

California Safe Cosmetics Program Informational Sheet The California Safe Cosmetics Act of 2005

1. Companies subject to the reporting provisions of the California Safe Cosmetics Act of 2005 (the Act)

A company is required to report if all of the following conditions are met:

- It has a total of at least \$1 million of cosmetic product sales both within and outside of California (according to previous year tax records);
- It is the manufacturer, packer, and/or distributor named on the label of a product which contains an ingredient known or suspected by an authoritative body cited in the Act to cause cancer or reproductive harm;
- That product meets the U.S. Food and Drug Administration's (U.S. FDA's) definition of a cosmetic (see CSCP Definitions Informational Sheet for the definition of a cosmetic); and
- That product was sold in California on or after January 1, 2007.

2. Products subject/not subject to the reporting provisions of the California Safe Cosmetics Act

The following holds true if the criteria listed in Section 1 above are met:

- Soaps as defined by U.S. FDA do not need to be reported. Body washes may or may not need to be reported, depending on its intended use and whether it meets the U.S. FDA definition of soap. (See <http://www.cfsan.fda.gov/~dms/cos-218.html> for more information).
- Not all ingredients in a product need to be reported. Only ingredients known or suspected by an authoritative body cited in the Act to cause cancer or reproductive harm need to be reported.
- Incidental ingredients do not need to be reported. (See the CSCP Definitions Informational Sheet for the definition of an incidental ingredient).
- If a chemical degrades into another chemical after application, the new chemical does not need to be reported. Only the chemicals identified in the product need to be reported.
- Products that contain *compounds* of reportable chemicals do not need to be reported if the *compounds* themselves are not reportable. For example, if the reportable chemical is acrylamide, products that contain acrylamide would need to be reported; products that contain polymers of acrylamide would not need to be reported. If an authoritative body cited in the Act lists the *compound* of a chemical as a known or likely carcinogen or reproductive toxicant, then products that contain polymers of that chemical would need to be reported.
- A product whose intended use is both therapeutic (drug) and cosmetic in nature, as defined by U.S. FDA, needs to be reported if that product meets the U.S. FDA's definition of a cosmetic. (See <http://www.cfsan.fda.gov/~dms/cos-218.html> for more information). Note: Questions regarding whether certain products are considered to be cosmetics will be referred to the California Department of Public Health (CDPH) Food and Drug Branch.
- Pursuant to the Act, products that contain any amount of a reportable chemical needs to be reported.
- Pursuant to the Act, products that contain a reportable chemical need to be reported regardless of whether the likely mode of exposure to the ingredient in that cosmetic product differs from the route of exposure identified by the authoritative body as the pathway that is likely to lead to cancer or reproductive harm.
- A product whose label states "may contain ingredient X" needs to be reported if ingredient X is reportable.
- Products sold in California anytime after January 1, 2007, will need to be reported, even if the product is no longer being manufactured.

3. Reporting Clarifications

On deciding which companies need to submit reports to the California Department of Public Health (CDPH)

- For any given product, more than one company may be listed on the product label. All listed companies meeting the above definitions will be required to report.
- A joint report for a product may be submitted by a company, on behalf of other companies listed on the product label. The company filing must state that they are filing on behalf of the other companies.
- Companies that make less than \$1 million of aggregate cosmetic product sales both within and outside of California will have the option of reporting.

Information to submit

- Reporting companies do not have to provide information on companies to whom they sell their products unless they are reporting on their behalf.
- A company that does not know the composition of a product is NOT exempt from reporting. It is responsible for obtaining and submitting required product information.
- Trade secret information is not exempt from reporting to CDPH.
- Multiple shades (of colored cosmetics products) can be reported as one product filing. Companies will be asked for any ingredients specific to the shade that needs to be reported.

Process

- Each company that will be reporting will be provided with a unique ID and asked to select a password to enter the online product reporting system. There may be a delay after selection of a password before access to the online reporting system is granted.
- The California Safe Cosmetics Program (CSCP) will attempt to provide companies with a printout of the information they submitted.
- All information submitted to CDPH will remain on file at CDPH in a secure location. An online product list of non-confidential data and summary reports will be developed.
- Companies will be able to request changes to previously submitted information.
- Reporting guidelines and specific form instructions will be posted online to assist manufacturers with reporting.
- The reporting system, guidelines, and form instructions will only be available in English.
- At this time, CSCP is unable to accept paper reporting forms; we are only accepting company/product information submitted through the online electronic reporting system. Companies that cannot report online through the CSCP online electronic reporting system must contact CSCP by calling the CSCP Helpline at 1-877-325-3223.

Schedule

- Companies will be given four months after the initial launch of the CSCP reporting system to submit their product information. After this time, reporting will be on a continuous basis; companies will need to report whenever a product becomes reportable.
- If a product becomes reportable after the initial four months of the reporting system, companies will be given one month to report.
- Companies can submit changes to previously submitted information, including product reformulation, at any time after launch of reporting.
- CSCP is aiming to have their product list updated as new information is received.

4. Confidential Information

- Companies will have the opportunity to mark ingredient, commercial or financial information as confidential. They will need to submit the same type of information that other CDPH programs request with regard to claims of confidentiality.

- CDPH may review confidentiality requests.
- CDPH will not make confidential information available to the public unless the outcome of an official investigation deems the information is not confidential.

5. Information Dissemination

- CSCP has established a contacts database of stakeholders and an email distribution list to send email notifications of program updates. CSCP will attempt to locate contact information for both industry stakeholders, including smaller companies, as well as stakeholders specifically interested in the product list. CSCP will attempt to include key stakeholders to distribute program information to others. Stakeholders should submit contact information via email (cosmetic@cdph.ca.gov) to be added to the email distribution list.
- When appropriate, CSCP will consult with stakeholders for input on language used to describe program products.

Note: The California Safe Cosmetics Program (CSCP) in the Department of Public Health (CDPH) developed this informational sheet primarily in response to questions stakeholders have raised about the California Safe Cosmetics Act of 2005 (the Act). It was developed with input from the CSCP Stakeholder Workshop Planning Committee and CDPH's Office of Legal Services. It is a compilation of material from either the Act or federal rules that are referenced in the Act. These CDPH determinations on what the law means have been taken either directly from the law itself, or is what CDPH has concluded embodies the only legally tenable interpretation of the Act. Thus, actions of CDPH in implementing the Act do not constitute formal rulemaking (see California Government Code Section 11340.9).