) of Division 7 of Title 1 of the Government Code)  
18 for the purposes of this section.

19 (b) Any information submitted pursuant to subdivision (a)  
20 shall identify each chemical both by name and Chemical Abstract  
21 Service number.

22 (c) If an ingredient identified pursuant to this section  
23 subsequently is removed from the product in which it was  
24 contained, is removed from the list of chemicals known to cause  
25 cancer or reproductive toxicity published under Section 25249.8,  
26 or is no longer a chemical identified as causing cancer or  
27 reproductive toxicity by an authoritative body, the manufacturer  
28 of the product containing the ingredient shall submit the new  
29 information to the department. Upon receipt of new information,  
30 the department, after verifying the accuracy of that information,  
31 shall revise the manufacturer’s information on record with the  
32 department to reflect the new information. The manufacturer  
33 shall not be under obligation to submit subsequent information  
34 on the presence of the ingredient in the product unless  
35 subsequent changes require submittal of the information.

36 111792.5. (a) In order to determine potential health effects  
37 of exposure to ingredients in cosmetics sold in the state, the  
38 department may conduct an investigation of one or more  
39 cosmetic products that contain chemicals identified as causing

1 *cancer or reproductive toxicity or other ingredients of concern to*  
2 *the department.*

3 *(b) An investigation conducted pursuant to subdivision (a)*  
4 *may include, but not be limited to, a review of available health*  
5 *effects data and studies, worksite health hazard evaluations,*  
6 *epidemiological studies to determine the health effects of*  
7 *exposures to chemicals in various subpopulations, and exposure*  
8 *assessments to determine total exposures to individuals in*  
9 *various settings.*

10 *(c) If an investigation is conducted pursuant to subdivision (a),*  
11 *the manufacturer of any product subject to the investigation may*  
12 *submit relevant health effects data and studies to the department.*

13 *(d) In order to further the purposes of an investigation, the*  
14 *department may require manufacturers of products subject to the*  
15 *investigation to submit to the department relevant health effects*  
16 *data and studies available to the manufacturer and other*  
17 *available information as requested by the department, including,*  
18 *but not limited to, the concentration of the chemical in the*  
19 *product, the amount by volume or weight of the product that*  
20 *comprises the average daily application or use, and sales and*  
21 *use data necessary to determine where the product is used in the*  
22 *occupational setting.*

23 *(e) The department shall establish reasonable deadlines for*  
24 *the submittal of information required pursuant to subdivision (d).*  
25 *Failure by a manufacturer to submit the information in*  
26 *compliance with the requirements of the department shall*  
27 *constitute a violation of this part.*

28 *111793. (a) The department shall submit the results of any*  
29 *investigation conducted pursuant to Section 111792.5 to*  
30 *appropriate entities within the Division of Environmental and*  
31 *Occupational Disease Control, including the Hazard Evaluation*  
32 *System and Information Service in the Occupational Health*  
33 *Branch and the Environmental Health Investigations Branch.*

34 *(b) If the department determines pursuant to an investigation*  
35 *that an ingredient in a cosmetic product is potentially toxic at the*  
36 *concentrations present in the product or under the conditions*  
37 *used, the department shall immediately refer the results of its*  
38 *investigation to the Division of Occupational Safety and Health*  
39 *in the Department of Industrial Relations.*

1 (c) Within 180 days after it receives the results of an  
2 investigation pursuant to subdivision (b), the Division of  
3 Occupational Safety and Health shall, pursuant to Section 147.1  
4 of the Labor Code, develop and present one or more proposed  
5 occupational health standards to the Occupational Safety and  
6 Health Standards Board in the Department of Industrial  
7 Relations, unless the division affirmatively determines, in a  
8 written finding within 90 days, that a standard is not necessary to  
9 protect the health of an employee who has regular exposure to  
10 the hazard for the period of his or her working life. The written  
11 finding shall identify the reasons for determining the standard is  
12 not necessary and the factual basis for the finding.

13 111793.5. (a) The Legislature finds and declares the  
14 following:

15 (1) The Cosmetic Ingredient Review (CIR) panel is a  
16 nongovernmental body established and funded by the cosmetics  
17 industry to review the safety of cosmetic ingredients.

18 (2) According to a 2004 analysis of the 2003 CIR  
19 Compendium by the Environmental Working Group, 54 cosmetic  
20 products violate the CIR's own safe use recommendations to  
21 manufacturers by containing an ingredient that the CIR has  
22 found is not safe for the specific use indicated on the product's  
23 label.

24 (3) Federal regulations (21 C.F.R. 740.10) require every  
25 ingredient in a cosmetic product and every finished cosmetic  
26 product to be adequately substantiated for safety prior to  
27 marketing, and state that any ingredient or product whose safety  
28 has not been adequately substantiated prior to marketing is  
29 misbranded unless it displays a warning statement declaring,  
30 "The safety of this product has not been determined."

31 (b) The department shall, as early as feasible within existing  
32 resources, determine whether the products identified in  
33 paragraph (2) of subdivision (a) have been adequately  
34 substantiated for safety pursuant to Section 740.10 of Title 21 of  
35 the Code of Federal Regulations. For any product adequately  
36 substantiated for safety, the department shall determine if the  
37 product contains any ingredient that the CIR has found is not  
38 safe for the specific use indicated on the product's label.

39 (c) If the department finds that a product has been adequately  
40 substantiated for safety despite containing an ingredient that the

1 *CIR has found is not safe for the specific use indicated on the*  
2 *product's label, the department shall refer its findings to the*  
3 *Attorney General and the federal Food and Drug Administration*  
4 *for possible enforcement action pursuant to this part and the*  
5 *federal Food, Drug and Cosmetic Act (21 U.S.C. Sec. 301 et*  
6 *seq.).*

7 *SEC. 3. No reimbursement is required by this act pursuant to*  
8 *Section 6 of Article XIII B of the California Constitution because*  
9 *the only costs that may be incurred by a local agency or school*  
10 *district will be incurred because this act creates a new crime or*  
11 *infraction, eliminates a crime or infraction, or changes the*  
12 *penalty for a crime or infraction, within the meaning of Section*  
13 *17556 of the Government Code, or changes the definition of a*  
14 *crime within the meaning of Section 6 of Article XIII B of the*  
15 *California Constitution.*

16 ~~105180. When the activities undertaken pursuant to Section~~  
17 ~~105175 duplicate or overlap the activities of another state~~  
18 ~~department or agency such as the Department of Industrial~~  
19 ~~Relations or Division of Occupational Safety and Health, the~~  
20 ~~department shall avoid duplication.~~