

AMENDED IN ASSEMBLY JUNE 15, 2005

AMENDED IN SENATE APRIL 26, 2005

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL

No. 484

Introduced by Senator Migden
(Coauthors: Senators Alquist and Ortiz)
(Coauthor: Assembly Member Nation)

February 18, 2005

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. Cosmetics: chronic health effects.

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,~~ *commencing January 1, 2007, would* require the manufacturer of any cosmetic product subject to regulation by the federal Food and Drug Administration that is sold in the state ~~to,~~ *with certain exceptions,* on a schedule determined by the *Division of Environmental and Occupational Disease Control*

within the department, to provide the ~~department~~ division 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~~ Since a violation of the provisions applicable to the packaging, labeling, and advertising of food, drugs, and cosmetics is a crime, this bill would impose a state-mandated local program.

The bill would authorize the ~~department~~ division 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~~ division. The bill would authorize the ~~department~~ division to require manufacturers of products subject to investigation to submit relevant health effects data and studies and other information as requested by the ~~department~~ division. The bill would require the ~~department~~ division 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~~ division determines that an ingredient in a cosmetic product is potentially toxic, the bill would require the ~~department~~ division 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~~ Division of Occupational Safety and Health, 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~~ Division of Occupational Safety and Health 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~~ division, 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~~ division finds that a product has been adequately substantiated for

safety despite containing an unsafe ingredient, the bill would require the ~~department~~ *division* 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: yes. State-mandated local program: yes.

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

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Independent testing in the United States and the European
- 4 Union has determined that some cosmetic products contain
- 5 substances known or suspected to cause cancer and reproductive
- 6 toxicity that can harm the mother, fetus, and nursing children.
- 7 (b) Neither the federal Food and Drug Administration (FDA)
- 8 nor the State Department of Health Services (DHS) require
- 9 premarket safety testing, review, or approval of cosmetic
- 10 products. According to the FDA, the regulatory requirements
- 11 governing the sale of cosmetics are not as stringent as those that
- 12 apply to other FDA-regulated products.
- 13 (c) Under the federal Food, Drug and Cosmetic Act (21 U.S.C.
- 14 Sec. 301), cosmetics and their ingredients are not required to be
- 15 approved before they are sold to the public and the FDA does not
- 16 have the authority to require manufacturers to file health and
- 17 safety data on cosmetic ingredients or to order a recall of a
- 18 dangerous cosmetic product.
- 19 (d) Under the state Sherman Food, Drug, and Cosmetic Act,
- 20 DHS has no authority to identify, review, or regulate ingredients
- 21 in cosmetic products that may cause chronic health effects, such
- 22 as cancer and reproductive toxicity.
- 23 (e) Cosmetic products are most heavily used by women of
- 24 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 reproductive
27 toxicity are readily available for use in cosmetic products. A
28 number of manufacturers, including both small domestic
29 producers and large multinational corporations, have eliminated
30 substances that cause cancer or reproductive toxicity from their
31 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 beauty
36 salons, the adverse impacts of these substances on human health,
37 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—~~

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

7

8 Article 3.5. Chronic Health Effects of Cosmetics

9

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

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

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

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

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

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

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

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

37 (c) “*Division*” means the *Division of Environmental and*
38 *Occupational Disease Control within the State Department of*
39 *Health Services.*

40 (e)

1 (d) “Ingredient” has the same meaning as that term is defined
2 in subdivision (e) of Section 700.3 of Part 700 of Chapter 1 of
3 Title 21 of the Code of Federal Regulations and does not include
4 any incidental ingredient as defined in subdivision (l) of Section
5 701.3 of Part 701 of Chapter 1 of Title 21 of the Code of Federal
6 Regulations.

7 111792. (a) ~~On or after~~ *Commencing* January 1, 2007, the
8 manufacturer of any cosmetic product subject to regulation by
9 the federal Food and Drug Administration that is sold in this state
10 shall, on a schedule determined by the ~~department~~, ~~provide the~~
11 ~~department~~ *division*, *provide the division* with a complete and
12 accurate list of its cosmetic products that are sold in the state as
13 of the date of submission and shall identify by product any
14 ingredient that is a chemical identified as causing cancer or
15 reproductive toxicity, including any chemical that meets either of
16 the following conditions:

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

19 (2) A chemical identified by the phrase “and other
20 ingredients” and determined to be a trade secret pursuant to the
21 procedure established in Part 20 and Section 720.8 of Part 720 of
22 Title 21 of the Code of Federal Regulations. Any ingredient
23 identified pursuant to this paragraph shall be considered to be a
24 trade secret and shall be treated by the office in a manner
25 consistent with the requirements of Part 20 and Part 720 of Title
26 21 of the Code of Federal Regulations. Any ingredients
27 considered to be a trade secret shall not be subject to the
28 California Public Records Act (Chapter 3.5 (commencing with
29 Section 6250) of Division 7 of Title 1 of the Government Code)
30 for the purposes of this section.

31 (b) Any information submitted pursuant to subdivision (a)
32 shall identify each chemical both by name and Chemical Abstract
33 Service number.

34 (c) If an ingredient identified pursuant to this section
35 subsequently is removed from the product in which it was
36 contained, is removed from the list of chemicals known to cause
37 cancer or reproductive toxicity published under Section 25249.8,
38 or is no longer a chemical identified as causing cancer or
39 reproductive toxicity by an authoritative body, the manufacturer
40 of the product containing the ingredient shall submit the new

1 information to the ~~department~~ *division*. Upon receipt of new
2 information, the ~~department~~ *division*, after verifying the accuracy
3 of that information, shall revise the manufacturer's information
4 on record with the ~~department~~ *division* to reflect the new
5 information. The manufacturer shall not be under obligation to
6 submit subsequent information on the presence of the ingredient
7 in the product unless subsequent changes require submittal of the
8 information.

9 *(d) This section shall not apply to any manufacturer of*
10 *cosmetic products with annual aggregate sales of cosmetic*
11 *products, both within and outside of California, of less than one*
12 *million dollars (\$1,000,000), based on the manufacturer's most*
13 *recent tax year filing.*

14 111792.5. (a) In order to determine potential health effects of
15 exposure to ingredients in cosmetics sold in the state, the
16 ~~department~~ *division* may conduct an investigation of one or more
17 cosmetic products that contain chemicals identified as causing
18 cancer or reproductive toxicity or other ingredients of concern to
19 the ~~department~~ *division*.

20 (b) An investigation conducted pursuant to subdivision (a)
21 may include, but not be limited to, a review of available health
22 effects data and studies, worksite health hazard evaluations,
23 epidemiological studies to determine the health effects of
24 exposures to chemicals in various subpopulations, and exposure
25 assessments to determine total exposures to individuals in
26 various settings.

27 (c) If an investigation is conducted pursuant to subdivision (a),
28 the manufacturer of any product subject to the investigation may
29 submit relevant health effects data and studies to the ~~department~~
30 *division*.

31 (d) In order to further the purposes of an investigation, the
32 ~~department~~ *division* may require manufacturers of products
33 subject to the investigation to submit to the ~~department~~ *division*
34 relevant health effects data and studies available to the
35 manufacturer and other available information as requested by the
36 ~~department~~ *division*, including, but not limited to, the
37 concentration of the chemical in the product, the amount by
38 volume or weight of the product that comprises the average daily
39 application or use, and sales and use data necessary to determine
40 where the product is used in the occupational setting.

1 (e) The ~~department~~ *division* shall establish reasonable
2 deadlines for the submittal of information required pursuant to
3 subdivision (d). Failure by a manufacturer to submit the
4 information in compliance with the requirements of the
5 ~~department~~ *division* shall constitute a violation of this part.

6 111793. (a) ~~The department shall submit the results of any~~
7 ~~investigation conducted pursuant to Section 111792.5 to~~
8 ~~appropriate entities within the Division of Environmental and~~
9 ~~Occupational Disease Control, including the Hazard Evaluation~~
10 ~~System and Information Service in the Occupational Health~~
11 ~~Branch and the Environmental Health Investigations Branch.~~

12 ~~—(b) If the department~~ *If the division* determines pursuant to an
13 investigation that an ingredient in a cosmetic product is
14 potentially toxic at the concentrations present in the product or
15 under the conditions used, the ~~department~~ *division* shall
16 immediately refer the results of its investigation to the Division
17 of Occupational Safety and Health in the Department of
18 Industrial Relations *and the Office of Environmental Health*
19 *Hazard Assessment.*

20 (e)

21 (b) Within 180 days after it receives the results of an
22 investigation pursuant to subdivision (b), the Division of
23 Occupational Safety and Health shall, pursuant to Section 147.1
24 of the Labor Code, develop and present one or more proposed
25 occupational health standards to the Occupational Safety and
26 Health Standards Board in the Department of Industrial
27 Relations, unless the ~~division~~ *Division of Occupational Safety*
28 *and Health* affirmatively determines, in a written finding within
29 90 days, that a standard is not necessary to protect the health of
30 an employee who has regular exposure to the hazard for the
31 period of his or her working life. The written finding shall
32 identify the reasons for determining the standard is not necessary
33 and the factual basis for the finding.

34 111793.5. (a) The Legislature finds and declares the
35 following:

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

39 (2) According to a 2004 analysis of the 2003 CIR
40 Compendium by the Environmental Working Group, 54 cosmetic

1 products violate the CIR’s own safe use recommendations to
2 manufacturers by containing an ingredient that the CIR has found
3 is not safe for the specific use indicated on the product’s label.

4 (3) Federal regulations (21 C.F.R. 740.10) require every
5 ingredient in a cosmetic product and every finished cosmetic
6 product to be adequately substantiated for safety prior to
7 marketing, and state that any ingredient or product whose safety
8 has not been adequately substantiated prior to marketing is
9 misbranded unless it displays a warning statement declaring,
10 “The safety of this product has not been determined.”

11 (b) The ~~department~~ *division* shall, as early as feasible within
12 existing resources, determine whether the products identified in
13 paragraph (2) of subdivision (a) have been adequately
14 substantiated for safety pursuant to Section 740.10 of Title 21 of
15 the Code of Federal Regulations. For any product adequately
16 substantiated for safety, the ~~department~~ *division* shall determine
17 if the product contains any ingredient that the CIR has found is
18 not safe for the specific use indicated on the product’s label.

19 (c) If the ~~department~~ *division* finds that a product has been
20 adequately substantiated for safety despite containing an
21 ingredient that the CIR has found is not safe for the specific use
22 indicated on the product’s label, the ~~department~~ *division* shall
23 refer its findings to the Attorney General and the federal Food
24 and Drug Administration for possible enforcement action
25 pursuant to this part and the federal Food, Drug and Cosmetic
26 Act (21 U.S.C. Sec. 301 et seq.).

27 SEC. 3. No reimbursement is required by this act pursuant to
28 Section 6 of Article XIII B of the California Constitution because
29 the only costs that may be incurred by a local agency or school
30 district will be incurred because this act creates a new crime or
31 infraction, eliminates a crime or infraction, or changes the
32 penalty for a crime or infraction, within the meaning of Section
33 17556 of the Government Code, or changes the definition of a
34 crime within the meaning of Section 6 of Article XIII B of the
35 California Constitution.

O