



Corporate Office

1111 Marcus Ave | Lake Success, NY 11042 | (516)587-5000

To: Whom It May Concern

RE: Notice of Intent to List – *Aloe Vera*, whole leaf extract

The Hain Celestial Group, Inc. is a manufacturer of personal care and food products sold in the natural and grocery channels around the United States and distributed around the world.

We appreciate the opportunity to provide comments to the agency in regards to the proposed Notice of Intent to List *Aloe vera*, whole leaf extract under California State's Proposition 65 (Prop 65) Labor Code Mechanism based on the International Agency on Research in Cancer's (IARC's) determination that the extract may be a human carcinogen based on "sufficient evidence of carcinogenicity in experimental animals."

We do not support a listing of *Aloe vera* whole leaf extract on Prop 65 for the following reasons:

1. The IARC monograph notes a specific chemical – "aloin" – as the agent found in the *Aloe vera* leaf that may be carcinogenic in experimental animals. In fact, the monograph (and OEHHA's notice of intent to list) specifically notes the mechanism of action of this anthraquinones to cause the carcinogenic changes in the intestinal tract of the rat. (See Figure 2 of report).
2. Many ingredients processed from the whole leaf extract of the *Aloe vera* plant will not contain significant levels of aloin. According to the National Institute of Health (NIH), aloin levels in most liquid products are less than 1 part per million (ppm). There is little analytical data on the level of aloin in a consumer product formulated with *Aloe vera* leaf extract or *Aloe Barbadosensis* leaf juice. For example, a powdered concentrated extract of the whole leaf of *Aloe vera* that is certified by the International Aloe Science Council (IASC) has been verified to contain <0.1 ppm (<100 parts per billion) aloin.
3. The current listing of *Aloe vera* whole leaf extract as purported in the Notice excludes several categories of aloe ingredients; however, the industry accepted International Nomenclature for Cosmetics (INCI) labeling used in personal care does not provide the distinction necessary for consumers to understand whether or not the ingredient used may or may not contain aloin as the proposed chemical of concern listed in Prop 65.

We respectfully request that Office of Environmental Health Hazard Assessment (OEHHA) to reconsider the Prop 65 listing of the whole leaf extract of the *Aloe vera* plant to more accurately reflect the scientific evidence and consumer awareness.

1. Determine safe harbor level as well as the mechanism of action for carcinogenicity of the specific chemical (aloin) by conducting additional research to determine the risk to human health prior to listing under Proposition 65.
2. Work with regulators and trade associations, such as the Personal Care Product Council and International Nomenclature Committee to ensure that the distinction is visible to consumers on a chemical vs. ingredient listing under Proposition 65.

Thank you for your consideration of our comments on the proposed Prop 65 listing for *Aloe vera* whole leaf extract.

Sincerely,

Vic Mencarelli

Senior Manager Regulatory Affairs, Personal Care Division.