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June 9, 2015

BY EMAIL

P65Public.Comments@OEHHA.ca.gov

Ms. Esther Barajas-Ochoa
Office of Environmental Health Hazard Assessment
101 I Street
Sacramento, California 95814

Re: NOIL-Aloe vera, whole leaf extract

Dear Ms. Barajas-Ochoa:

Our office serves as outside counsel to Independent Cosmetic Manufacturers and Distributors (ICMAD) and we submit the following comments on behalf of ICMAD in response to the Notice of Intent to List (NOIL) Aloe vera, whole leaf extract published by the Office of Environmental Health Hazard Assessment (OEHHA) on April 23, 2015.

ICMAD is a non-profit trade association dedicated to providing programs and services to creative and innovative cosmetic companies to help them succeed in the rapidly changing, highly competitive cosmetics and personal care industries. Since 1974, ICMAD has been the voice of the independent cosmetic companies around the world. ICMAD is currently participating in an industry-wide coalition that supports science-based legislative and regulatory policies that enhance consumer and product safety standards grounded upon fair, objective and non-detrimental criteria. To that end, ICMAD respectfully requests that any agency action adding *Aloe vera*, whole leaf extract to the Prop. 65 list continue to preserve the clarifying statements in the NOIL to the effect 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, which [are] not ... covered by this ... listing."

Since most consumers are not familiar with the scientific names used to describe the exempt Aloe materials, ICMAD specifically requests that all Aloe products and derivatives thereof that are used in cosmetic and personal care products and which are not included in the NOIL, be separately listed not by just their scientific names but by their International Nomenclature of Cosmetic Ingredients (INCI) names since these are the names used on all consumer product ingredient labeling. We believe this is the only way that consumers will be able to readily understand that the Prop 65 listed Aloe materials are not the ingredients used in their personal care products.

Personal Care products that contain Aloe ingredients

There are myriad beneficial consumer products manufactured and distributed by small and mid-sized cosmetics and personal care companies which include Aloe vera gel, Aloe vera gel extract or Aloe vera latex or constituents thereof and it is vitally important to the industry and to the public to minimize any consumer or market confusion which may arise from listing of Aloe vera, whole leaf extract.

Aloe and its derivatives are widely-used in cosmetics and other personal care products. The Cosmetic Ingredient Review (CIR), which is conducted by panels of experts in the field of toxicology, reviewed the Aloe ingredients used in cosmetics and personal care products. As reported in the panel review, these Aloe ingredients function as skin conditioning agents in products such as shaving cream, aftershave lotion, skin cleansing creams, face and body skin care products, depilatories, makeup, deodorant, and tanning products. Aloe is also present in over-the-counter first aid, wound healing, and burn care (including sunburn care) products. According to CIR, Aloe-derived ingredients may safely be used in personal care product formulations if anthraquinone content does not exceed 50 ppm, a limit established by the International Aloe Science Council (IASC).¹

According to the NOIL, "IARC concludes that *Aloe vera*, whole leaf extract ... [is] classified in Group 2B (the agent is 'possibly carcinogenic to humans'), and that there is 'sufficient evidence of carcinogenicity in experimental animals. . . (Grosse *et al.*, 2013)." However, the unpurified Aloe material upon which the IARC analysis was apparently based is not the same material found in products marketed by ICMAD members in their cosmetics and personal care products. As noted, the CIR review concluded that the purified decolorized aloe materials were safe for use in cosmetic and personal care products.

The analytical data supporting the IARC classification indicates that the Aloe vera material tested contains well over 10,000 mg/L of aloin, implying it is an unfiltered or unpurified Aloe vera material, which has been suggested as the constituent of concern with regard to the conclusions of the IARC study. However, again this is not the ingredient that consumers are using in the vast majority of commercially available Aloe vera products which conform to the limitations established by the International Aloe Science Council (IASC) industry group that require that the Aloe materials be purified decolorized.

1 Cosmetic Ingredient Review (CIR). 2007. Final report on the safety assessment of Aloe andongensis extract, Aloe andongensis leaf juice, Aloe arborescens leaf extract, Aloe arborescens leaf juice, Aloe arborescens leaf protoplasts, Aloe barbadensis flower extract, Aloe barbadensis leaf, Aloe barbadensis leaf extract, Aloe barbadensis leaf juice, Aloe barbadensis leaf polysaccharides, Aloe barbadensis leaf water, Aloe ferox leaf extract, Aloe ferox leaf juice, and Aloe ferox leaf juice extract. *Int. J. Toxicol.* 26(Suppl. 2): 1-50.

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ICMAD respectfully requests that either listing of Aloe on the Prop 65 list incorporates not just the exclusionary language from the NOIL but also that it includes either in the listing or in a separate document that is made part of the regulatory record, the common or usual names for all Aloe materials that are not included in the listed material including the INCI names which are used to identify these materials on personal care products. We believe this will be an important step in avoiding the consumer confusion which is likely to follow from the listing of Aloe on the Prop 65 list even if it is qualified as suggested in the NOIL. Appended to this letter as Attachment A is a list of the cosmetic INCI names for materials that were reviewed by the CIR and would be included in the Aloe materials that are exempted under the terms of the NOIL.

Exemption for Topical uses

Additionally since the studies that gave rise to this listing were based upon solely on findings from oral consumption of the Aloe material and that no such findings were concluded for the topical use of Aloe, we respectfully request that topical uses be excluded from the listing of Aloe on Prop 65.

We appreciate the opportunity to express the views of ICMAD with regard to this proposed agency action. We would be happy to meet with OEHHA or provide any additional information in order to minimize potential confusion arising out of a listing of Aloe vera whole leaf extract and to distinguish it from Aloe vera decolorized whole leaf extract, Aloe vera gel, Aloe vera gel extract and Aloe vera latex found in various cosmetic and personal care products throughout the State of California and around the world.

Very truly yours,



M. Taylor Florence

MTF:cj

Enclosure



Cosmetic
Review



SEARCH>> aloe



A B C D E F G H I J K L M N O P Q R S T U V W X Y Z ALL

SEARCH HELP

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CIR Ingredient Status Report

CIR Ingredient Name:	U.S. INCI Name:
Aloe Andongensis Extract	Aloe Andongensis Leaf Extract
Aloe Andongensis Leaf Extract	Aloe Andongensis Leaf Extract
Aloe Andongensis Leaf Juice	Aloe Andongensis Leaf Juice
Aloe Arborescens Leaf Extract	Aloe Arborescens Leaf Extract
Aloe Arborescens Leaf Juice	Aloe Arborescens Leaf Juice
Aloe Arborescens Leaf Protoplasts	Aloe Arborescens Leaf Protoplasts
Aloe Barbadosensis Flower Extract	Aloe Barbadosensis Flower Extract
Aloe Barbadosensis Leaf	Aloe Barbadosensis Leaf
Aloe Barbadosensis Leaf Extract	Aloe Barbadosensis Leaf Extract
Aloe Barbadosensis Leaf Juice	Aloe Barbadosensis Leaf Juice
Aloe Barbadosensis Leaf Polysaccharides	Aloe Barbadosensis Leaf Polysaccharides
Aloe Barbadosensis Leaf Water	Aloe Barbadosensis Leaf Water
Aloe Ferox Leaf Extract	Aloe Ferox Leaf Extract
Aloe Ferox Leaf Juice	Aloe Ferox Leaf Juice
Aloe Ferox Leaf Juice Extract	Aloe Ferox Leaf Juice Extract

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