

June 9, 2015

Ms. Esther Barajas-Ochoa
Office of Environment Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, CA 95812-4010

Sent electronically to: P65Public.comments@oehha.ca.gov

SUBJECT: NOIL: Aloe vera, whole leaf extract

Dear Ms. Barajas:

The Consumer Healthcare Products Association (CHPA) is the 134-year-old trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements (chpa.org). I am writing on behalf of CHPA members to address the Office of Environmental Health Hazard Assessment's April 23, 2015 notice of intent to list (under the Labor Code mechanism) "*Aloe vera*, whole leaf extract" as a chemical known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

As described in more detail below, we ask that OEHHA explicitly name the non-decolorized version of *Aloe vera*, whole leaf extract when including this substance on the Proposition 65 list. Due to the widespread use of purified (decolorized) *aloe vera* in consumer products including cosmetics, sunscreens, health foods, and beverages, unnecessary consumer confusion and concern would likely be triggered without this additional descriptor. We also ask that OEHHA provide the *aloe vera* ingredients that are excluded from this listing and specify that only the oral route of exposure is covered.

Non-decolorized versus decolorized *Aloe vera*

OEHHA bases the listing of "*Aloe vera*, whole leaf extract" on the recent classification by the International Agency for Research on Cancer (IARC) that this substance exhibits "sufficient evidence of carcinogenicity in experimental animals" and is a Group 2B carcinogen (possibly carcinogenic to humans).¹ In the 2 year feeding study underlying this conclusion, performed by the National Toxicology Program,² rats were exposed via the drinking water to the **non-decolorized** preparation of *Aloe vera*, whole leaf extract. Importantly, this substance is distinct from the majority of commercial *aloe vera* extracts available in the United States marketplace which have been purified ("decolorized") to remove anthraquinoid constituents, some of which are known to be carcinogenic.³

¹ IARC Monograph, 2014

² NTP TR 577, August 2013

³ Westendorf *et al.*, 1990; Genotoxicity of naturally occurring hydroxyanthraquinones *Mut Res*, 240 (1): 1-12

The IARC Monograph for Aloe vera provides a Table of definitions for terms commonly used in the aloe industry which specifies that use of the “whole leaf” terminology “without adequate additional descriptors is not recommended”. Consumer information available from the National Institutes of Health [National Toxicology Program](#)⁴ also specifically refers to the non-decolorized version of aloe vera, whole leaf extract. OEHHA has previously provided similarly detailed descriptions for complex chemical mixtures added to the Proposition 65 list, including the following:

- Bitumens, extracts of steam-refined and air-refined
- Emissions from high-temperature unrefined rapeseed oil
- Unleaded gasoline (wholly vaporized)
- Soots, tars, and mineral oils (untreated and mildly treated oils and used engine oils)
- Carbon black (airborne, unbound particles of respirable size)
- Titanium dioxide (airborne, unbound particles of respirable size)

Incorporation of excluded Aloe vera ingredients on the Proposition 65 listing

CHPA also requests that OEHHA incorporate the list of excluded aloe vera ingredients in the final Proposition 65 listing for Aloe vera, whole leaf extract. In the April 23, 2015 Notice of Intent to list, OEHHA provided a list of excluded Aloe vera ingredients including *Aloe vera* decolorized whole leaf extract, *Aloe vera* decolorized leaf juice; *Aloe vera* gel; *Aloe vera* gel extract, and *Aloe vera* latex. OEHHA has previously utilized explanatory notes to fully describe other Proposition 65 listed chemicals including Retinol/retinyl esters.⁵

Inclusion of only orally-ingested Aloe vera, whole leaf extract on the Proposition 65 listing

Lastly, we request that OEHHA explicitly include only the orally-ingested form of Aloe vera, whole leaf extract on the Proposition 65 list. OEHHA has previously used a similar qualifier to distinguish a particular route of exposure when incorporating a chemical onto the Proposition 65 list.⁶ While the NTP did evaluate the effect of various forms of aloe vera (including a whole leaf extract) in a short-term (1 year) mouse photocarcinogenicity study, no significant increase in skin neoplasms was observed in animals exposed only to aloe vera products.

⁴ NTP Botanical Dietary Supplements Program, May 2014; NTP Aloe vera, April 2011; NTP Speaks About Aloe Vera, November 2014

⁵ Text for this listing reads as follows “Retinol/retinyl esters, when in daily dosages in excess of 10,000 IU, or 3,000 retinol equivalents. (NOTE: Retinol/retinyl esters are required and essential for maintenance of normal reproductive function. The recommended daily level during pregnancy is 8,000 IU).”

⁶ The Proposition 65 listing for tetracycline (also tetracyclines; tetracycline hydrochloride) includes the qualifier “internal use” in the listing.

CHPA thus proposes that the final Proposition 65 listing reads as follows:

Aloe vera, non-decolorized whole leaf extract (NOTE: Oral consumption only. Aloe vera, non-decolorized whole leaf extract is not the same as *Aloe vera* decolorized whole leaf extract, *Aloe vera* decolorized leaf juice; *Aloe vera* gel; Aloe vera gel extract, or *Aloe vera* latex which are not covered by this listing.)

Thank you for the opportunity to provide these comments. Should you have any questions or require additional information please do not hesitate to contact me.

Respectfully submitted,

A handwritten signature in blue ink that reads "Jay Sirois". The signature is written in a cursive style with a horizontal line above it.

Jay Sirois, Ph.D.
Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association