

GUIDANCE on California Proposition 65 and Herbal Products

Revised August 2018

Prepared by the American Herbal Products Association



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The information contained herein is not and should not be considered to be legal advice. This publication is not a substitute for the California Proposition 65 laws and regulations that apply to businesses in the State of California. Instead, it should be viewed as a supplementary guide to these laws and regulations. Information contained herein is not intended to replace or supersede instructions, guidelines or regulations issued by the State of California. In addition, no other issues related to the manufacture, marketing, or sale of products entering commerce in California are addressed herein.

While AHPA believes that all of the information contained here is accurate, any company that uses this information does so as its own choice; is wholly responsible for any policies established therefrom; and is advised to discuss all aspects related to compliance with Proposition 65 with a qualified attorney or consultant.



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Introduction and Background

Consumer goods sold in the State of California are, with certain exceptions, subject to that State's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986. The regulations that have been implemented in the years since the Proposition was passed place specific warning requirements on marketers of products sold in the State of California if the product contains chemicals listed by the State as carcinogens or reproductive toxicants. Failure to provide such warnings can result in action by the California Attorney General or by "any person in the public interest."

In the past decades numerous companies that sell or manufacture herbal products, including brand marketers, contract manufacturers, and retailers, have been the subject of complaints filed or threatened by several organizations and individuals and local district attorneys and the state attorney general. These lawsuits have alleged that natural products sold by these companies contain amounts of heavy metals and other listed chemicals (primarily lead, and in some cases arsenic, cadmium and mercury) that require a warning. Companies that had not provided a warning prior to receipt of complaints have reached settlements that have resulted in payments of up to \$682,000 per company, with average settlements in the range of \$85,000 to \$100,000 per dietary supplement company. Also of concern is the Proposition 65 listing of several chemical constituents which are naturally occurring in some botanicals used in teas and dietary supplements. Most recently, two processed botanicals have been added to the Proposition 65 list due to the results observed after testing these materials in long-term carcinogenicity assays.

Since July 2016, numerous companies that sell or manufacture tea and tea products, primarily marketers of branded finished products, have been the subject of complaints alleging violation of Proposition 65 for failure to provide the required warnings due to the presence of lead and, in a few cases, naphthalene. To date, several of these cases have been settled, either individually or through one joint settlement involving 19 defense parties reportedly acting under a joint defense agreement. Individual settlements have averaged \$22,623 per company, and joint defense parties have settled for amounts ranging from \$19,500 to \$58,500.

This document was prepared with a narrow focus; it is concerned only with the regulatory and liability implications of Proposition 65 for constituents that may be present in herbal and other natural products sold in the State of California. It is not intended to address any other elements of Proposition 65 except as necessary for the present purpose, nor does it serve as a substitute for this law, its implementing regulations, or legal counsel.

For more information on this law see the website of the California Office of Environmental Health Hazard Assessment (OEHHA), which oversees Proposition 65 issues, at oehha.ca.gov. Additional helpful information is available at www.prop65news.com and www.prop65clearinghouse.com. OEHHA also maintains a consumer-oriented Proposition 65 website at www.p65warnings.ca.gov.

This document was originally authored by Michael McGuffin, AHPA President, and Trent Norris (Arnold & Porter Kaye Scholer LLP), AHPA's Counsel for Proposition 65, and was titled *Background on California Proposition 65: Issues related to heavy metals and herbal products*. This version updates documents of that title dated November 2004, December 2008, October 2010, and October 2017. It also incorporates AHPA guidance documents previously issued for the naturally-occurring constituents pulegone and β -myrcene (August 2016) and the processed botanicals goldenseal root powder (August 2016) and aloe



vera, non-decolorized whole leaf extract (August 2016) in order to consolidate AHPA's guidance on this topic.

General requirements

What warnings are required by Proposition 65?

Any company with ten or more employees that operates within the state or sells products in California must provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical in an amount exceeding established standards (see "How much of a chemical?," below).

Warnings provided by the product manufacturer

Proposition 65 warnings are typically provided by the manufacturer, producer, packager, importer, supplier, or distributor of a product in commerce in California. Examples of the Proposition 65 warnings as applicable to food and dietary supplements are as follows:

- For any chemical listed as a carcinogen:

WARNING: Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/food.

- For any chemical listed as a reproductive toxicant:

WARNING: Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.

- For a chemical listed as a carcinogen and a different chemical listed as a reproductive toxicant:

WARNING: Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.

- For any chemical listed as both a carcinogen and as a reproductive toxicant:




WARNING: Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.

Where a warning is being provided for an exposure to a single chemical, the words "chemicals including" may be deleted from the warning above, but in that circumstance the warning will only cover the identified chemical.

Where the warnings above are provided on a food or dietary supplement product label, the warning must be set off from other surrounding information and enclosed in a box.



Companies can also comply with the warning regulation using the short-form warning option. This warning option contains a symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline¹ placed to the left of the warning text, as well as the following:

- For consumer products that cause exposures to a listed carcinogen:
 **WARNING:** Cancer - www.P65Warnings.ca.gov.
- For consumer products that cause exposures to a listed reproductive toxicant:
 **WARNING:** Reproductive Harm - www.P65Warnings.ca.gov.
- For consumer products that cause exposures to both a listed carcinogen and a reproductive toxicant:
 **WARNING:** Cancer and Reproductive Harm - www.P65Warnings.ca.gov.

For short-form warnings, the warning language must be no smaller than the largest type size used for other consumer information² on the product, and in no case shall the warning appear in a type size smaller than 6-point type. Short-form warnings are not required to include the name or names of a listed chemical within the text of the warning.

Warnings provided by the product retailer

The manufacturer, producer, packager, importer, supplier, or distributor of a product may also comply with the Proposition 65 warning requirements by providing a written notice directly to the authorized agent for a retail seller, which includes all of the following:

1. States that the product may result in an exposure to one or more Proposition 65 listed chemicals;
2. Includes the exact name or description of the product or specific identifying information for the product such as a Universal Product Code (UPC) or other identifying designation;
3. Includes all necessary warning materials such as labels, labeling, shelf signs or tags, and warning language for products sold on the Internet;
4. Has been sent to the retail seller, and the manufacturer, producer, packager, importer, supplier, or distributor has obtained confirmation electronically or in writing of receipt of the notice.

The product retailer is directly responsible for providing Proposition 65 warnings to consumers under certain other circumstances, such as when the retailer knowingly introduces a listed chemical into the product, or when the retailer obscures a warning label that has already been affixed to the product.

¹ If the sign, label, or shelf tag for the product is not printed using the color yellow, the symbol may be provided in black and white. The warning symbol can be downloaded from the OEHHA website.

² “Consumer information” includes warnings, directions for use, ingredient lists, and nutritional information. “Consumer information” does not include the brand name, product name, company name, location of manufacture, or product advertising.



Which chemicals require warnings under Proposition 65?

Proposition 65 requires the State of California to publish and maintain a list of chemicals known to cause cancer or reproductive toxicity. The list is updated periodically; the most recent list is accessible on the OEHHA website³.

Chemicals can be added (or occasionally removed) from the list by various mechanisms, such as a declaration by an authoritative body or by scientific testing.

Of most interest to any company that sells herbs, or any consumer product manufactured from plants for that matter, are certain heavy metals. Metals such as arsenic, cadmium, lead and mercury are found in soils all over the world, both in naturally occurring amounts and in some cases as a result of human activity over the centuries. Each of these metals is on the current list as reproductive toxins, i.e., as chemicals capable of causing birth defects or other reproductive harm if consumed in sufficient quantity. In addition, arsenic and lead are listed as carcinogens by oral ingestion and cadmium is listed as a carcinogen by inhalation.

Of these four heavy metals, it is lead that requires the most attention for botanical ingredients. Lead is found almost everywhere in the environment, both as a result of natural processes and sometimes as a byproduct of the use of fossil fuels, lead-containing agricultural chemicals, and leaded brass implements for harvesting, processing, or irrigating plants. As with other heavy metals, lead is readily absorbed into the tissues of many plants. And the level of lead that requires a warning (see below) is exceptionally low.

Other chemicals listed include the botanical constituents pulegone and β -myrcene, and the processed botanicals aloe vera, non-decolorized whole leaf extract and goldenseal root powder. AHPA's understanding is that Proposition 65 warnings are generally not needed on foods (including dietary supplements) for listed chemicals which are naturally occurring (see further discussion below).

How much exposure to a chemical triggers a warning?

Proposition 65 mandated warnings are not required when a product presents exposure to listed chemicals below certain levels. For carcinogens, this level is one that "poses no significant risk assuming lifetime exposure at the level in question." Said another way, and according to OEHHA:

For a chemical that is listed as a carcinogen, the "no significant risk" level is defined as the level which is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. In other words, if you are exposed to the chemical in question at this level every day for 70 years, theoretically it will increase your chances of getting cancer by no more than 1 case in 100,000 individuals so exposed.

For reproductive toxicants the level below which a warning is not required is that which "will have no observable effect assuming exposure at one thousand (1000) times the level in question." According to OEHHA:

³ OEHHA revises this document on a regular basis. Please see the following url for access to the most recent version - <https://oehha.ca.gov/proposition-65/proposition-65-list>.



For chemicals that are on the list as reproductive toxicants, the no significant risk level is defined as the level of exposure which, even if multiplied by 1,000, will not produce birth defects or other reproductive harm. That is, the level of exposure is below the “no observable effect level (NOEL),” divided by 1,000. (The “no observable effect level” is the highest dose level which has not been associated with an observable reproductive harm in humans or test animals.)

Who is responsible for all of this? Who is liable?

The law states that “No person in the course of doing business shall knowingly and intentionally expose an individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual [with exceptions].” This “person” can be any company in the stream of commerce, e.g., a manufacturer, distributor or retailer. Enforcement is most often against the manufacturer of a product, but there have been cases brought against retailers. There is also some concern as to whether a medical practitioner who uses herbal products in his or her practice might bear some liability.

Companies with fewer than ten employees are exempt from the requirements to provide warnings under Proposition 65. However, both the California Attorney General and private enforcers have taken the position that Proposition 65 liability applies to any company with ten or more employees that is in the stream of commerce for the product. In this view, a manufacturer with fewer than ten employees would not be liable under Proposition 65, but its distributors and retailers, assuming they each have at least ten employees, would be liable. As a result of common indemnity practices and business customs, therefore, the small manufacturer may still be asked to take financial responsibility for compliance by or a lawsuit against the larger distributor or retailer.

How is Proposition 65 enforced?

This law is enforced by civil suits against companies that are believed to be in violation of its requirements. The State Attorney General and local district and city attorneys have authority to take such actions, but, unlike most of the laws in the State of California, such a suit may also be brought by “any person in the public interest.” Almost all of the cases that have been brought against herbal companies to date have, in fact, been the result of actions by private plaintiffs outside of government offices.

An action against a company by a private plaintiff will be initiated by a “60-day Notice.” In this Notice the company is informed that the plaintiff claims violations of Proposition 65 and intends to bring enforcement action against the company within 60 days unless the Attorney General has first begun to prosecute the company for the alleged violations.

The violations described in the cases involving herbal companies have been based on allegations by the plaintiffs that, although the company’s products do not bear Proposition 65 warning labels, there are one or more heavy metals in the company’s products at levels that in fact require warnings. In several cases the Notices have attached an Appendix that lists the company’s entire product line.

Proposition 65 generally places the burden of proof on the defendant. Once a company has received a 60-day Notice, the company will be required to provide actual evidence that the alleged violation has not occurred. A company may also be called upon to prove that its customers actually use their products



in the amounts specified on the labels. Furthermore, although the law specifies that exposure be made “knowingly and intentionally,” these terms as they are usually understood have not proven to be a practical impediment to enforcers in the past.

The law specifies that civil liability in a Proposition 65 action “shall not exceed \$2,500 per day for each violation.” Plaintiffs typically argue that a violation occurs each time that each consumer consumes a daily serving of a product, such that a broadly sold product can be argued to represent a large number of violations each day. As stated at the outset, payments and attorney fees of up to \$682,000 have been levied against some manufacturers of herbal dietary supplement products whose products were alleged to contain heavy metals in amounts that were in excess of the established “safe harbor” levels.

What should a company do if it gets a 60-day notice?

The defense of a lawsuit brought under California Proposition 65 is a complex process requiring special expertise. It is strongly advised that anyone in receipt of a 60-day Notice contact an attorney who is knowledgeable about this law. AHPA maintains communications with several legal firms who specialize in environmental and consumer law and can sometimes provide an introduction.

How can a company doing business in California best deal with Proposition 65?

The best advice would appear to be simple: know your products. That said, companies should be aware that any testing they perform may be discoverable by prosecutors and therefore used against them, so legal advice should be sought on these issues.

Articles have been published in scientific journals that have recorded laboratory analyses of heavy metals in herbal products at levels that may require warnings under Proposition 65, depending on serving sizes, naturally occurring levels, and other factors. At this time there are also the existing cases and settlements that have occurred in the past several years. Any company selling herbal products should be prepared to answer any charges that are brought against them in this matter promptly, as the burden of proof is on the company.

Heavy metals under Proposition 65

Are specific levels established for these chemicals?

The burden of showing that an exposure is below the threshold levels is on the company that “exposes” the consumer to a product. OEHHA has, however, established “safe harbors” for many chemicals on the State’s lists, including most of the heavy metals that may be of interest to marketers of herbal products. These levels are stated as “no significant risk levels” (NSRL) for carcinogens and as “maximum allowable daily levels” (MADL) for chemicals listed as reproductive toxins.

NSRL and MADL levels for arsenic, cadmium, lead and mercury are given in Table 1. All quantities are those that are given in OEHHA’s publication of May 2017, *Proposition 65 Safe Harbor Levels: No*



Significant Risk Levels for Carcinogens and Maximum Allowable Dose Levels for Chemicals Causing Reproductive Toxicity⁴ unless otherwise stated.

Table 1 – Current “safe harbor” levels of relevant heavy metals

	Carcinogen	Reproductive toxicant
	NSRL (µg/day)	MADL (µg/day)
arsenic ^a	10 ^b	none established ^c
cadmium	0.05 (inh) ^d	4.1
lead	15	0.5
mercury ^e	none established ^f	none established ^g

- ^a The specific listed carcinogenic chemical is “arsenic (inorganic arsenic compounds);” that listed as a developmental toxin is “arsenic (inorganic oxides).”
- ^b Limit for inhaled arsenic is 0.06 µg/day; the level given here is the limit for exposure by other routes, e.g., ingestion, and is given for “arsenic” rather than the more specific listed chemical (i.e., “arsenic (inorganic arsenic compounds)”).
- ^c “Arsenic (inorganic oxides)” is listed in the September 2012 publication⁵ as a “second priority” for establishment of a MADL. As recently as October 2007 this chemical was listed as a “first priority,” and a “draft oral MADL” of 0.1 µg/day was published by OEHHA in 2003. At least one settlement from July 2008 establishes a limit of 10 µg/day as total arsenic⁶.
- ^d The NSRL for cadmium is for inhalation; no level is given for oral consumption and cadmium is not generally considered carcinogenic by the oral route; the listing of cadmium in the current list does not, however, state this clearly.
- ^e The relevant carcinogenic chemical is listed as “methylmercury compounds;” those listed as developmental toxins are “mercury and mercury compounds” and “methyl mercury.”
- ^f Currently listed as a “third priority” for establishment of an NSRL.
- ^g Mercury and mercury compounds, as well as methyl mercury, are listed in the September 2012 publication as “second priorities” for setting MADLs, though they were both formerly listed, in October 2007, as “first priorities.” A “draft MADL” for methyl mercury of 0.3 µg/day was identified by OEHHA in 1994. At least one settlement from July 2008³ establishes a limit of 0.30 µg/day for mercury compounds, except for inorganic mercury which has a limit of 3.0 µg/day.

⁴ See the following link for the latest list of safe harbor levels: <https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum>. Accessed on August 29, 2017.

⁵ Priority List for the Development of Proposition 65 Safe Harbor Levels. OEHHA, September 2012 Update.

⁶ One such example settlement is found in *Steven D. Gillett v. Madison One Acme Inc., a Company doing business as Solstice Medicine Company*, 2008, Superior Court of the State of California, Case No. CGC-07-469239.



How should heavy metals be tested in herbal products?

Several analytical methods are available for measuring the heavy metal content of plant material such as herbs. Proposition 65 does not specify which method must be used, but due to the need for very low limits of detection, especially for lead, quite sensitive analytical methods are required.

The most widely available methods are ICP-MS (inductively coupled plasma / mass spectroscopy), GFAA (graphite furnace / atomic absorption), and ICP-AES (inductively coupled plasma / atomic emission spectroscopy, usually known simply as ICP). For some purposes analysis of mercury at very low levels may be accomplished by the more sensitive FIMS method (flow injection mercury analyzer).

In choosing the most appropriate analytical method the limits of detection should be specified at levels that take into account the conforming level under Proposition 65 for each tested heavy metal and the daily serving size of the product to be tested.⁷ Tables 2 and 3 below may be useful in making such determinations.

Analytical labs offer ICP and ICP-MS testing for individual heavy metals or for a 5-metal screen (the four metals named earlier plus chromium). Pricing should be between \$50 and \$100 for a single element and \$150 to \$250 for the 5-metal analysis. Contract labs may also charge a modest sample preparation charge, regardless of the analytical method used. AHPA can sometimes negotiate better pricing on behalf of their members for some of these analyses, and member companies are invited to contact the AHPA office for further information.

When testing for heavy metals or contracting an analytical laboratory for such testing, it is essential to know the limits of detection for the method that will be used. Analytical results will be stated in parts per million (ppm); this is sometimes stated as, and is equivalent to, milligrams per kilogram (mg/kg) or micrograms per gram (mcg/g or µg/g). As noted in Table 1 above, the limits set by Proposition 65 for these heavy metals, however, are in micrograms (identified in this document as “µg”) per day.

In order to convert analytical results stated in parts per million to California Proposition 65 limits in micrograms per day, a manufacturer must make a calculation that takes into account the amount of the product consumed per day in ordinary use.

For example, if an herbal tablet of 500 mg is found to contain 0.4 ppm of lead, and the usual consumption rate (often, but not necessarily, the same as the labeled serving size) is one tablet twice daily, the daily consumption of lead can be calculated to be 0.4 µg per day (0.4 ppm [concentration of lead in tablet] × 0.5 gram [weight of tablet] × 2 tablets/day = 0.4 µg/day) and will therefore be below the limit which would require a warning as a reproductive toxin. If, however, the product is usually consumed at the rate of three tablets per day, the daily consumption of lead will increase to 0.6 µg (0.4 ppm × 0.5 gram × 3 tablets/day = 0.6 µg/day) and a warning would therefore be required under the law.

⁷ Some attention may also need to be given to analysis for particular forms of certain of these metals. This is particularly true for arsenic, as it is only the inorganic form that is listed under Proposition 65 (see notes in Table 1). Use of analytical methods that quantify total arsenic will therefore produce results that include forms of arsenic that are not currently under this law's jurisdiction. A similar consideration exists for mercury, though the fact that both mercury itself and methyl mercury are listed chemicals implies that total mercury needs to be measured. Commentary on the pragmatic effect of using results from analysis of total arsenic and total mercury is beyond the scope of this document, as is any guidance on more specific analytical methods.



In the following Table 2 maximum values are given over a range of daily serving sizes, stated as a concentration in parts per million, for each of the heavy metals in Table 1 that are subject to labeling as a reproduction toxin. Note that the MADL given for each of these metals is stated in micrograms and is subject to the notes provided in Table 1.

Table 2 – Serving size in relation to presence of heavy metals / reproductive toxins

HEAVY METAL	MADL	Maximum concentration (ppm) at usual daily consumption rate										
		250 mg	500 mg	1 g	2 g	2.5 g	3 g	4 g	5 g	6 g	8 g	10 g
arsenic (inorganic oxides)	0.1 µg ^a	<0.4	<0.2	<0.1	<0.05	<0.04	<0.03	<0.025	<0.02	<0.017	<0.012	<0.01
arsenic (total)	10 µg ^b	<40	<20	<10	<5	<4	<3	<2.5	<2	<1.7	<1.2	<1
cadmium	4.1 µg	<16.4	<8.2	<4.1	<2.05	<1.64	<1.36	<1.02	<0.82	<0.68	<0.51	<0.41
lead	0.5 µg	<2.0	<1.0	<0.5	<0.25	<0.2	<0.16	<0.12	<0.1	<0.08	<0.06	<0.05
methyl mercury	0.3 µg ^c	<1.2	<0.6	<0.3	<0.15	<0.12	<0.1	<0.07	<0.06	<0.05	<0.03	<0.03
mercury (inorganic)	3 µg ^d	<12	<6	<3	<1.5	<1.2	<1	<0.7	<0.6	<0.5	<0.3	<0.3

^a The MADL used here is the “draft oral MADL” of 0.1 µg/day of arsenic (inorganic oxides) published by OEHHA in 2003. At this time an actual established MADL has not been established for this chemical. The relevance of the data presented here to total arsenic is not known.

^b The MADL used here is the 10 µg limit for total arsenic as established in multiple legal settlements, such as that referenced in footnote 6.

^c The MADL used here is the “draft MADL” for methyl mercury of 0.3 µg/day identified by OEHHA in 1994. The relevance of the data presented here to total mercury is not known.

^d The MADL used here is the 3 µg limit for inorganic mercury as established in multiple legal settlements, such as that referenced in footnote 6.

In **Table 3** maximum values are given over a range of daily serving sizes, stated as a concentration in parts per million, for each of the heavy metals in **Table 1** that are subject to labeling as a carcinogen. Note that the daily maximum given for each of these metals is stated in micrograms and is subject to the notes delineated in **Table 1**. Also note that mercury is not included here since no NSRL has been established or proposed for the relevant listed chemical, methylmercury compounds. Cadmium is also excluded based on the assumption that carcinogenicity for cadmium is relevant only to inhalation, as discussed in the notes to **Table 1**.



Table 3 – Serving size in relation to presence of heavy metals / carcinogens

HEAVY METAL	NSRL	maximum concentration (ppm) at usual daily consumption rate										
		250 mg	500 mg	1 g	2 g	2.5 g	3 g	4 g	5 g	6 g	8 g	10 g
arsenic (inorganic oxides)	10 µg	<40	<20	<10	<5.0	<4.0	<3.33	<2.5	<2.0	<1.66	<1.25	<1.0
lead	15 µg	<60	<30	<15	<7.5	<6.0	<5.0	<3.75	<3.0	<2.5	<1.87	<1.5

As can be seen from the data in **Table 2** and **Table 3**, the detection limits of the analytical methods used to measure heavy metals in a sample are dependent upon daily serving size. If the daily serving of an herbal product is 5 grams, it can be seen from **Table 2** that the analytical method used to measure lead, for example, must be sensitive to a detection level of 0.1 ppm (= 100 parts per billion) in order to assure that labeling a product as a reproductive toxin is not required. Similarly, **Table 3** shows that the measurement of arsenic must be sensitive at a detection of 5.0 ppm with daily consumption of 2 grams.

In order to assure that a product is analyzed with sufficient sensitivity for California Proposition 65, a manufacturer must require that the limit of detection of the analysis is sufficiently low to detect the concentration that is calculated to take into account the amount of the product consumed per day in ordinary use. This can be accomplished either, for example, by specifying the required limit of detection (e.g., “analyze lead at 0.1 ppm”) or by informing the analytical lab of the amount of the product consumed per day, in grams, as well as the MADL or NSRL, in micrograms.

The following worksheet may be useful in determining the implication of analytical results of the concentration of heavy metals, stated in parts per million, on the daily limits established by Proposition 65, given in micrograms per day. Note that the quantity given in column (1) must be the quantity of the same product for which analysis has been performed, as reported in column (2). Note also that this worksheet does not account for usual variations among different lots and sources of a product or its ingredients. Multiple tests of the same product are often necessary to make an informed decision on whether a warning is required.

Worksheet – Determination of requirement for Proposition 65 labeling – conversion of analysis of heavy metal concentration to daily intake of heavy metal

Values for heavy metals listed as reproductive toxins						
HEAVY METAL	daily max	(1) TOTAL daily intake of product (in grams/day)		(2) concentration of heavy metal in product (in ppm)		(3) TOTAL daily intake of heavy metal (in µg/day)
arsenic (inorganic oxides)	0.1 µg		x		=	



Values for heavy metals listed as reproductive toxins						
HEAVY METAL	daily max	(1) TOTAL daily intake of product (in grams/day)		(2) concentration of heavy metal in product (in ppm)		(3) TOTAL daily intake of heavy metal (in µg/day)
cadmium	4.1 µg		x		=	
lead	0.5 µg		x		=	
methyl mercury	0.3 µg		x		=	
If TOTAL daily intake (column 3) in any of the four rows above is greater than the stated “daily max” for that row, a reproductive toxin warning should be provided for the product unless all of that part of the heavy metal that is present in the product above the “daily max” is “naturally occurring” or is otherwise exempt.						
Values for heavy metals listed as carcinogens						
HEAVY METAL	daily max	(1) TOTAL daily intake of product (in grams/day)		(2) concentration of heavy metal in product (in ppm)		(3) TOTAL daily intake of heavy metal (in µg/day)
arsenic	10 µg		x		=	
lead	15 µg		x		=	
If TOTAL daily intake (column 3) in either of the two rows above is greater than the stated “daily max” for that row, a carcinogen warning should be provided for the product unless all of that part of the heavy metal that is present in the product above the “daily max” is “naturally occurring” or is otherwise exempt.						

Where do heavy metals that are found in plant-based products come from?

As noted in the previous paragraphs, plants are capable of accumulating heavy metals from the soil in which they grow. This is true whether the metals are naturally present in the soil or have come to be there as a result of some human activity. Heavy metals can also come into plant-based products during manufacturing, storage, or transport if it comes into contact with equipment that leaches heavy metals, or by the addition of non-plant ingredients that are high in one or more of the metals.

What about “naturally occurring” chemicals?

The regulations that have been developed to implement Proposition 65 have recognized that if a listed chemical is naturally occurring in a food, a food that naturally contains that chemical should be exempt from the labeling requirements of the law. For example, safrole, a naturally occurring constituent of



basil, black pepper, and several other spices, is listed as a carcinogen with a “safe harbor level” of only 3 µg per day. According to the National Toxicology Program at the National Institutes of Health, safrole is present in black pepper at a concentration of 100 ppm and the average daily black pepper consumption of an American, as of 1979, was 280 mg per day. This equates to 28 µg per day of safrole. Even though this amount is almost 10 times the “safe harbor” level, no one to date has contended that there is any requirement to warn consumers of pepper of this fact because safrole is naturally occurring in black pepper. Other Proposition 65 chemicals that are naturally occurring in plants are discussed in specific sections below.

Heavy metals can also be perceived as naturally occurring contaminants in herbal ingredients, and in fact in all or many plants – at least to the degree that the plant naturally accumulates the metals that are naturally occurring in the soil in which it grows. How this can be determined and calculated, however, is dependent upon complex factors. Also, the responsibility for proving that any amount of heavy metal in an herbal or other product is naturally occurring falls to the manufacturer. All this leads to a *de facto* assumption that none of the heavy metal found in an herbal product will be considered to be “naturally occurring” when it comes to enforcement, unless a manufacturer has evidence and resources to establish the presence of a naturally occurring portion.

What is the relevance of settlements that have established “naturally occurring” levels for lead for some brands?

Starting in mid-2005 several herbal supplement marketers and the plaintiff that has brought most of the complaints against such companies to date reached court-approved settlements that established certain conditions under which their products could contain higher levels of lead than the MADL of 0.5 µg/day without being required to provide the developmental toxicity warning usually required at such lead levels. In the first five such settlements, the plaintiff and each defendant agreed to accept 3.5 µg/day of lead to be “naturally occurring,” so that only products that, when used at the highest labeled level, provide more than 4.0 µg/day of lead (this 3.5 µg of naturally occurring lead plus the 0.5 µg set by the regulatory safe harbor MADL) require Proposition 65 warnings. These settlements also stipulate that reproductive toxicity warnings will be provided on any product where use at the highest labeled level provides in excess of any of the following: 0.30 µg/day of mercury and mercury compounds, except inorganic mercury; 3.0 µg/day of inorganic mercury; 4.1 µg/day of (total) cadmium; or 10.0 µg/day of (total) arsenic.

The defendants in each of these settlements also agreed to numerous other criteria, including an active testing program for raw materials and finished products; use of specified analytical methods to determine heavy metal levels; and restriction from selling any products that would provide lead in excess of 14.0 µg/day when used at the highest labeled daily consumption.

An additional settlement in June 2008 adopted similar provisions for lead (this settlement did not address other heavy metals), but lowered the “naturally occurring” tolerance to 2.25 µg/day of lead (so no warning is required below 2.75 µg/day), and lowered to 10.0 µg/day the level above which products will simply not be offered for sale.



A 2015 California appeals court decision⁸ is significant in that it upheld the ability of a manufacturer to use averaging of exposures to a contaminant, in this case lead, to demonstrate compliance with the MADL of 0.5 µg/day. This decision also allowed the use of a geometric mean of test results over multiple product lots rather than evaluation of individual lots. However, on August 28, 2015, OEHHA announced its intent to propose clarifying regulations for measurement of chemicals in food products. OEHHA's initial proposal stipulated use of the arithmetic mean for determining exposures to chemicals causing reproductive toxicity and does not allow for averaging, but instead would provide a set limit for exposures over a given number of days. OEHHA did not formally initiate the rulemaking process, and the 2015 case that allowed averaging is still good law. That said, marketers of herbal products may wish to consult with their counsel regarding the applicability of this court ruling to any the determination of lead exposure from an herbal product.

It is essential to understand that these settlements, even though each was approved by a California court, do not provide any relief to any other marketer of herbal supplements, or of any other product for that matter. In fact, the settling companies cannot be assured that some other plaintiff will not at some point in the future challenge these settlements, and bring new complaints against these same companies if any of their products provide more than 0.5 µg/day of lead.

Nevertheless, the details of these several settlements are of interest to marketers of dietary supplement products offered for sale in California.

Other naturally-occurring constituents

What are other naturally-occurring constituents that are listed under Proposition 65?

On April 18, 2014, OEHHA listed pulegone as a chemical "known to cause cancer."⁹ On March 27, 2015, OEHHA also listed β-myrcene (beta-myrcene) as a chemical "known to cause cancer."¹⁰

Pulegone

Pulegone is a ketonic monoterpene that is a naturally present constituent in numerous plant species, especially mints (e.g., peppermint and spearmint) and particularly concentrated in the essential oils derived from these plants. Use of these plants and their essential oils as ingredients in foods, supplements, cosmetics and other consumer products may therefore result in the presence of small amounts of pulegone in these products.

It is important to acknowledge that the studies that resulted in OEHHA's listing of pulegone as a carcinogen were tests of the toxicity of 96% pure pulegone on laboratory animals that were force-fed

⁸ *Environmental Law Foundation (ELF) v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307, 1317 (Cal. Ct. Ap., No. A139821, 3/17/15)

⁹ OEHAA Notice of Chemical Listed Effective April 18, 2014, http://www.oehha.org/prop65/prop65_list/files/041814ListingNoticeLCSet%2020Pulegone.pdf.

¹⁰ OEHAA Notice of Chemical Listed Effective March 27, 2015, http://oehha.ca.gov/prop65/CRNR_notices/list_changes/032415listbetamyrcene.html



over virtually their entire lifetime doses that far exceed any human exposure related to common uses of mints and other plants and their essential oils. While appropriate as a hazard identification exercise, this research study does not constitute an appropriate risk assessment applicable to human exposure through normal dietary intake of this natural botanical constituent.

β-Myrcene

β-Myrcene is an acyclic, unsubstituted monoterpene found in numerous plant species such as hops, lemongrass, thyme, verbena, parsley, cannabis, and mangoes. It is used as an intermediate in the production of flavorings and fragrances. Use of these plants and their essential oils as ingredients in foods, supplements, beverages, cosmetics and other consumer products may therefore result in the presence of small amounts of β-myrcene in these products. β-Myrcene can also be produced through synthetic chemical pathways. The presence of synthetically produced β-myrcene in products sold in the State of California is not addressed by this guidance.

It is important to acknowledge that the studies that resulted in OEHHA's listing of β-myrcene as a carcinogen were tests of the toxicity of over 90% pure β-myrcene on laboratory animals that were forced over virtually their entire lifetime doses that far exceed any human exposure related to common uses of β-myrcene containing plants and their essential oils. While appropriate as a hazard identification exercise, this research study does not constitute an appropriate risk assessment applicable to human exposure through normal dietary intake of this natural botanical constituent.

What exemptions apply to Prop 65 warnings for naturally occurring botanicals constituents?

There are several means to be exempted from Prop 65's warning rule for chemicals listed by California as known to cause cancer. For example, warnings are not required to be provided by companies with fewer than 10 employees or for exposures below the level at which there is no significant risk of cancer (defined in the law as the level of exposure at which not more than one excess case of cancer would occur in an exposed population of 100,000, assuming 70-year lifetime exposure at the level in question).¹¹

But the most relevant exemption in the case of naturally occurring botanical constituents is for chemicals that are "naturally occurring" food constituents. OEHHA's regulations clarify that an exposure to a Prop 65 listed chemical does not occur, such that no warning is required, in the following situations:

- For a food, when the chemical is naturally occurring in the food and is a natural constituent of the food;^{12, 13}

¹¹ OEHHA itself may establish an NSRL (no significant risk level) for chemicals listed as known to the state to cause cancer; it has not done so for pulegone or β-myrcene. Independent persons and companies may also make an NSRL determination but this would be a complex undertaking and could be subject to challenge by the California Attorney General, a district attorney, or a private plaintiff purportedly acting in the public interest.

¹² Title 27 California Code of Regulations §25501(a)(1).

¹³ Note that other rules apply to a Prop 65 listed chemical that is a "contaminant" (see CA HSC §25501(a)(4)).



- For a consumer product other than food, when the chemical is a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, “exposure” can only occur as to that portion of the chemical from other sources.¹⁴

Importantly, OEHHA’s 2014 Notices of Intent to List these chemicals cite that they are naturally occurring botanical constituents. Pulegone is noted as being “a natural constituent of various plants, including mint and other herbs, and of their essential oils” and β -myrcene is described being a constituent of “food plants, such as hop, bay, verbena, lemongrass, citrus, pomegranate, and carrot, and of their juices and essential oils.”

In addition, a 2002 letter OEHHA commented on naturally occurring regulatory exemptions as applicable to methyleugenol. This article is a constituent of basil and other plants in commerce and listed in 2001 as a chemical known to the State of California to cause cancer. OEHHA agreed in this letter that methyleugenol was found to be a natural constituent of basil and thereby the “naturally occurring” exemption was applicable. OEHHA additionally concluded that by adding the naturally occurring methyleugenol to a food or a consumer product would not create an “exposure” within the meaning of Prop 65, and thereby such food or consumer product would also qualify for the “naturally occurring” exemption.

For products sold in California, should Prop 65 warnings be provided on products that contain herbs and essential oils in which chemicals are present as a naturally occurring botanical constituent?

OEHHA’s regulations for providing warnings for exposures to Prop 65 listed chemicals can be read to mean:

- A food that contains a chemical due to the presence of an herb or botanical, or an essential oil in which the chemical is known to be a natural constituent does not constitute an exposure to the chemical for the purposes of Prop 65, as clearly established by 27 CCR § 25501(a)(1); no Prop 65 warning should be required for such foods.
- A dietary supplement is a food for purposes of the naturally occurring provisions of OEHHA’s regulation on Prop 65 warnings¹⁵ such that 27 CCR § 25501(a)(1) also established that a dietary supplement that contains a chemical due to the presence of an herb or botanical, or an essential oil in which the chemical is known to be a natural constituent does not constitute an exposure to the chemical for purposes of Prop 65; no Prop 65 warning should be required for such dietary supplements.
- A cosmetic or other consumer product that contains a chemical due to the presence of a food ingredient consisting of an herb or botanical, or an essential oil in which the chemical is known

¹⁴ Title 27 California Code of Regulations §25501(b).

¹⁵ *Gillett v. Garden Of Life, Inc. et al.* (San Francisco Superior Court, Case No. CGC-08-479027). See also 27 Cal. Code Regs. sec. 25600.1(g) (defining “food” to include “dietary supplement”).



to be a natural constituent does not constitute an exposure to the chemical for purposes of Prop 65, as clearly established by 27 CCR § 25501(b); no Prop 65 warning should be required for such cosmetics or other consumer products.

On April 20, 2015 several marketers of essential oil of pennyroyal intended to be applied topically to the skin were given notice alleging violations of Proposition 65 for failure to provide warnings for these products. The plaintiff who issued this notice apparently takes the position that pennyroyal (or pennyroyal oil) is not a food or food ingredient so that while pulegone is known to be naturally occurring in pennyroyal the above discussed exemption should not apply. Note however that both European pennyroyal (*Mentha pulegium*) and American pennyroyal (*Hedeoma pulegioides*) are listed in federal regulation as “natural flavoring substances ... [that] may be safely used in food” under certain conditions (21 CFR 172.510). This issue has not been resolved as of the date of issuance of this document and readers are advised to consult with qualified Proposition 65 counsel.

Botanicals listed to Proposition 65

Aloe vera, non-decolorized whole leaf extract

On December 4, 2015, the California Office of Environmental Health Hazard Assessment (OEHHA), the agency responsible for the administration of Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986, hereinafter Prop 65) listed “*Aloe vera*, non-decolorized whole leaf extract” as a chemical “known to cause cancer.”¹⁶ Under Prop 65 regulations, a person who causes an exposure to a listed carcinogen must provide a “clear and reasonable warning” within 12 months from the date of OEHHA’s listing unless otherwise exempted. Under the current rules this warning, when required, would be deemed to be “clear and reasonable” if it states: “WARNING: This product contains a chemical known to the State of California to cause cancer.”¹⁷

What is *Aloe vera*, non-decolorized whole leaf extract and where is it found?

In the April 2015 OEHHA Notice of Intent to List, *Aloe vera*, non-decolorized whole leaf extract is described as “the liquid portion of the *Aloe vera* leaf (e.g., what remains after removal of fibrous material, such as lignified plant fibers), and is a natural constituent of the *Aloe barbadensis* Miller plant.”¹⁸ For the research studies that are the basis of OEHHA’s listing, the *Aloe vera* non-decolorized whole leaf extract “was produced by grinding the whole leaves of *Aloe vera* plants and treating the slurry with cellulase (23 mg/L) to reduce viscosity and maximize yields.”¹⁹ The research test material was also irradiated to maintain stability and kill endogenous bacteria.

¹⁶ OEHHA Notice of Chemical Listed Effective December 4, 2015, http://oehha.ca.gov/prop65/CRNR_notices/list_changes/120415listAloeGoldenseal.html

¹⁷ OEHHA has proposed a revision to the regulations for “clear and reasonable warnings” that would require the inclusion of the name of one or more of the listed chemicals for which the warning is being provided, to the extent that an exposure to that chemical or chemicals is at a level that requires a warning, unless providing a short-form warning label. (accessed February 8, 2016) http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/112715WarningRegText.pdf

¹⁸ OEHHA Notice of Intent to List April 23, 2015, http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/NOI1042315AloeGoldenseal.html

¹⁹ National Toxicology Program (NTP) Technical Report 577



While appropriate as a hazard identification exercise, this research does not constitute an appropriate risk assessment applicable to human exposure to *Aloe vera* as reflected by products in the consumer marketplace. It is important to acknowledge that *Aloe vera*, non-decolorized whole leaf extract is an unrefined, unpurified material that does not represent the *Aloe vera* ingredients that are typically utilized in products such as dietary supplements, beverages, cosmetics, and personal care products.

What exemptions may apply to Prop 65 warnings for *Aloe vera*, non-decolorized whole leaf extract?

There are several means to be exempted from Prop 65's warning rule for chemicals listed by California as known to cause cancer. For example, warnings are not required to be provided by companies with less than 10 employees or for exposures below the level at which no significant risk of cancer exists (defined in the law as the level of exposure at which not more than one excess case of cancer would occur in an exposed population of 100,000, assuming 70-year lifetime exposure at the level in question).²⁰

Exemptions from the warning requirements are also applicable in the case of chemicals that are "naturally occurring" food constituents. Notably, in its December 2015 Listing of "*Aloe vera*, non-decolorized whole leaf extract," OEHHA identified this substance as "the liquid portion of the *Aloe vera* leaf and . . . a natural constituent of the *Aloe barbadensis* Miller plant."²¹ OEHHA provided further reference to Prop 65's provisions for naturally-occurring chemicals in foods as part of this identification.

OEHHA's regulations clarify that an exposure to a Prop 65 listed chemical does not occur, such that no warning is required, in the following situations:

- For a food, when the chemical is naturally occurring in the food and is a natural constituent of the food;^{22, 23}
- For a consumer product other than food, when the chemical is a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product.

While it has been positively identified as a natural constituent of the *Aloe barbadensis* Miller plant, it is not clear whether *Aloe vera*, non-decolorized whole leaf extract is present as a natural constituent in food. "Aloe" is recognized as a flavoring agent food additive (21 CFR 172.510) and this citation is inclusive of *Aloe vera* and several other aloe species. Whole leaf *Aloe vera* may be used in beverages and dietary supplements (which are considered to be food for the purposes of Prop 65), but it is most commonly used in these products after undergoing the process of decolorization, or filtration to remove specific constituents present in the latex of the whole leaf. At present, AHPA is not aware of any foods

²⁰ OEHHA itself may establish an NSRL (no significant risk level) for chemicals listed as known to the state to cause cancer; it has not done so for *Aloe vera*, non-decolorized whole leaf extract. Independent persons and companies may also make an NSRL determination but this would be a complex undertaking and could be subject to challenge by the State of California or by a private plaintiff purportedly acting in the public interest.

²¹ OEHHA Notice of Intent to List *Aloe vera*, whole leaf extract

http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/NOI1042315AloeGoldenseal.html

²² Title 27 California Code of Regulations §25501(a)(1).

²³ Note that other rules apply to a Prop 65 listed chemical that is a "contaminant" (see CA HSC §25501(a)(4)).



that contain *Aloe vera*, non-decolorized whole leaf extract or other consumer products derived from such foods.

At present, it is unknown whether any private plaintiff will challenge whether the naturally-occurring chemical exemption is applicable for *Aloe vera*, non-decolorized whole leaf extract. AHPA is aware of a 60-day notice²⁴ brought by one private plaintiff against several marketers of pennyroyal oil due to absence of warnings for the naturally-occurring presence of pulegone, another substance listed as a carcinogen.

Should Prop 65 warnings be provided on products that contain *Aloe vera*, non-decolorized whole leaf extract as a naturally occurring constituent?

OEHHA's regulations for providing warnings for exposures to Prop 65 listed chemicals can be read to mean the following with respect to the need for Prop 65 warnings for *Aloe vera*, non-decolorized whole leaf extract; marketers should undertake a legal evaluation for their specific product(s) to determine whether a warning may be required:

- A food or beverage that contains *Aloe vera*, non-decolorized whole leaf extract due to the presence of the *Aloe barbadensis* Miller plant does not constitute an exposure to *Aloe vera*, non-decolorized whole leaf extract for the purposes of Prop 65, as established by 27 CCR § 25501(a)(1).
- A dietary supplement is a food for purposes of the naturally occurring provisions of OEHHA's regulation on Prop 65 warnings²⁵ such that 27 CCR § 25501(a)(1) also established that a dietary supplement that contains *Aloe vera*, non-decolorized whole leaf extract due to the presence of the *Aloe barbadensis* Miller plant does not constitute an exposure to *Aloe vera*, non-decolorized whole leaf extract for purposes of Prop 65.

A cosmetic or other consumer product that contains *Aloe vera*, non-decolorized whole leaf extract due to the presence of a food ingredient consisting of the *Aloe barbadensis* Miller plant in which *Aloe vera*, non-decolorized whole leaf extract is known to be a natural constituent does not constitute an exposure to *Aloe vera*, non-decolorized whole leaf extract for purposes of Prop 65, as clearly established by 27 CCR § 25501(b).

Are Prop 65 warnings required on products that contain *Aloe vera* ingredients other than *Aloe vera*, non-decolorized whole leaf extract?

The inclusion of the term "non-decolorized" in the chemical name for the Prop 65 listing of this substance provides an important differentiation of the chemical listed under Prop 65 compared to other aloe vera ingredients commonly used in consumer products such as dietary supplements, beverages, and cosmetics. The April 2015 Notice of Intent to List specifically states that the chemical that is the subject of the listing "is not the same as *Aloe vera* decolorized whole leaf extract, *Aloe vera* gel, *Aloe vera* gel extract, or *Aloe vera* latex, which would not be covered by this . . . listing."²⁰ OEHHA has stated

²⁴ This 60-day notice can be accessed at the following url: <http://oag.ca.gov/system/files/prop65/notices/2015-00413.pdf>

²⁵ *Gillett v. Garden Of Life, Inc. et al.* (San Francisco Superior Court, Case No. CGC-08-479027). See also 27 Cal. Code Regs. sec. 25600.1(g) (defining "food" to include "dietary supplement").



that “The processed form of *Aloe vera* typically used in consumer products is not covered by the listing. Consequently, these products would not require a Proposition 65 warning and would not be subject to public or private enforcement actions.”²⁶

The International Aloe Science Council (IASC) maintains a labeling guide²⁷ for aloe vera products that may be of assistance in determining appropriate labeling practices.

It is possible that private plaintiffs will test aloe vera products for the presence of aloin (one of the chemical constituents of the latex portion of the *Aloe vera* leaf) to determine whether the aloe vera ingredients are indeed decolorized. Marketers may wish to have their products analyzed for aloin as a marker for the absence of *Aloe vera*, non-decolorized whole leaf extract. According to standards set by the IASC, aloin content of less than 10 ppm is accepted as an indication that an aloe vera raw material or finished product does not contain non-decolorized *Aloe vera*.

For products sold in California, what, if anything, can marketers of products containing *Aloe vera* do to protect against Prop 65 litigation?

Marketers whose products are made using ingredients other than *Aloe vera*, non-decolorized whole leaf extract, and who are concerned about the potential confusion of consumers and private plaintiffs regarding the need for Prop 65 warnings on their products, should ensure the clear labeling of the aloe vera ingredient(s) in their products by implementing the following:

- Label any whole leaf aloe vera ingredients as “decolorized” (when in fact they have been filtered or purified to remove constituents of the latex in the whole leaf) to clearly differentiate these ingredients from the Prop 65 listed chemical.
- Utilize the aloe vera ingredient names noted in the OEHHA Notice of Intent to List announcement [i.e., *Aloe vera* decolorized whole leaf extract, *Aloe vera* gel, *Aloe vera* gel extract, or *Aloe vera* latex] to the extent that they appropriately describe the aloe vera ingredient used and comply with any applicable product labeling regulations.

Product marketers who do utilize *Aloe vera*, non-decolorized whole leaf extract as an ingredient in their products can consider the following options:

- Take the position that *Aloe vera*, non-decolorized whole leaf extract is a naturally occurring constituent of food and do not provide a warning.
- Provide the Prop 65 warning (“This product contains a chemical [*Aloe vera*, non-decolorized whole leaf extract] known to the state of California to cause cancer”) and be confident of having no risk of a Prop 65 claim.
- Reformulate products containing *Aloe vera*, non-decolorized whole leaf extract to discontinue use of this ingredient.

²⁶ “Clearing Up Errors on Aloe vera and Prop 65,” Lauren Zeise, Ph.D. February 19, 2016. Published in Fox and Hounds (accessed February 22, 2016) <http://www.foxandhoundsdaily.com/2016/02/clearing-up-errors-on-aloe-vera-and-prop-65/>

²⁷ IASC Labeling Guidance and Definitions, March 2009

http://www.iasc.org/Portals/19/Documents/Members/10_0405_IASC_Labeling_Guidance_Definitions.pdf



Goldenseal root powder

On December 4, 2015, the California Office of Environmental Health Hazard Assessment (OEHHA), the agency responsible for the administration of Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986, hereinafter Prop 65) listed Goldenseal root powder as a chemical “known to cause cancer.”²⁸ Under Prop 65 regulations, a person who causes an exposure to a listed carcinogen must provide a “clear and reasonable warning” within 12 months from the date of OEHHA’s listing unless otherwise exempted. Under the current rules this warning, when required, would be deemed to be “clear and reasonable” if it states: “WARNING: This product contains a chemical known to the State of California to cause cancer.”²⁹

What is Goldenseal root powder and where is it found?

In the April 2015 OEHHA Notice of Intent to List, goldenseal root powder is identified as “the powdered dried roots and underground stems of goldenseal plants,”³⁰ known as *Hydrastis canadensis*. This plant has a long history of use in traditional medicine and is commonly marketed as a dietary supplement in the United States, both as a single herb and in combination with other herbs. It can be obtained in several forms, including bulk powder, teas, capsules, and liquid extracts.

It is important to acknowledge that the studies that resulted in OEHHA’s listing of goldenseal root powder as a carcinogen were tests of the toxicity of this substance on laboratory animals that were fed doses over virtually their entire lifetime that far exceed any human exposure related to common uses of goldenseal root powder.³¹ As an example, the highest dose level fed to rodents would be roughly equivalent to between 72 and 116 grams per day for an average weight human, while the standard dose of goldenseal is 2 grams daily and the ingredient is used only occasionally. The conclusion that goldenseal root powder is a carcinogen was based on the development of a single liver cancer in male rats, an occurrence that is within the historical controls for the species.

While this may be appropriate as a hazard identification exercise, this research does not constitute an appropriate risk assessment applicable to human exposure to goldenseal root powder as reflected in products in the consumer marketplace.

What exemptions may apply to Prop 65 warnings for Goldenseal root powder?

There are several means to be exempted from Prop 65’s warning rule for chemicals listed by California as known to cause cancer. For example, warnings are not required to be provided by companies with less than 10 employees or for exposures below the level at which no significant risk of cancer exists

²⁸ OEHHA Notice of Chemical Listed Effective December 4, 2015

http://oehha.ca.gov/prop65/CRNR_notices/list_changes/120415listAloeGoldenseal.html

²⁹ OEHHA has proposed a revision to the regulations for “clear and reasonable warnings” that would require the inclusion of the name of one or more of the listed chemicals for which the warning is being provided, to the extent that an exposure to that chemical or chemicals is at a level that requires a warning, unless providing a short-form warning label. (accessed February 8, 2016) http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/112715WarningRegText.pdf

³⁰ OEHHA Notice of Intent to List, April 23, 2015

http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/NOI1042315AloeGoldenseal.html

³¹ National Toxicology Program, NTP TR 562



(defined in the law as the level of exposure at which not more than one excess case of cancer would occur in an exposed population of 100,000, assuming 70-year lifetime exposure at the level in question)³².

Exemptions from the warning requirements are also applicable in the case of chemicals that are “naturally occurring” food constituents. Notably, in its December 2015 listing announcement for goldenseal root powder, OEHHA identified this chemical as “a natural constituent of the goldenseal plant (*Hydrastis canadensis*).”³³ OEHHA provided further reference to Prop 65’s provisions for naturally-occurring chemicals in foods as part of this identification.

OEHHA’s regulations clarify that an exposure to a Prop 65 listed chemical does not occur, such that no warning is required, in the following situations:

- For a food, when the chemical is naturally occurring in the food and is a natural constituent of the food;^{33, 34}
- For a consumer product other than food, when the chemical is a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product.³⁵

Goldenseal root powder is used in dietary supplements, which are considered to be food for the purposes of Prop 65.

Should Prop 65 warnings be provided on products that contain goldenseal root powder as a naturally occurring constituent?

OEHHA’s regulations for providing warnings for exposures to Prop 65 listed chemicals can be read to mean the following with respect to the need for Prop 65 warnings for goldenseal root powder; marketers should undertake a legal evaluation for their specific product(s) to determine whether a warning may be required:

- A food or beverage that contains goldenseal root powder due to the presence of the *Hydrastis canadensis* plant does not constitute an exposure to goldenseal root powder for the purposes of Prop 65, as clearly established by 27 CCR § 25501(a)(1), because it is naturally occurring in the food or beverage.
- A dietary supplement is a food for purposes of the naturally occurring provisions of OEHHA’s regulation on Prop 65 warnings³⁶ such that 27 CCR § 25501(a)(1) also establishes that a dietary supplement that contains goldenseal root powder due to the presence of the *Hydrastis*

³² OEHHA itself may establish an NSRL (no significant risk level) for chemicals listed as known to the state to cause cancer; it has not done so for goldenseal root powder. Independent persons and companies may also make an NSRL determination but this would be a complex undertaking and could be subject to challenge by the State of California or by a private plaintiff purportedly acting in the public interest.

³³ Title 27 California Code of Regulations §25501(a)(1).

³⁴ Note that other rules apply to a Prop 65 listed chemical that is a “contaminant” (see CA HSC §25501(a)(4)), though this is not relevant to goldenseal root powder or other naturally-occurring constituents.

³⁵ Title 27 California Code of Regulations §25501(b).

³⁶ *Gillett v. Garden Of Life, Inc. et al.* (San Francisco Superior Court, Case No. CGC-08-479027). See also 27 Cal. Code Regs. sec. 25600.1(g) (defining “food” to include “dietary supplement”).



canadensis plant does not constitute an exposure to goldenseal root powder for purposes of Prop 65.

- A cosmetic or other consumer product that contains goldenseal root powder due to the presence of a food ingredient consisting of the *Hydrastis canadensis* plant in which goldenseal root powder is known to be a natural constituent does not constitute an exposure to goldenseal root powder for purposes of Prop 65, as clearly established by 27 CCR § 25501(b).

At present, it is unknown whether any private plaintiff will challenge whether the naturally-occurring chemical exemption is applicable for goldenseal root powder. AHPA is aware of a related situation in which a 60-day notice³⁷ has been issued by one private plaintiff against several marketers of pennyroyal oil due to absence of warnings for the naturally-occurring presence of pulegone, another substance listed as a carcinogen under Prop 65. This example does differ from the situation for goldenseal root powder, in which case the naturally-occurring chemical is also the marketed product.

Are Prop 65 warnings required on products that contain other goldenseal ingredients?

It is not known at this time whether any private plaintiff will attempt to target goldenseal ingredients other than the root powder, such as liquid extracts of the root. A strict reading of the OEHHA chemical listing implies that only the powdered form of the goldenseal root is included, but the listing did not provide further explanation regarding other forms of goldenseal that are specifically excluded.

As outlined in the final announcement of the Proposition 65 listing of goldenseal root powder, this listing is based on the OEHHA administrative Labor Code listing mechanism following the classification of this substance as a Class 2B carcinogen (possibly carcinogenic to humans) by the International Agency for Research on Cancer (IARC). No other form of goldenseal has been classified by IARC as a carcinogen, so the Proposition 65 listing applies only to goldenseal root powder.

In any case, the same provisions for naturally-occurring chemicals should apply to any plaintiff attempt to extend the scope of the Prop 65 listing beyond the powdered root form.

For products sold in California, what, if anything, can goldenseal root powder marketers do to protect against Prop 65 litigation?

Product marketers can consider the following options:

- Make a determination that products containing goldenseal root powder do not require a Prop 65 warning due to the naturally-occurring constituent provisions of the regulations. AHPA strongly suggests making this determination in consultation with experienced Prop 65 legal counsel;
- Provide the Prop 65 warning (currently, “This product contains a chemical [, goldenseal root powder] known to the state of California to cause cancer”) and be confident of having no risk of a Prop 65 claim;

³⁷ This 60-day notice can be accessed at the following url: <http://oag.ca.gov/system/files/prop65/notices/2015-00413.pdf>



- Consider reformulation of products containing goldenseal root powder to discontinue use of this ingredient (this may be an option for products containing goldenseal root powder in combination with other herbs).

