



THE AMERICAN HERBAL PRODUCTS ASSOCIATION'S

## **GUIDANCE**

# **CA PROPOSITION 65: LISTING OF ALOE VERA, NON-DECOLORIZED WHOLE LEAF EXTRACT**

**AUGUST 2016**

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Listing of Aloe vera, non-decolorized whole leaf extract.  
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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 California Proposition 65 or relevant regulations that apply to businesses in the State of California. Instead, it should be viewed as a supplementary guide to this law and these 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.

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### **Regulatory background.**

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.”<sup>1</sup> 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.”<sup>2</sup>

### **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.”<sup>3</sup> 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.”<sup>4</sup> The research test material was also irradiated to maintain stability and kill endogenous bacteria.

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.

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<sup>1</sup> OEHHA Notice of Chemical Listed Effective December 4, 2015,

[http://oehha.ca.gov/prop65/CRNR\\_notices/list\\_changes/120415listAloeGoldenseal.html](http://oehha.ca.gov/prop65/CRNR_notices/list_changes/120415listAloeGoldenseal.html)

<sup>2</sup> 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 an on-product warning label. (accessed February 8, 2016)

[http://oehha.ca.gov/prop65/CRNR\\_notices/WarningWeb/pdf/112715WarningRegText.pdf](http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/112715WarningRegText.pdf)

<sup>3</sup> OEHHA Notice of Intent to List April 23, 2015,

[http://oehha.ca.gov/prop65/CRNR\\_notices/admin\\_listing/intent\\_to\\_list/NOIL042315AloeGoldenseal.html](http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/NOIL042315AloeGoldenseal.html)

<sup>4</sup> National Toxicology Program (NTP) Technical Report 577

**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<sup>5</sup>).

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."<sup>6</sup> 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;<sup>7,8</sup>
- 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

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<sup>5</sup> 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.

<sup>6</sup> OEHHA Notice of Intent to List *Aloe vera*, whole leaf extract  
[http://oehha.ca.gov/prop65/CRNR\\_notices/admin\\_listing/intent\\_to\\_list/NOIL042315AloeGoldenseal.html](http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/NOIL042315AloeGoldenseal.html)

<sup>7</sup> Title 27 California Code of Regulations §25501(a)(1).

<sup>8</sup> Note that other rules apply to a Prop 65 listed chemical that is a "contaminant" (see CA HSC §25501(a)(4)).

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 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 notice<sup>9</sup> 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 warnings<sup>10</sup> 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

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<sup>9</sup> This 60-day notice can be accessed at the following url:

<http://oag.ca.gov/system/files/prop65/notices/2015-00413.pdf?>

<sup>10</sup> *Gillett v. Garden Of Life, Inc. et al.* (San Francisco Superior Court, Case No. CGC-08-479027).

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.”<sup>6</sup> OEHHA has stated 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.”<sup>11</sup>

The International Aloe Science Council (IASC) maintains a labeling guide<sup>12</sup> 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

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<sup>11</sup> “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/>

<sup>12</sup> IASC Labeling Guidance and Definitions, March 2009  
[http://www.iasc.org/pdfs/10\\_0405\\_IASC\\_Labeling\\_Guidance\\_Definitions.pdf](http://www.iasc.org/pdfs/10_0405_IASC_Labeling_Guidance_Definitions.pdf)

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.