



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

The National Toxicology Program (NTP) has been conducting a two-year study on an ingredient identified as “aloe vera whole leaf extract (native).” While from a purely scientific point of view it may be of interest to know more about this substance, the International Aloe Science Council (IASC) is not aware of any products that can be readily found in the current marketplace that contain this particular ingredient.

### **Background on the NTP and the Two-year Oral-Consumption Study of Aloe Vera**

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 are expected to be released sometime in 2011, and the IASC has been informed of the high probability the study will conclude that there is clear evidence of carcinogenic activity in test animals. It is important that consumers and the industry understand the difference between the ingredient used in the study and those ingredients in products available in the marketplace. Therefore, the IASC is acting now to assure that the NTP accurately describes the tested ingredient so that it is not confused with other widely available aloe vera products. The organization has also drafted this information to clearly describe and define the differences between the ingredient used in the NTP study and those 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 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 “whole leaf” or “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. 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.

### **NTP Study Ingredient – Aloe vera whole leaf extract (native)**

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 40,000 and 60,000 mg/L, implying it is an unfiltered aloe vera ingredient. 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 4,000-6,000 times the amount of aloin found in the vast majority of readily available commercial products.



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**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 40,000 and 60,000 mg/L of aloin. This is not the material 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.