

GUIDANCE on California Proposition 65 and Tea & Infusion Products

Revised April 2020

Prepared by the American Herbal Products Association



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DISCLAIMER

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."

Proposition 65 requires persons doing business to provide "clear and reasonable" warnings prior to exposing individuals to chemicals known to the State to cause cancer and/or reproductive toxicity. The State is required to publish a list of the chemicals it considers to cause cancer and/or reproductive toxicity.

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 lead¹ and, in a few cases, naphthalene. To date, several of these cases have been settled, either individually or through a joint settlement involving 19 defense parties reportedly acting under a joint defense agreement. Individual settlements have averaged over \$24,000 per company (total of civil penalties and attorney's fees), and joint defense parties have settled for amounts ranging from \$19,500 to \$58,500 per party.

Historically, numerous companies that sell or manufacture herbal products (generally dietary supplement 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 (primarily lead, and in some cases arsenic, cadmium and mercury) and other listed chemicals 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.

This document was prepared with a narrow focus; it is concerned only with the regulatory and liability implications of Proposition 65 for tea and infusion 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. as does AHPA at www.ahpa.org/Consumers/CaliforniaProposition65FAQ.aspx. This document is based on guidance

¹ A single complaint was filed in 2010 against a company alleging the presence of lead in a green tea product; this case was settled in 2012 for \$80,000 and the company apparently ceased marketing products in California.



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 incorporates details specific to the tea and infusion products industry.



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 any of the warnings above is provided for an exposure to a single chemical, the words “chemicals including” may be deleted from the warning, 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 outline² 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 information³ 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 every retail seller of the product in the State of California, 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.

If a retailer receives such a written notice inclusive of all the above requirements, the retailer is legally obligated to provide the Proposition 65 warning using the warning materials provided.

A product retailer is directly responsible for providing Proposition 65 warnings to consumers under certain other circumstances, such as the following:

- The retailer obscures or covers a warning label that has already been affixed to the product; or
- The retailer knowingly introduces a listed chemical into the product (an unlikely situation for tea products).

² 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.

³ "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 website⁴.

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 teas, 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.

One other listed chemical that may be found in some tea products is naphthalene, a carcinogen for which private plaintiffs have issued 60-day notices to tea companies alleging its presence in certain smoked tea products. Additional information on the relevance of this chemical is provided in the following sections.

Other chemicals listed and that are of interest to the herbal products industry 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

⁴ 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>.



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:

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.

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 tea product companies have been based on allegations by the plaintiffs that, although the company’s products do not bear Proposition 65 warning labels, lead and/or naphthalene are present in the company’s products at levels that in fact require warnings.



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. 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 may argue that a violation occurs each time that each consumer consumes a serving of a tea 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 \$58,000 per company have been levied against some manufacturers of tea products whose products were alleged to contain lead and naphthalene 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.

Any company selling tea 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. Companies selling tea products may consider potential exposure levels to listed chemicals present in brewed tea prepared for consumption or other ready-to-drink forms, and may also, to be most cautious, consider the level present in the dried tea (bulk or teabag) form. Further details on these considerations is provided below in discussion of representative product settlements.

AHPA notes that no new 60-day Notices for tea products have been filed as of November 2017. While private plaintiffs targeting tea products may have turned their attention to other potential product non-compliances, tea companies doing business in California should remain aware of the need to comply with the law.

Chemical testing 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 such as tea products. These levels are stated as “no significant risk levels” (NSRL) for chemicals listed as 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 March 2019, *Proposition 65 No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity*⁵ 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 the specific listed chemical “arsenic (inorganic arsenic compounds).”
^c “Arsenic (inorganic oxides)” is listed in the September 2012 publication⁶ as a “second priority” for establishment of a MADL. In 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 arsenic.⁷
^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 As of 2012, listed as a “third priority” for establishment of an NSRL.

⁵ 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 October 16, 2019.

⁶ Priority List for the Development of Proposition 65 Safe Harbor Levels. OEHHA, September 2012 Update.

⁷ 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.



	Carcinogen	Reproductive toxicant
	NSRL (µg/day)	MADL (µg/day)
<p>⁸ 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.</p>		

Naphthalene is classified as a carcinogen under Proposition 65, and OEHHA has determined the NSRL for this chemical is 5.8 µg/day.

How should heavy metals or other contaminants be tested in tea products?

Several analytical methods are available for measuring the heavy metal content of plant material such as tea products. 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 serving size of the product to be tested.⁸

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

⁸ 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.



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.

While the California Proposition 65 safe harbor limits are defined as an amount of the chemical consumed on a daily basis (micrograms per day), settlements against tea companies have been based on concentrations of listed chemicals in brewed and/or dried tea (see Table 2).

To be most cautious, tea companies may consider development or review of analytical data to identify the levels of any Proposition 65 listed chemicals in the tea leaf material itself (bagged or loose) as well as the brewed tea form of their products, which is the more obvious form of consumer exposure. Such data can inform quality control decisions such as performance of any periodic contaminant testing as well as provide information for comparison with historical settlement standards (see Table 2).

Review of the settlements posted to date provides information on the various analytical approaches being used in the settlement agreements for tea products. The “Injunctive Relief” sections of the settlements outline the different “standards” to which the parties have agreed the company’s products will comply as of a defined effective date in lieu of providing a Proposition 65 warning for the product. In some cases, the tea company stipulates to selling either “reformulated” products which meet the defined standards (for either lead or naphthalene) or providing a proposition 65 warning.

Table 2 summarizes representative examples of the different standards defined in settlements to date. While these standards represent the unique settlement details for individual companies, other tea companies can utilize these details in determining how to assess their own products for Proposition 65 compliance. It is noteworthy that the brewed tea standard established for Settlement 3 of not more than 10 ppb lead in a 200 mL serving represents a consumption of lead equal to four (4) times the current lead MADL of 0.5 µg/day in a single serving.

Table 2 – Representative tea product standards as established in Proposition 65 settlements

Settlement	Contaminant	Brewed tea or Infusion standard	Dried tea or content standard
Settlement 1	Lead	<0.8 µg/L ¹	< 0.25 mg/kg
Settlement 2	Lead	< 1.00 µg/L ²	< 0.25 mg/kg
Settlement 3 ³	Lead	Not more than 10 ppb ¹ (10 µg/L)	n/a
Settlement 4	Naphthalene	<0.1 µg/L ⁴	< 1.0 µg/kg

¹ Prepared using one tea bag or 2 grams of dried tea leaves in 200 mL of boiling water for 5 minutes.
² Prepared using one tea bag or 2 grams of dried tea leaves in 237 mL of 100°C water for 3 minutes.
³ Settlement 3 represents a joint settlement covering 19 defendant companies. ⁴ Preparation method not defined in the settlement.

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 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 , in grams (as dried tea) or milliliters (as brewed tea), 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 intake of heavy metal per serving

Values for heavy metals listed as reproductive toxins						
Heavy metal	Daily max	(1) TOTAL daily intake of product (in mL/day) ¹		(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		=	
cadmium	4.1 µg ²		x		=	
lead	0.5 µg		x		=	
methyl mercury	0.3 µg ³		x		=	
<p>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.</p> <p>¹ Note that tea company settlements are based on a single serving of 200-237 mL.</p> <p>² The NSRL of 0.05 µg/day for cadmium is for inhalation; no NSRL 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.</p> <p>³ While not officially established, 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.</p>						
Values for heavy metals listed as carcinogens						
Heavy metal	Daily max	(1) TOTAL daily intake of product (in mL/day) ¹		(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		=	
<p>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.</p> <p>¹ Note that tea company settlements are based on a single serving of 200-237 mL.</p>						



Where do heavy metals found in tea products come from?

As noted in the previous sections, 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 the plant material 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.

Where does the naphthalene that is found in tea products come from?

Naphthalene is a polyaromatic hydrocarbon (PAH) chemical consisting of two fused benzene rings that has a strong mothball odor. It is found in the essential oils of numerous plants such as basil and magnolia. In commercial applications it is best known as the primary ingredient in mothballs and other moth repellents, as well as being a precursor to the synthesis of other chemicals.

Naphthalene may become a contaminant in tea leaves during the process of smoke-drying some tea products through the exposure to combustion gases from burning wood or oil, such as the traditional pinewood fires used to produce lapsang souchong teas. The smoking process aids in drying the tea leaves, as well as imparting a distinctive smoky flavor to the tea. In addition to lapsang souchong tea, Russian Caravan is another tea that is traditionally smoked during processing of the leaves. Companies marketing such products should be aware of the potential for naphthalene or other PAH chemicals to be present due to the smoke-drying process associated with these types of teas.

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 is 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.

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?

Starting in mid-2005 several herbal supplement marketers and the plaintiff that had brought most of the complaints against such companies at that time 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 decision⁹ 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. 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

⁹ *Environmental Law Foundation (ELF) v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307, 1317 (Cal. Ct. Ap., No. A139821, 3/17/15)



some point in the future challenge these settlements, and bring new complaints against these same companies if any of their products present an exposure of more than 0.5 µg/day of lead.

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

