



## California Proposition 65 Listing of “*Aloe vera*, non-decolorized whole leaf extract”

### Frequently Asked Questions

#### What is Proposition 65?

Proposition 65 (“Prop 65”), formally titled “The Safe Drinking Water and Toxic Enforcement Act of 1986,” is a California right-to-know law that was passed by voters in 1986<sup>1</sup>. Among other things, the law requires that companies inform the public about the presence - even at trace levels - of certain substances in the products they sell or use. These “Prop 65-listed chemicals” are ones for which the State of California has determined that information about the chemical’s toxicity satisfies the regulatory requirements for addition to the Prop 65 list of chemicals.

#### Is Prop 65 intended to protect consumer safety?

Prop 65 is not a product safety law. Rather, it is a right-to-know law requiring the public to be informed when they may be exposed to a Prop 65 listed chemical above a very low threshold. The law specifically requires that the level of a listed substance triggering a Prop 65 warning is significantly lower than the level at which any harm has been documented. As the California agency responsible for implementing Prop 65 has noted, “A Proposition 65 warning does not necessarily mean that a product is in violation of any product-safety standards or requirements.”<sup>2</sup>

#### How are Prop 65 warnings provided to the public?

When a Prop 65-listed chemical is present in a product above a very low level, the company is required to provide “clear and reasonable” warnings to the public that the product contains or exposes the consumer to “chemicals known to the State of California to cause cancer” or “chemicals known to the State of California to cause birth defects or other reproductive harm.” Companies may provide the warning by printing it on product labels, including it in documents that accompany the product when it is shipped to a consumer in California, or posting it on signs in California businesses.

#### What kinds of substances are included in the Prop 65 list?

The Prop 65 list includes a wide range of substances, including both synthetic chemicals and those which naturally occur in the environment<sup>3</sup>. It includes individual chemicals as well as complex chemical mixtures. The substance does not have to be intentionally added to the product to trigger the Prop 65 warning requirement. Prop 65 warnings are required for chemicals that are commonly present in

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<sup>1</sup> Safe Drinking Water and Toxic Enforcement Act of 1986, title 27, California Code of Regulations. <http://www.oehha.ca.gov/prop65/law/P65law72003.html> (Accessed January 12, 2016)

<sup>2</sup> OEHHA, Proposition 65 Frequently Asked Questions <http://www.oehha.ca.gov/prop65/p65faq.html> (Accessed January 12, 2016)

<sup>3</sup> OEHHA “Chemicals Known to the State to Cause Cancer or Reproductive Toxicity” [http://www.oehha.ca.gov/prop65/prop65\\_list/Newlist.html](http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html) (Accessed January 12, 2016)



everyday products such as foods, beverages, dietary supplements, personal care products as well as for substances such as pesticides, gasoline, automotive exhaust, and cigarette smoke. As a result, warnings can be seen not only on product labels but also posted throughout California in places such as restaurants, coffee shops, hotels, stores, buildings, and parking garages.

### **How are chemicals chosen for listing under Prop 65?**

The Prop 65 regulations define several mechanisms for identifying chemicals to be added to the Prop 65 list<sup>4</sup>. The State's scientific experts can identify candidate chemicals through independent review, or can review the findings of other "authoritative bodies" as to whether a chemical is a carcinogen or a reproductive toxicant. The State may propose a chemical for listing if the chemical is formally required to be labeled as a carcinogen or a reproductive toxicant by another State or Federal agency. Finally, if the chemical is identified as a "hazardous substance" by the California Labor Code, it is automatically proposed for listing under Prop 65.

### **Are there warning requirements for chemicals that are naturally present in a product?**

The Prop 65 regulations include a provision stating that Prop 65-listed chemicals that are naturally-occurring substances in food do not trigger the warning requirement. This same exception applies to consumer products other than food (such as personal care products), 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. The listing announcement for "*Aloe vera*, non-decolorized whole leaf extract" specifically notes that this substance "is a natural constituent of the *Aloe barbadensis* Miller plant."

### **Why is "*Aloe vera*, non-decolorized whole leaf extract" on the Prop 65 list?**

The National Toxicology Program (NTP) conducted a two-year carcinogenicity study on a substance identified as "nondecolorized whole leaf extract of *Aloe barbadensis* Miller<sup>5</sup>," an unpurified aloe material. Chemical analysis of this material detected the aloin content was between 10,000 – 13,000 mg/L, indicating it was an unfiltered or unpurified aloe vera material (non-decolorized).

The results of the NTP oral consumption study concluded that there was "clear evidence of carcinogenicity" in the rats, but not in the mice, after oral exposure to the aloe material for the animals' lifetime. Based on the conclusions of this study, the International Agency for Research on Cancer (IARC) issued a classification of "possibly carcinogenic to humans (Class 2B)" specific to the aloe material that was utilized in the NTP testing. The IARC classification prompted the State of California to propose the addition of this substance to the Prop 65 list via the "Labor Code" listing mechanism.

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<sup>4</sup> Mechanisms for Listing and Delisting Chemicals Under Proposition 65, [http://www.oehha.ca.gov/prop65/policy\\_procedure/listde051007.html](http://www.oehha.ca.gov/prop65/policy_procedure/listde051007.html) (Accessed January 12, 2016)

<sup>5</sup> Toxicology and Carcinogenicity Studies of a Nondecolorized Whole Leaf Extract of *Aloe barbadensis* Miller (*Aloe vera*) in F344/N Rats and B6C3F1 Mice. NTP Technical Report 577. [Please note that *Aloe barbadensis* Miller is a synonym of the plant name *Aloe vera*.]



### **Is “*Aloe vera*, non-decolorized whole leaf extract” in products sold in California?**

The *Aloe vera* chemical proposed for listing under Prop 65 is not the ingredient that consumers are ingesting when they use the vast majority of commercially available aloe vera products. International Aloe Science Council (IASC) members do not market such products to consumers for oral consumption. The Notice of Intent to List specifically stated that the aloe vera substance proposed for 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 proposed listing.”<sup>6</sup> These ingredients are specifically not covered by the proposed listing and do not require a Prop 65 warning.

### **Did the IASC provide comments on the initial proposed listing of “*Aloe vera*, whole leaf extract”?**

The IASC provided detailed comments to OEHHA that requested clarification of the chemical substance that is the subject of the listing. The primary comments provided by the IASC are as follows:

- The chemical name for the proposed listing should be amended to “*Aloe vera*, non-decolorized whole leaf extract” – this comment was accepted.
- The listing should specifically reference the aloe vera substances that are not included in the listing.
- The proposed listing should be limited to oral exposure, as this was the route of exposure used in the NTP testing of this substance.

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<sup>6</sup> OEHHA Notice of Intent to List Chemicals by the Labor Code Mechanism: Aloe vera, whole leaf extract and Goldenseal root powder, April 23, 2015  
[http://www.oehha.ca.gov/prop65/CRNR\\_notices/admin\\_listing/intent\\_to\\_list/NOIL042315AloeGoldenseal.html](http://www.oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/NOIL042315AloeGoldenseal.html)  
(Accessed January 12, 2016)