

**From:** [Jane Wilson IASC](#)  
**To:** [P65Public Comments](#)  
**Cc:** [Jane Wilson IASC](#)  
**Subject:** NOIL - Aloe vera whole leaf extract  
**Date:** Thursday, May 21, 2015 10:20:05 AM  
**Attachments:** [15\\_0521\\_IASC\\_comments\\_to\\_OEHHA\\_-\\_Aloe\\_vera.pdf](#)  
[11\\_0404\\_IASC\\_Comments\\_to\\_NTP\\_on\\_TR-577.pdf](#)

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Hello,

Attached please find the comments and supporting documents of the International Aloe Science Council (IASC) in response to the April 23, 2015 announcement of the intent to list "Aloe vera, whole leaf extract" under Proposition 65 by the Labor Code mechanism.

Best regards,

Jane Wilson  
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May 21, 2015

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

Dear Ms. Barajas-Ochoa,

The International Aloe Science Council (IASC) is providing here comments to OEHHA's April 23, 2015 announcement of the intent to list "*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). The IASC understands that this proposed listing is based on the "Labor Code" listing mechanism, and the recent International Agency for Research on Cancer (IARC) classification of this material as "possibly carcinogenic to humans (Group 2B)."

The IASC is the international trade association representing domestic and foreign businesses that cultivate *Aloe vera* (commonly referred to as aloe vera) plants and manufacture and market products containing aloe vera derived ingredients, including foods, dietary supplements, and personal care items. Of the IASC members that distribute aloe vera ingredients or market consumer goods derived from aloe vera leaf, almost none are engaged in selling products for human oral consumption containing non-decolorized or unpurified aloe vera whole leaf extracts that are the sole subject of the proposed aloe vera listing.

In the interest of consistency with the clear nomenclature regarding the non-decolorized aloe vera whole leaf extract test material employed in the National Toxicology Program (NTP) two-year carcinogenicity study (NTP TR 577), which is the foundational study for the IARC classification of this material as a Group 2B carcinogen, the IASC requests that OEHHA use the same terminology in establishing the chemical name for this material on the Proposition 65 list "Chemicals Known to the State to Cause Cancer or Reproductive Toxicity" as was used in the NTP study. Specifically, the IASC requests that the aloe vera material be identified with the underlined term inserted to read "*Aloe vera*, non-decolorized whole leaf extract." The IASC also requests OEHHA to clarify in the listing that the only relevant route of exposure is the oral route.

In the event that OEHHA is inclined to list "*Aloe vera*, whole leaf extract" without the incorporation of any further explanations, the IASC respectfully requests the opportunity to meet with the agency to discuss the nomenclature clarifications requested in these comments prior to formal listing of this substance.

## Rationale for IASC Comments

The NTP conducted a 2-year feeding study in both rats and mice using an extract of aloe vera whole leaf that retained the complete latex constituent. The results of this study are presented in NTP Technical Report 577 (NTP TR 577), dated August 2013. NTP TR 577 clearly and appropriately identified the substance studied as “a Nondecolorized Whole Leaf Extract of *Aloe Barbadensis* [sic] Miller (Aloe Vera)” in the website abstract.<sup>1</sup> This is important as it differentiates the NTP test substance from the vast majority of commercial aloe vera leaf extracts available in the marketplace, which have been decolorized/purified in order to remove the latex anthraquinoid constituents present in non-decolorized whole leaf extracts.

This differentiation with respect to the test substance was endorsed in comments provided to NTP by the IASC regarding the TR 577 draft report (“Comments of the International Aloe Science Council on the National Toxicology Program’s Draft Report TR 577, April 4, 2011”). IASC strongly encourages OEHHA to incorporate this same precise nomenclature in the proposed Proposition 65 listing and any related publications on and discussion relating to aloe vera non-decolorized whole leaf extracts.

The terminology of “non-decolorized” aloe vera whole leaf extract as established in the NTP TR 577 extends to other resources for information on aloe vera that may be referenced by consumers seeking information on this botanical and the meaning of this terminology. For example, the following National Institutes of Health websites provide information about aloe vera, and all utilize the term “non-decolorized” (or erroneously as “noncolorized” in the first instance) in reference to the NTP study material:

Overview of the NTP Botanical Dietary Supplements Program:

[http://www.niehs.nih.gov/health/materials/ntp\\_botanical\\_fact\\_new\\_508.pdf](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](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>

The IASC acknowledges that use of the Labor Code listing mechanism is triggered by the classification of a chemical by IARC, as is the case for “*Aloe vera*, whole leaf extract.” However, when reviewing IARC Monograph 108 for *Aloe vera*, it is noted that p.2 of the text cites the IASC recommendations for terminology commonly used in the aloe industry (IASC, 2009). Of note is the term “whole leaf”:

**Whole leaf** Historically used to describe products derived from the entire leaf that were filtered/purified. However, use of this terminology without adequate additional descriptors is not recommended. This terminology is now seen on products or in reference to raw material where the entire leaf is used as a starting ingredient to create *Aloe vera* juice.

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<sup>1</sup> The actual title of NTP TR 577 refers to the test substance as “noncolorized,” which is an apparent editorial error as the text of the report makes clear.

Later, when describing “*Aloe vera* whole leaf,” IARC notes that “*Aloe vera* whole leaf extract (sometimes referred to as whole leaf *Aloe vera* juice, Aloe juice or nondecolorized whole leaf extract), is the aqueous extract of the whole leaf with lignified fibres removed.” The IARC publications “Agents classified by the IARC Monographs, Volumes 1-112” (IARC, 2015) and “Carcinogenicity of some drugs and herbal products” (Grosse, 2013) used as the references for OEHHA’s proposed listing, regrettably do not consistently use the “non-decolorized” descriptor. However the IARC carcinogenicity classification is clearly based on the NTP 577 report, which, except for the actual title of the report, correctly incorporates this material distinction.

With respect to other routes of exposure, the IASC notes that IARC mischaracterizes the results of the NTP photocarcinogenicity study of aloe vera extracts (NTP TR 553, 2010). While IARC reports a “significant enhancing effect” of the aloe vera test materials on the photocarcinogenic activity of solar simulated light on mice, the NTP report describes the results as only a “weak enhancing effect” in its study. The NTP’s actual conclusions, which are misstated in the IARC monograph, do not support a finding that there is “sufficient evidence” in animal studies that *any* of the *Aloe vera* materials evaluated in the photocarcinogenicity study are known to cause cancer, as Proposition 65 and related case law require. Thus, it is not appropriate to predicate a listing on that aspect of the monograph. Further, the monograph indicates the IARC Working Group concluded that the one-year duration of the NTP TR 553 study was “too short” for it to be considered as a full carcinogenicity study. Therefore the current listing should be limited to oral exposure.

### **Additional comments**

More generally, the IASC brings to OEHHA’s attention that similarly detailed descriptions have been established for other complex chemical mixtures that have been added to the Proposition 65 chemicals list, specifically 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).

A detailed description is justified in the case of *Aloe vera*, non-decolorized whole leaf extract as well, in order to ensure that the chemical entity listed under Proposition 65 is sufficiently differentiated from the aloe vera products that are most commonly available in the consumer products marketplace.

In addition to the necessary specification of the chemical name to “*Aloe vera*, non-decolorized whole leaf extract,” the IASC strongly suggests that clarification be provided in the Proposition 65 entry for this chemical by listing the aloe vera derived ingredients that are excluded from this proposed listing. While it is appreciated that these exclusions are mentioned in the April 23, 2015 OEHHA announcement, the exclusions must be provided in the formal Proposition 65 entry to avoid any confusion that aloe vera ingredients other than the one subjected to NTP testing are part of the listing. The IASC observes that explanatory notes or other parenthetical material have been utilized

for other Proposition 65 listed chemicals, so the addition of a note listing the specific exclusions does not create a precedent. The list of excluded aloe vera ingredients should also be representative of the predominant industry terminology, as presented in the IASC publication *Definition of Terms Commonly Used in the Aloe Industry*<sup>2</sup>.

OEHHA's final listing should be explicit that only the oral route of exposure is relevant based on a proper reading of the IARC monograph and the actual characterization of the underlying NTP TR 553 photocarcinogenicity study conclusions. OEHHA has previously allowed for listings based on limited routes of exposure, 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).

The IASC proposes the final listing, including the explanation of exclusions to read 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.)

The IASC appreciates the clear communication of the fact that "*Aloe vera*, whole leaf extract" is "a natural constituent of the *Aloe barbadensis* Miller plant," with reference to the corresponding Article in the California Code of Regulations (Title 27, Cal. Code of Regs., section 25501(a)(1)). In a 2002 letter regarding the naturally-occurring compound methyleugenol, OEHHA 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. The IASC expects that the same conclusion would be reached when considering the use of *Aloe vera*, nondecolorized whole leaf extract in foods, dietary supplements, or other consumer products such as cosmetics.

### Summary

Proposition 65 is a "right to know" regulation in the State of California. Consumers have the right to be informed of which specific "*Aloe vera*, whole leaf extract" is "known to the State to cause cancer" to more easily make their purchasing decisions. Consumers have the right to not receive unnecessary Proposition 65 warnings that may be precipitated by a less precise description of this chemical entity. This will also support the industry to continue to provide pure, high-quality aloe vera products to this important market.

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<sup>2</sup> International Aloe Science Council, 2009.

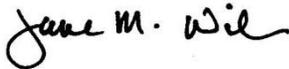
The IASC maintains that the addition of the term “non-decolorized” to the chemical name, along with the limitation to oral exposure and the aloe vera derived ingredients that are excluded from this chemical listing, is vital to convey important information to California consumers who utilize aloe vera products. The NTP 577 report provides a precise, consistent description of the tested chemical entity, and this same description must be used in any Proposition 65 listing based on the NTP body of work.

IASC recommends the appropriate title of “*Aloe vera*, non-decolorized whole leaf extract” to identify the listed ingredient with an appropriate description, and exclusions, as discussed previously in these comments.

As previously indicated, should OEHHA decide to list “*Aloe vera*, whole leaf extract” without all of the requested explanations, the IASC respectfully requests the opportunity to meet with the agency to discuss these comments.

The IASC appreciates OEHHA’s thoughtful consideration of these comments. I am available to answer any questions as may be needed to clarify these comments.

Sincerely,



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Attachment:  
Comments of the International Aloe Science Council on the National Toxicology Program’s Draft Report TR 577 (April 4, 2011)

cc:  
IASC Board of Directors



**Comments of the  
International Aloe Science Council**

**On the**

**National Toxicology Program's  
Draft Report - TR-577**

**April 4, 2011**



## INTRODUCTION

Science is a tool that can provide accurate and nonmisleading information based on results obtained using the scientific method. In order to be appropriately understood by the general public, this information often needs to be qualified so that consumers can properly determine its importance to them. To qualify the National Toxicology Program's (NTP) report on a 2-year oral consumption study of "non-decolorized whole leaf extract of *aloe barbadensis* Miller" the material used in the study needs to be clearly defined and the difference between it and the majority of marketplace ingredients made. Without this distinction there exists a potential and serious opportunity for consumer confusion about the results of the authoritative work of the NTP with regard to what was studied in this case.

As an industry trade group, the International Aloe Science Council (IASC) has a responsibility to protect the aloe vera product trade, a multi-billion dollar industry employing thousands of people worldwide, from potential damage that may be caused by confusion regarding the material used in the NTP study and the ingredient IASC member-manufacturers, and the majority of the industry, use in orally consumed products.

### **“NON-DECOLORIZED WHOLE LEAF EXTRACT OF *Aloe barbadensis* MILLER” vs. PURIFIED ALOE VERA LEAF JUICE**

In the case of aloe vera, confusion regarding terminology already abounds in the scientific and regulatory communities, much of it due to the lack of an accurate and true Aloe vera juice monograph, which, were one to exist, would describe the parts of the plant used in the manufacture and sale of Aloe vera beverages and other orally-consumed products as the aloe vera inner leaf juice (often described as “inner leaf fillet” or “inner gel”), and the processed leaf or aloe vera leaf juice (often described as “whole leaf” or “purified aloe vera leaf juice”). For example:

From the United States Pharmacopeia (USP) monograph on Aloe<sup>1</sup>:

*Aloe is the dried latex of the leaves of *Aloe barbadensis* Miller (*Aloe vera* Linné), known in commerce as Curaçao Aloe, or of *Aloe ferox* Miller and hybrids of this species with *Aloe africana* Miller and *Aloe spicata* Baker, known in commerce as Cape Aloe (Fam. Liliaceae).*

From the European Pharmacopeia 6.0<sup>2</sup>:

*Aloe Barbadensis:*

*Definition: Concentrated and dried juice of the leaves of the *Aloe barbadensis* Miller*

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<sup>1</sup> Aloe USP 32

<sup>2</sup> European Pharmacopeia 6.0, p. 1137 Aloes, Barbados

*Content: Minimum 28.0 per cent hydroxyanthracene derivatives, expressed as barbaloin (C<sub>21</sub>, H<sub>22</sub>, O<sub>9</sub>; M<sub>r</sub> 418.4) (dried drug)*

Both of the above, well recognized and respected monographs claim “aloe juice” as aloe latex whereas industry considers “aloe vera juice” to be anything but the aloe latex.

From the WHO Aloe Monograph<sup>3</sup>:

*Plant material of interest: dried juice*

*Solidified juice originating in the cells of the pericycle and adjacent leaf parenchyma, and flowing spontaneously from the cut leaf, allowed to dry with or without the aid of heat.*

*It is not to be confused with Aloe Vera Gel, which is the colourless mucilaginous gel obtained from the parenchymatous cells in the leaves of Aloe vera (L.) Burm. f.*

Though the WHO monograph above attempts to differentiate between the “juice” related to the aloe latex and what they call “Aloe Vera Gel”, there is still ample confusion in regards to terminology.

From the Natural Standard Aloe (Aloe vera) Monograph<sup>4</sup>:

### **Background**

*Transparent gel from the pulp of the meaty leaves of Aloe vera has been used topically for thousands of years to treat wounds, skin infections, burns, and numerous other dermatologic conditions. Dried latex from the inner lining of the leaf has traditionally been used as an oral laxative.*

*There is strong scientific evidence in support of the laxative properties of aloe latex, based on the well-established cathartic properties of anthroquinone glycosides (found in aloe latex). However, aloe's therapeutic value compared with other approaches to constipation remains unclear.*

The Natural Standard monograph is one that attempts to *combine* aloe vera and aloe latex and to discuss them at the same time. Though the purveyors attempt to clearly define one from the other, this format makes it very difficult to distinguish between the two materials.

### **TERMINOLOGY**

In order to provide accurate and non-misleading information on aloe vera, it is important to understand commonly used terminology. As described above, there has been a great deal of confusing information published in what are considered “authoritative” works

<sup>3</sup> <http://apps.who.int/medicinedocs/en/d/Js2200e/5.html#Js2200e.5> – accessed 4/4/11

<sup>4</sup> [http://www.mayoclinic.com/health/aloe-vera/NS\\_patient-aloe](http://www.mayoclinic.com/health/aloe-vera/NS_patient-aloe) – accessed 4/4/11



regarding aloe vera and the materials derived from it. The majority of the information provided here is from the *Encyclopedia of Dietary Supplements, 2<sup>nd</sup> Edition* published by the National Institutes of Health – Office of Dietary Supplements. It can serve as a lexicon for the NTP study report and future published works.

## DESCRIPTION

The leaf of aloe vera is normally described as consisting of three major parts that are used in commercial products: the outer mesophyll (rind or cuticle), the interior parenchyma (inner leaf, gel or gel fillet, inner gel, inner leaf gel fillet), and the aloe latex (sap, bitter element, yellow sap, yellow latex). Researchers, raw material manufacturers, and finished goods manufacturers have utilized all three plant parts separately or in combination for aloe vera research and in the formulation of consumer products.

### Outer Mesophyll (Rind)

Aloe vera rind or cuticle is the site of photosynthesis and primarily consists of cellulose, monosaccharides, water soluble and insoluble carbohydrates, chlorophyll, amino acids, proteins, and lipids.

### Interior Parenchyma (Inner Leaf)

Aloe vera inner leaf is the colorless, mucilaginous parenchyma of the aloe vera plant leaf consisting of water, monosaccharides, water-soluble carbohydrates, water-soluble polysaccharides, and water-insoluble fibrous pulp. The compound beta-(1–4)-acetylated mannan, a polysaccharide also known as “acemannan” or “polymannan,” is widely considered to be the biologically most important component of the inner leaf. After removal of fibrous pulp from the inner leaf, the resulting juice also contains about 0.5% to 1.5% solids.

### Aloe Latex (Aloe Sap, Aloe Bitters)

Aloe latex is a yellow-green bitter exudate that contains the anthraquinone glycosides aloins A and B, formerly known as “barbaloin” and “isobarbaloin,” respectively. The aloin content of aloe latex changes with the season and the age of the leaf but usually makes up 10% to 25% of the dried latex by weight. Products made from aloe latex have been used historically as a laxative. The source plant is most commonly *Aloe ferox* from Africa or Argentina.

Industry uses the following terminology in regards to aloe vera and the parts of the plant:

- Aloe vera leaf juice – juice derived by using the entire leaf of the plant as the starting ingredient. Synonymous with “purified whole leaf juice”
- Aloe vera inner leaf juice – juice derived by using only the inner, gelatinous section of the plant as the starting ingredient
- Aloe vera juice – used to describe either of the above (aloe vera leaf juice or aloe vera inner leaf juice)



- Aloe latex – yellowish-brown, sap-like exudate found between the rind and the inner leaf material. Contains anthraquinones (aloin A&B, aloe emodin, dyastalic rhein) some of which are powerful laxatives

There are two parts of the plant used as the starting material to make the finished raw aloe vera juice ingredient that are used and found in products commonly seen in the marketplace: the entire leaf and the inner leaf. Below is a typical processing flow for both starting materials for oral consumption. Both processes are designed to remove or vastly reduce aloe latex content.

- Aloe vera inner leaf juice:
  - Leaf harvest/cleaning & sanitation
  - Manual or machine removal of the majority of outer rind
  - Removal/washing away of aloe latex
  - Processing of inner leaf material to puree (crushing, pulverizing)
  - Enzyme treatment (may or may not be done) to reduce viscosity
  - Filtration of insoluble pulp and remaining rind
  - Filtration via active charcoal (or similar) to remove phenolic compounds (aloe latex, etc.) – not done by all manufacturers
  - Microbial reduction (typically by pasteurization)
  - Reduction of water content (concentration – may or may not be done)
  - Preservation & packaging
- Aloe vera leaf juice (or Purified whole leaf juice):
  - Leaf harvest/cleaning & sanitation
  - Maceration/pulverization of entire leaf into puree/slurry
  - Enzyme treatment (may or may not be done) to reduce viscosity
  - Filtration of insoluble pulp and rind
  - Filtration via active charcoal (or similar) to remove phenolic compounds (aloe latex, etc.)
  - Microbial reduction (typically by pasteurization)
  - Reduction of water content (concentration – may or may not be done)
  - Preservation & packaging

The material used in the NTP study was an unpurified aloe vera juice, meaning that the phenolic constituents, including the anthraquinones found in aloe vera latex, were not removed via activated charcoal or some other form of filtration. These are the materials that are known for their powerful laxative effect. Industry removes this fraction from raw materials to product ingredients intended for use in products designed for oral consumption as outlined in the processing flow above. The finished raw ingredient used in commercial products, depending on the starting material, is termed “aloe vera leaf juice” (or “purified whole leaf juice”) or “aloe vera inner leaf juice”.

## **NTP PEER REVIEW DRAFT REPORT TERMINOLOGY – SUGGESTED CORRECTIONS**

In several places within the NTP peer review draft report (TR-577), NTP refers to the material studied and provides synonyms which are either erroneous or not in congruence with the standard terminology provided here. There are many other such instances, and all should be considered for review and possible correction to provide greater clarity in regards to terminology.

### **Page 17, Introduction – Chemical & Physical Properties, paragraph 1**

*“Aloe, a genus within the Liliaceae family, is composed of approximately 420 species of plants. Aloe barbadensis Miller, Aloe vera, is one species of Aloe. Other common names of Aloe barbadensis Miller include Barbados aloe... and Curacao aloe.” (emphasis added)*

Both of the underlined "common names" are typically used to refer to the drug aloes (aloe latex) and not the aloe vera found in the vast majority of products in the marketplace<sup>5</sup>.

### **Page 19, Aloe Vera Nondecoblized Whole Leaf Extract, paragraph 1**

*The Aloe vera nondecoblized whole leaf extract, commonly referred to as whole leaf Aloe vera juice or Aloe juice, is the aqueous extract of the whole Aloe vera leaf with lignified fibers removed. The Aloe vera whole leaf extract contains both the gel from the inner parenchyma leaf pulp and the latex. (emphasis added)*

The information underlined in the first sentence above is erroneous. Nondecoblized whole leaf extract is or would be commonly referred to as “unpurified aloe vera leaf juice” or “unpurified aloe juice”. In the second sentence, the underlined statement that “The Aloe vera whole leaf extract contains both the gel from the inner parenchyma leaf pulp and the latex would be accurate if qualified to include “the aloe vera whole leaf extract used in this 2-year study contains both the gel from...” but is inaccurate in regards to marketplace terminology. In order to avoid confusion, it is recommended that more clarification be made to this information.

### **Page 21, Aloe Vera Decoblized Whole Leaf Extract**

*“Activated carbon adsorption of the Aloe vera nondecoblized whole leaf extract to remove the anthraquinone components of aloe latex results in a product termed decoblized whole leaf extract that has quite different*

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<sup>5</sup> [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Herbal\\_-\\_Community\\_herbal\\_monograph/2009/12/WC500017822.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_Community_herbal_monograph/2009/12/WC500017822.pdf)



*properties. Aloe vera decolorized whole leaf extract is also referred to as whole leaf aloe vera gel.*” (emphasis added)

Products derived from the entire aloe vera leaf and which have been filtered using activated charcoal or carbon are termed “purified aloe vera leaf juice” or have similar qualifiers (“filtered”, etc).

In regards to the second underlined item, aloe vera decolorized whole leaf extract is not referred to as “whole leaf aloe vera gel”. Typically raw ingredients made from only the inner leaf of the plant are termed “gel”, or those in which a thickening agent has been added (carrageenan, etc.).

## **CONCLUSION**

In order to accurately and adequately inform all parties who may become aware of and interested in the NTP research on aloe vera, the IASC requests that the study adequately and accurately define and describe the material used in the study (“non-decolorized whole leaf extract of *Aloe barbadensis* Miller”), but should also include a glossary as to what these terms mean (non-decolorized, for example). A lexicon of definitions is provided with these comments as a guide and suggestion, and the IASC is willing to cooperate with NTP in any way to assist in the development and inclusion of such information within the reports on aloe vera.

In addition, in order to mitigate any possible confusion among the scientific community and the general public and to promote greater clarity amongst all parties involved, the IASC recommends the inclusion of accurate and non-misleading information regarding not only the study material, but also suggests the NTP provide contrasting information, again accurately and in a non-misleading manner, as to what ingredients are commonly available in the marketplace and how those ingredients may (or may not) differ from the NTP study material. The information provided here in the “Terminology” and “Description” sections would be a useful addition to the NTP report and would suffice for this purpose.

The IASC would also appreciate consideration for the suggested revisions provided in these comments, and for the NTP to consider a complete review of the draft report with due consideration for the terminology and definitions as provided.

ee: IASC Labeling Guidance & Definitions



## Definition of Terms Commonly Used in the Aloe Industry

<u>Term</u>	<u>Definition</u>
Grind	Biomaterial from entire leaf is ground up into a mash
Cold Pressed	Biomass is claimed to be pressed and treated without any heat. It is recommended that this term not be adopted and removed from use as it is believed to be misleading. Unless a company can provide information on substantiation for this process.
Enzyme Treated	Entire leaf biomass is ground into a slurry, enzymes are added to assist in breaking down the fiber into a liquid. The enzymes are then neutralized/deactivated.
Non Enzyme Treated	Biomass is processed into a liquid without the use of enzymes
Filtered	Biomass is mechanically forced thru a filtering device (screen; sieve; membrane, etc.) to remove soluble material
Activated Charcoal Filtered	A form of filtration using activated charcoal; utilized primarily to remove anthraquinones
De-colored	A process, usually by filtration with activated charcoal, that makes the liquid aloe mass clear
De-carmelized	Same as De-colored
HTST (Pasteurization)	High Temperature Short Time process utilized to reduce microbial counts.
Low Heat Process	A process to concentrate or powder material
Evaporative Concentrate	The process of removing water from the biomass so the material is more concentrated
Evaporative Concentrate Vacuum	The process of using a vacuum environment to remove water from the Biomass so the material is more concentrated
Preserved	Use of chemical components to maintain freshness. Individual ingredients used as preservatives must be designated as such on labels for raw materials and finished products
Non-Preserved	Raw material and finished product does not contain preservatives
Organic Certified	Product or raw material that complies with USDA or country of origin certification requirements
Spray-dried	The liquid concentrated aloe is mechanically processed to force evaporation of water and convert it into a powdered form
Freeze-dried	The liquid concentrated aloe is frozen in a vacuum state to remove water and convert it into a powdered form
Reflective Dried	The liquid concentrated aloe is placed on mylar over high heat to remove water and convert it into a powdered form
Granulated/Powdered	Powder that has been processed to a specific screen size/dried Aloe vera.
Reconstituted from Concentrate	A liquid aloe vera concentrate that is diluted with water



<u>Term</u>	<u>Definition</u>
Reconstituted from Powder	Aloe vera powder that is liquefied by adding water
Hand Fillet	Aloe leaves that have the outer rind of the leaf removed manually to leave only the inner leaf
Machine Fillet	Aloe leaves that have the outer rind of the leaf removed by mechanical means to leave only the inner leaf
Alcohol Precipitated	Alcohol is used to remove water and isolate the solids of the inner leaf
Squeezed Fillet	A process that via mechanical pressure extracts the inner leaf without manually or mechanically removing the rind first
Inner leaf	Plant part used to describe the clear, central parenchymatous tissues of the aloe leaf
Aloe Latex	Brown, yellow-brown, or occasionally red exudate found in between the rind and inner leaf. Also called “sap”, it contains several constituents, but most notably anthraquinones
Anthraquinone	An organic compound primarily found in the aloe latex whose structure serves as a basic building block for a number of naturally occurring plant pigments. The substance is commonly utilized for laxative purposes
Juice	Liquid product derived from <i>Aloe vera</i> leaf
Gel	Liquid product typically derived from the inner leaf that may contain pulp, and may or may not have added thickening agents (which must be identified on the label)
Leaf	The part of the <i>Aloe vera</i> plant utilized in commerce where processing is begun without stripping off of the rind
“Whole leaf”	Historically used to describe products derived from the entire leaf that were filtered/purified. However, usage of this terminology without adequate additional descriptors is not recommended in order to avoid misbranding concerns and is considered technically inaccurate otherwise.  This terminology is now seen on products or in reference to raw material where the entire leaf is used as a starting ingredient to create aloe vera juice. The IASC now recognizes this terminology to be accurate only if no purification, filtration or other treatment (enzyme, etc.) is conducted on the ingredient beyond removal of any insoluble material <sup>1</sup>
Purified/Filtered “whole leaf”	Terminology used on products or raw material where the entire leaf is used as a starting ingredient <u>and</u> where some sort of purification or filtration is utilized (and may also be treated with enzymes, etc.) to remove or substantially reduce unwanted material and substances from the resulting juice or powder, such as the rind and aloe latex. Other terms such as “charcoal filtered” or “treated” may also be seen in use as descriptors <sup>2</sup>

<sup>1, 2</sup> \*See IASC Labeling Guidance – Section 4  
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