

### REMINDER -- DEADLINE FOR REPORTING COSMETIC PRODUCTS UNDER THE CALIFORNIA SAFE COSMETICS PROGRAM

Covington & Burling LLP is issuing this alert to remind companies that the deadline to report required information under the California Safe Cosmetics Program is **OCTOBER 15, 2009**, one month from today.

#### BACKGROUND

On June 15, 2009, the California Safe Cosmetics Program (CSCP) launched its online reporting system.<sup>1</sup> Companies subject to reporting under the California Safe Cosmetics Act of 2005 (the Act) must submit all reportable cosmetic products to the California Department of Public Health (CDPH) by October 15, 2009 and then must file further updates or information on new products within one month of the product becoming reportable. Summarized below are the reporting requirements as provided by CDPH in the online reporting instructions and informational sheets.

#### WHO IS REQUIRED TO REPORT?

- Companies (both domestic and foreign) that have sold a reportable cosmetic product in California since January 1, 2007 and that have a total of at least \$1 million or more in aggregate sales of cosmetic products, including product sales both within and outside of California, are required to report. The determination of \$1 million threshold is based on the previous year's tax records.
  - The term, "companies", is defined as manufacturers, packagers, and/or distributors named on the label of a product.
  - When more than one company is listed on a product's label, all listed companies subject to the reporting requirements are required to report. One listed company may submit a joint report for a product on behalf of other listed companies, provided the report reflects that it is a joint report.
- A company must submit all reportable chemicals in a product, even if the reportable chemical is supplied by another company.
- A company that does not know the composition of a product is not exempt from reporting and is responsible for obtaining and submitting required product information.

BEIJING

BRUSSELS

LONDON

NEW YORK

SAN DIEGO

SAN FRANCISCO

SILICON VALLEY

WASHINGTON

WWW.COV.COM

<sup>1</sup> <http://www.cdph.ca.gov/programs/cosmetics/Pages/New.aspx>.

## WHAT PRODUCTS/INGREDIENTS ARE REQUIRED TO BE REPORTED?

- The instructions state that companies must report all cosmetic products sold in California on or after January 1, 2007 that contain ingredients known or suspected to cause cancer, birth defects, or other reproductive harm.
- CDPH has compiled an online list of chemicals that companies can use as a guide to determine what products must be reported.<sup>2</sup>
- According to the CDPH instructions, companies must report all reportable cosmetic products that were sold in California on or after January 1, 2007, even if the product is no longer being manufactured, packaged, or distributed.
- Companies must report cosmetic products that contain any amount of a reportable chemical (except for incidental ingredients), regardless of whether the mode of exposure to which a consumer would be subjected from the particular product differs from the mode of exposure identified on the chemical list.
- The CDPH instructions direct that companies must report products having labels stating the product “may contain” ingredients that are reportable chemicals.
- Companies must report products for which the intended use is both cosmetic and therapeutic, i.e., that are drugs, as long as the products meet FDA’s definition of a cosmetic.
- Cosmetic products having different formulations are separately reportable. The same product sold as a spray and a cream would be considered two separate reportable products if the formulas are different.
- Two products having different names but the same formulation and products for which the name has been changed must be separately reported under each name.
- On the other hand, multiple colors, scents, or flavors of cosmetics or collections thereof can be reported as one product filing. Companies must report any reportable ingredient specific to the color, scents, flavors, or collections.

## WHAT PRODUCTS/INGREDIENTS ARE NOT REQUIRED TO BE REPORTED?

- Companies are not required to report chemicals that degrade into other chemicals after application. Only chemicals identified in the products must be reported.
- Companies are not required to report compounds of reportable chemicals if the compounds themselves are not reportable. For example, if acrylamide is a reportable chemical but acrylamide polymers are not, products that contain acrylamide must be reported but products that contain poly acrylamide are not reportable.
- Incidental ingredients do **NOT** need to be reported.
- Soaps, as defined by FDA, do not need to be reported. Body washes may need to be reported, depending on the intended use and whether the product meets FDA’s definition of soap.

## IS TRADE SECRET INFORMATION REQUIRED TO BE REPORTED?

- Trade secret information is not exempt from the reporting requirements, but confidential/trade secret information is not subject to the California Public records Act.
- Companies that claim information as confidential/trade secret must submit supporting written documentation to justify this designation.

---

<sup>2</sup> <http://www.cdph.ca.gov/programs/cosmetics/Documents/ChemicalAndProductLists.pdf>.

## HOW AND WHEN IS A COMPANY REQUIRED TO REPORT?

- Online reporting began June 15, 2009.
- Companies must submit reports to CDPH by **OCTOBER 15, 2009**.
- Companies should report using the online reporting system at <https://www.safecosmeticsact.org/SafeCosmetics/>. Instructions for using the online reporting system are available at <http://www.cdph.ca.gov/programs/cosmetics/documents/reportinginstructions.pdf>.
- To initiate online reporting, a company must create a user name and password on the online reporting system. Consultants or companies reporting on behalf of another company must create a separate user name and password for each company for which a report is being submitted.
- CDPH is unable to accept paper reports. Companies that cannot report online must contact the CSCP at (877) 325-3223.
- After October 15, 2009, companies will have one month to report a product after it becomes reportable.
- Companies can submit at any time changes to previously-submitted information, including reformulations.
- Additional information is available online at <http://www.cdph.ca.gov/programs/cosmetics/Pages/CosmeticsCompanies.aspx>.
- Violations of the statutory reporting requirements of the Act are incorporated by reference from Chapter 8 of the California Sherman Food, Drug, and Cosmetic Law, and include criminal penalties.<sup>3</sup>

## POTENTIAL FUTURE ISSUES

As part of the launch, CDPH issued guidance in the form of instructions and informational sheets on the reporting obligations. This guidance appears to expand the statutory reporting requirements in several ways:

1. According to the CDPH instructions, companies must report all reportable cosmetic products that were sold in California on or after January 1, 2007, even if the product is no longer being manufactured, packaged or distributed. The Act itself states:

Commencing January 1, 2007, the manufacturer of any cosmetic product subject to regulation by the federal Food and Drug Administration that is sold in this state shall ... provide the division with a complete and accurate list of its cosmetic products that, as of the date of submission, are sold in the state and that contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity, ...

Because the commencement of the reporting requirement was delayed until this year, CDPH evidently reads this statutory provision as permitting retroactive reporting of products marketed on or after January 1, 2007, even if these products have since been discontinued. It is not clear, however, that this interpretation would withstand judicial challenge given the Act's requirement that companies report their "cosmetic products that, *as of the date of submission*, are sold in the state and that contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity ... ." (Emphasis added.)

---

<sup>3</sup> See <http://www.dhs.ca.gov/fdb/html/General/sheindex.htm>.

2. The CDPH instructions also direct companies to report products having labels that state the products “may contain” ingredients that are reportable chemicals. The Act does not specifically address ingredients that may or may not be present in the product.

3. The instructions require that ingredient information including concentrations and areas of intended application be provided. The Act discusses the collection of this information only in connection with CDPH investigations.

In light of the differences between the statute and the CDPH guidance, companies should review their products and should consult with their technical experts and legal counsel to determine how to report their products properly.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

Jeannie Perron

202.662.5687

[jperron@cov.com](mailto:jperron@cov.com)

MaryJoy Ballantyne

202.662.5933

[mballantyne@cov.com](mailto:mballantyne@cov.com)

---

This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP is one of the world’s preeminent law firms known for handling sensitive and important client matters. This promotional communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to [unsubscribe@cov.com](mailto:unsubscribe@cov.com) if you do not wish to receive future emails or electronic alerts. Covington & Burling LLP is located at 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401.

© 2009 Covington & Burling LLP. All rights reserved.