



Council for Responsible Nutrition

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June 8, 2015

Ms. Esther Barajas-Ochoa
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010
Via Email: P65Public.Comments@oehha.ca.gov

Re: Notice of Intent to List Aloe Vera, Whole Leaf Extract

Dear Ms. Barajas-Ochoa:

On behalf of the Council for Responsible Nutrition (CRN), thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's (OEHHA) intent to list *Aloe vera*, whole leaf extract pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). CRN, founded in 1973 and based in Washington, DC, is the leading trade association representing the manufacturers and marketers of dietary supplements, functional foods, and their nutritional ingredients, including those containing *Aloe vera*-derived ingredients.

CRN understands this action is being proposed pursuant to the Labor Code listing mechanism, following a determination by the International Agency for Research on Cancer (IARC) that *Aloe vera*, whole leaf extract, should be classified in Group 2B as "possibly carcinogenic to humans."¹ For the reasons stated below, we request that OEHHA specify that the listing applies only to *Aloe vera*, non-decolorized whole leaf extract; provide a list of excluded *Aloe vera* ingredients; specify that oral consumption is the only relevant route of exposure; and, clarify that the naturally occurring exemption would be applicable for consumer products containing *Aloe vera*, non-decolorized whole leaf extract. We also encourage OEHHA to consult with the International Aloe Science Council² (IASC) as the agency moves forward to ensure that the listing is comprehensive and accurate.

- **Non-decolorized *Aloe vera*:** IARC's classification of *Aloe vera*, whole leaf extract as a Group 2B carcinogen is based on a National Toxicology Program (NTP) carcinogenicity study. This two-year feeding study in rats and mice, presented in NTP Technical Report 577,³ used a non-decolorized preparation of *Aloe vera*, whole leaf extract, which retained the complete latex constituent. This distinction is significant because the majority of commercial *Aloe vera* extracts available in the marketplace have been "decolorized" or purified, which removes the latex anthraquinoid constituents found in non-decolorized

¹ "Agents classified by the IARC Monographs, Volumes 1-112" (IARC, 2015): <http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf>.

² <http://www.iasc.org/>.

³ NTP TR 577 (August 2013): https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr577_508.pdf.

whole leaf extracts. In the past, OEHHA has provided detailed descriptions for other Proposition 65 listed chemicals, such as the following:

- Bitumens, extracts of steam-refined and air-refined;
- Emissions from high-temperature unrefined rapeseed oil;
- Soots, tars, and mineral oils (untreated and mildly treated oils and used engine oils).

In addition, IARC Monograph 108 provides recommendations for terminology used in the aloe industry. With regard to the term “whole leaf”, it states that “use of this terminology without adequate additional descriptors is not recommended.”⁴ The National Institutes of Health NTP Program also makes reference to non-decolorized *Aloe vera* in its materials for consumers seeking information on aloe.⁵ Thus, the Proposition 65 listing for *Aloe vera*, whole leaf extract should accord with these NTP reference materials as well as the NTP 577 Report.

- **Excluded *Aloe vera* ingredients:** The April 23, 2015 Notice of Intent to list *Aloe vera*, whole leaf extract correctly notes that “*Aloe vera*, whole leaf extract is not the same as *Aloe vera*, decolorized whole leaf extract, *Aloe vera* gel, *Aloe vera* gel extract, or *Aloe vera* latex” and therefore these ingredients would not be covered by the proposed listing. CRN requests that the final Proposition 65 listing incorporates these excluded ingredients to avoid any confusion and distinguish these from the material (i.e., non-decolorized whole leaf extract) used in the NTP carcinogenicity study. OEHHA has provided similar explanatory notes for other Proposition 65 listed chemicals.⁶
- **Oral Route of Exposure:** The inconclusive results of the NTP photocarcinogenicity study of *Aloe vera* extracts⁷ and limited, one-year duration of the study indicate that the final Proposition 65 listing should be specific to oral exposure of *Aloe vera*, non-decolorized whole leaf extract. OEHHA has specified limited routes of exposure in Proposition 65 listings, such as the following:
 - Carbon black (airborne, unbound particles of respirable size);
 - Ceramic fibers (airborne particles of respirable size);
 - Doxycycline (internal use);
 - Silica, crystalline (airborne particles of respirable size).

⁴ IARC Monograph 108, Aloe Vera, Table 1.1 Definition of terms commonly used in the Aloe industry: <http://monographs.iarc.fr/ENG/Monographs/vol108/mono108-01.pdf>.

⁵ Overview of the NTP Botanical Dietary Supplements Program: http://www.niehs.nih.gov/health/materials/ntp_botanical_fact_new_508.pdf; NTP Aloe vera summary: http://www.niehs.nih.gov/health/materials/aloe_vera_508.pdf; NTP Speaks about Aloe vera: <http://www.niehs.nih.gov/news/newsroom/interviews/aloevera/index.cfm>.

⁶ For example, the listing for Retinol/retinyl esters states: “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).”

⁷ NTP TR 553, 2010: http://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr553.pdf.

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- **Naturally occurring exemption:** OEHHA's Notice of Intent states that "*Aloe vera*, whole leaf extract consists of the liquid portion of the *Aloe vera* leaf and is a natural constituent of the *Aloe barbadensis* Miller plant," citing Title 27, section 25501(a)(1) of the California Code of Regulations, which addresses exposures to naturally occurring chemicals in a food. OEHHA has previously indicated that the addition of a naturally occurring chemical to a food or a consumer product does not create an "exposure" within the meaning of Proposition 65, and thereby such food or consumer product would also qualify for the "naturally occurring" exemption. Thus, CRN asks OEHHA to confirm that this exemption applies to the use of *Aloe vera*, non-decolorized whole leaf extract in foods, dietary supplements, or other consumer products such as cosmetics.

In summary, to avoid consumer confusion and provide clarification to the industry, CRN recommends that OEHHA specify the type of *Aloe vera*, whole leaf extract that is subject to Proposition 65 as well as the relevant route of exposure. Thus, we suggest the following text in the final Proposition 65 listing:

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.)

We further request that OEHHA explicitly confirm that the naturally occurring exemption is applicable to foods, dietary supplement and other consumer products containing *Aloe vera*, non-decolorized whole leaf extract. We also encourage OEHHA to consult with IASC on this matter, especially if OEHHA determines that a detailed listing as described above is unnecessary.

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

Sincerely,



Rend Al-Mondhiry, Esq.
Regulatory Counsel