



POSITION PAPER OF THE INTERNATIONAL ALOE SCIENCE COUNCIL on THE NATIONAL TOXICOLOGY PROGRAM STUDY OF ORALLY-INGESTED ALOE VERA

The National Toxicology Program (NTP) conducted a two-year study on an ingredient identified as “non-decolorized whole leaf extract of *Aloe barbadensis* Miller,” an unpurified aloe material. While from a purely scientific point of view it may be of interest to know more about this substance, International Aloe Science Council (IASC) members do not market such products to consumers for oral consumption.

Background on the NTP and the Two-year Oral-Consumption Study

The NTP is an interagency program whose objective is to evaluate substances of possible public health concern by developing and applying tools of modern toxicology and molecular biology. Aloe vera was nominated along with several other substances for review by NTP in the late 1990s for both phototoxic and oral consumption toxicity analysis. All phototoxicity studies came back either inconclusive or with no negative conclusions.

The results of the NTP 2-year oral consumption study concluded that there was “clear evidence of carcinogenicity” in the rats (but not in the mice). It is important that consumers and the industry understand the difference between the material used in the study and those ingredients in products available in the marketplace. Therefore, the IASC has drafted this information to clearly describe and define the differences between the material used in the NTP study and the ingredient used in products currently available in the marketplace.

Aloe Vera Juice in Commercially Available Products in the Marketplace

There are two types of processed aloe vera juice that are used in commercially available products today: aloe vera leaf juice and aloe vera inner leaf juice.

Aloe vera leaf juice (some products can also be seen labeled as “purified/filtered whole leaf”) is obtained by grinding or macerating the entire aloe vera leaf, then removing the rind material and the bitter, yellow substance (called “aloe latex”), typically through filtration via activated charcoal.

Aloe vera inner leaf juice (some products can also be seen labeled as “gel”, “inner leaf fillet” and “fillet gel”) is manufactured by stripping off the outer rind of the leaves by machine or by hand, rinsing or washing away the aloe latex, then collecting and transferring the remaining inner leaf material, a gelatinous substance, for further processing into juice.

Both of the aforementioned aloe vera juice processes remove virtually all of the aloe latex substance, which is naturally occurring in the botanical and can be found in between the rind and the inner leaf material. Aloe latex contains a constituent called aloin, which is known to have strong laxative properties and which the NTP has suggested may be the constituent of concern with regards to the conclusions of the study. The vast majority of manufacturers of aloe vera juice products for oral consumption produce products with less than 10mg/L of aloin. IASC has established a quality standard of <10mg of aloin per liter of aloe vera juice products for oral consumption, and as noted above, this substance is virtually removed during initial processing. The NTP study material contained quantities of aloin vastly greater than this amount.

In order to ensure the content and purity of products available to consumers meet acceptable industry standards the IASC developed and manages a certification program for aloe vera products – which includes the <10mg/L aloin content. Though there may be products manufactured by non-IASC members in the marketplace that contain greater aloin concentrations – concerned consumers should look for and purchase products displaying the IASC seal (and verify the company’s participation by looking on the IASC website).



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NTP Study Ingredient

In cooperation with FDA and National Center for Toxicological Research (NCTR), IASC obtained a sample specimen of the aloe vera material that was the subject of the NTP rodent feeding studies. Chemical analysis of this material has identified it as an ingredient with aloin content between 10,000 – 13,000 mg/L, implying it is an unfiltered or unpurified aloe vera material. As mentioned prior, the industry standard for products currently in the marketplace is to use filtered material from which the aloe latex has been largely removed, and IASC's current policy limits aloin in orally consumed products to 10mg/L. This would indicate the NTP study material contains approximately 1,000-1,300 times the amount of aloin found in the vast majority of readily available commercial products.

What Consumers & Industry Should Know – The Bottom Line

- The IASC has analytically demonstrated that the aloe vera material tested by the NTP for oral toxicity contains between 10,000 – 13,000mg/L of aloin. This is not the ingredient that consumers are ingesting when they use the vast majority of commercially available aloe vera products.
- Even though the IASC has proven analytically that the ingredient tested by the NTP is not what is currently being sold in products available in the marketplace, the NTP may publish findings that could be misleading or confusing to consumers, regulators, and the industry.
- The IASC will be continuing its efforts to work with the NTP, regulators, and Congressional leaders, as well as state officials, if necessary, in order to clearly define the difference between the NTP study ingredient and the ingredient used in products currently available in the marketplace.
- Manufacturers and distributors of aloe vera leaf juice products should analytically verify their products are in compliance with the IASC position that aloe vera products for oral consumption have an aloin content of 10mg/L or less, and be able to provide that information to consumers upon demand.
- The IASC created and manages a certification program to ensure the content and purity of aloe vera products are in line with program standards. Products in the program are analytically tested for aloin content to ensure compliance with the 10mg/L aloin limit. Consumers who are concerned that they are purchasing aloe vera products that meet this standard should look for the IASC seal and purchase IASC certified products.

The organization maintains lists of products that are actively participating in the program and have been analytically proven to meet the program's standards (<http://www.iasc.org/complete.html>), as well as those products that are no longer certified (http://www.iasc.org/not_certified.html), and those that have never been certified but have been found displaying the seal illegally (http://www.iasc.org/never_certified.html).