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# Aloe Vera Update: A New Form Questions Integrity of Old

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During the past several years, aloe vera has attained such a reputation that its use is no longer confined to the natural cosmetics and health food industries. Major cosmetic companies also have now incorporated aloe vera into their products. Trade associations formed by producers of aloe vera ingredients and products have been established for the promotion of aloe vera, and standards for aloe vera identification and quality have been proposed. At least two companies have claimed to have isolated active principles from aloe vera gel and to have devised methods for testing its biological effects (though to date none of these claims or test results have been published or authenticated).

Although many major cosmetic marketers have aloe in their products, most have done so in response to market pressures rather than because of actual experience with the beneficial effects of the gel. So far, no credible evidence has been offered that processed aloe vera gel possesses the activity of fresh gel. Furthermore, due to the absence of analytical and identification standards, no assurance is provided that any of the commercially available aloe vera gel products contain any active ingredients at all. This difficulty in pinning down aloe vera gel purity may be a factor for those cosmetic marketers who have resisted putting aloe vera into their products, the feeling among their chemists being that they will wait for gels with consistent qualities that will yield consistent positive results.

Despite heavy promotion in aloe vera products, the following difficulties remain:

1. Lack of meaningful identification or purity standards, to a point where no one can mount a successful challenge to producer claims that they have the best or purest products (even though some of their liquid products may be mostly water with citric acid and preservatives and their concentrates nothing but diluents).

2. Powdered aloe vera concentrates, currently pro-



duced by spray-drying, freeze-drying, and solvent precipitation (after initial evaporation), contain diluents, referred to in the trade as carriers, stabilizers, preservatives, etc. These diluents are incorporated for easy handling, storage, or for other purposes. Most gel concentrates are claimed to be 200 times more concentrated than the original gel; and

3. Though there are a few genuine aloe gel liquids and concentrates (10X, 40X, etc.) currently available, unfortunately, due to methods used in their extraction, they contain mostly decomposed gel components.

Adding to these problems are those that are significant in aloe vera research. These include different sorts of complications:

1. Although freshly obtained aloe vera gel is well known for its ability to relieve pain due to sunburn or

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thermal burns, and to promote wound-healing in minor skin irritations, cuts and bruises, its active principle(s) is unstable and present only in minor amounts (water alone constituting over 99 percent of the gel). Any meaningful attempts to isolate the active principle requires the work-up of large quantities of liquid. During this work-up process, the active components have plenty of time to undergo degradation and by the conclusion of the process most probably are destroyed. A general belief in the trade is that evidence of this destruction can be seen in darkening and loss of viscosity of the gel. Also persistent is the notion that even trace amounts of aloin in the gel render it ineffective and even harmful, a belief that has prompted aloe vera suppliers to stress the low aloin content of their gels (even though it is common knowledge to those who have used aloe vera gel from freshly split leaves that fresh gels always contain certain levels of the bitter yellow juice (aloin), without loss of efficacy. Nevertheless, some manufacturers take pains to make sure their liquid aloe is clear and colorless like water, even to the extent of removing most of the active components during processing. Other manufacturers may add gums to make their liquid aloe resemble the fresh gel, or simply formulate what amounts to a synthetic aloe vera gel with a token amount of the genuine material to give it credibility. It is amusing that in spite of the increased demand for aloe vera gel and the widely reported severe frosts in the past two winters in the Texas growing areas, we have seen no evidence of any shortage of aloe vera in the U.S.

2. Due to inconsistencies in processed aloe vera, research results based on commercial, processed materials so far have been inconsistent or meaningless.

3. Since the active principle of aloe vera gel still isn't known, attempts to purify or stabilize the gel are bound to be futile. Or to put it another way, without

assurances that the active ingredient remains intact after purification and stabilization of the gel, scientists find it well nigh impossible to assess and then select the appropriate gels for chemical/biological studies. Not helping here are claims from some manufacturers that they have "purified" or "stabilized" via "cold-stabilization" or "enzyme-stabilization," all without demonstrating that the active ingredients have been retained. Without identification of the key ingredient (or ingredients), how can it be demonstrated that processing requiring solvent extraction, precipitation, chemical treatment, enzyme digestion or whatever can be done without loss of that same key ingredient?

Such factors have inhibited meaningful scientific research on aloe vera, including attempts to determine quality or active components by chemical analyses. Thus much remains to be done in identifying the active components and in setting meaningful analytical standards for quality control, objectives that can be achieved only when scientists have at their disposal a consistent, genuine aloe vera gel. Until now, no such product has been available, so that research so far done on the gel of any one company's product cannot represent an industry standard.

Currently, aloe vera gels are processed by a basic method: filleting of the fresh aloe vera leaves by hand or machine to remove the centers, which are then subjected to such processes as pulping, homogenizing, filtering, heating and chemical or solvent treatment. To produce single-strength gel the liquified or homogenized gel usually is filtered, heated or pasteurized, then treated ("preserved" and "stabilized") with antimicrobial agents, antioxidants, and acidulants to retard color change and microbial growth. As has been indicated above, the resulting product is usually water-clear (and water-thin), and bears no resemblance to the original gel and with little evidence that it still retains the active ingredient. To

make it look like the original gel, some manufacturers even add gums to impart viscosity. Single strength gel also is produced from gel concentrates by dilution or "reconstitution" with water.

For gel concentrates, (liquids or powders, the filtered gel (single-strength) is evaporated under vacuum (at 40 to 60 degrees C.) to increase its solids content from about 0.5 to about 20 percent. At this point, the concentrated liquid is considered as being 40X strength. After pasteurization or sterilization by gamma ray radiation, this is marketed by some suppliers as the 40X liquid concentrate. For the powder concentrate, the concentrated liquid is subjected to either spray-drying, freeze-drying, and solvent treatment followed by oven drying. To produce a 200X strength gel concentrate, theoretically the liquid concentrate should be dried without use of carriers. But it is a fact that most suppliers add carriers to increase yield and facilitate handling, to a point where carriers constitute the major component of the concentrate.

For spray-dried aloe vera, gums or hydrolyzed starches are commonly used. For the freeze-dried variety, anti-caking agents are also used. Freeze-drying of the unconcentrated gel (which, keep in mind, is 99.5 percent water) is not done commercially because of high costs. For a solvent-precipitated powdered concentrate, the liquid concentrate is treated with a solvent to precipitate the gel, the precipitated gel then being filtered off, oven-dried, and milled to yield a powdered gel, which is mixed with carriers (gums, sugars, etc.) to the desired strength.

Although most of the powdered gels described above are sold as 200X concentrates, few if any are in fact that strength---especially when one considers that the usual selling price (\$75 to \$125 per pound) often is less than the cost of raw materials alone. To illustrate the point, it takes two to three pounds of aloe vera leaves to produce a pound of gel fillets. To produce one pound of 200X strength aloe vera powder, theoretically 200 pounds of fillets containing 0.5 percent solids are needed (which in turn converts to 500 pounds of aloe leaves). At an average cost of 12 cents per pound in the U.S. (FOB the aloe fields), the aloe leaves alone figure to cost \$60. To fillet 500 pounds of leaves, it would take an experienced worker six hours or more, at a cost of at least \$24. Total cost up to this point already is more than \$84 per pound for a processor close to the aloe fields. For far away processors, freight costs of leaves could help push material/labor costs alone over the \$125 per pound mark. Thus it would seem obvious that most 200X strength powdered gel concentrates currently offered are not what they claim to be.

All this suggests that current aloe vera concentrates on the market leave much to be desired, either because of adulteration, mislabeling, or because they contain decomposed aloe gel. Ideally, an aloe vera gel or concentrate should retain all or most of the active



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components present in the fresh gel but is prevented from doing so by usually destructive processing methods. What is needed are non- or less-destructive methods based on better utilization of appropriate biological principles.

Until now no plausible explanation has been offered to address instability problems. As indicated earlier, fresh gel's beneficial qualities (relief of burns, minor skin irritations, cuts) are well known, but seldom if ever are carried forward to processed gels. When fresh viscous gel is allowed to stand or is handled (homogenized or filtered, for example), it soon darkens and turns water thin. If, as commonly believed, the active principle were a polysaccharide, rapid loss of viscosity could be attributable to breaking of hydrogen bonding or to hydrolysis of the sugar linkages. The former can occur under relatively mild conditions, but the latter most likely would involve specific enzymes, as processing conditions normally aren't harsh enough to allow chemical hydrolysis. Although a polysaccharide is the most popular candidate as aloe vera's active component, it may not be the only one. Other enzyme-hydrolyzable components may be responsible. This leads to the following hypothesis: The active principle(s) in the gel are readily hydrolyzed by specific enzymes already present in the plant's central cells, enzymes normally kept apart from the active components by cell structures. Thus no hydrolysis or destructive breakdown occurs in the intact leaf; but if the leaf is bruised, chopped up, or frozen and then thawed, the gel deteriorates over a relatively short time. Such damage breaks up the cell structure, bringing the active components into contact with the destructive enzymes, producing decomposition and yielding a degraded mix of components. In the plant kingdom there are similar examples of a specific enzyme being responsible for setting free or destroying an active component when the two are brought together after cell structures are broken down—garlic (alliinase and alliin), mustard (myrosin and sinigrin),

wintergreen and sweet birch (methyl salicylate), for example.

If the above hypothesis has merit (or even if the breakdown is attributable to outside forces), it is obvious that processing plays a major role in destruction of the active components and that the industrial users would be better served by some process which would prevent destructive interactions from occurring among active components and enzymes. Such a process has been discovered by Agrolabs Inc., (1414 Ave. of the Americas, NY, NY 10019).

This process allows the responsible enzymes and active components to remain separate while water is removed under mild conditions, without chemical or solvent treatment. The result is a completely natural, genuine dehydrated aloe vera gel that is about 200X concentrated (based on an average of 99.5 percent water concentrate in the fresh gel). Appropriately named Natural Sun-Aloe after its sources in the tropics, this is different from other commercially available aloe vera products in that preliminary studies have shown it to possess the well-known qualities of fresh aloe gel when it is reconstituted in water. Thus for the first time a consistent and pure concentrated gel is available to save the trouble and cost of shipping or handling enormous amounts of water, at the same time that loss of activity due to traditional processing or work-up is greatly reduced. Another worry removed is the peril of frosts to the domestic growing regions (in Texas and Florida), since Agrolabs has chosen the Caribbean islands as its source. The plants are grown in rich tropical soil without the need for chemical fertilizers or pesticides, with weeding done either by hand or with the aid of goats and sheep, which have no taste for aloe leaves. The material remains inert until rehydrated, thus making it a candidate for some interesting skin care applications. And it can also serve as a source of concentrated aloe vera gel for the research and production of aloe vera's active components for drug claim substantiation.

A Richmond, Va., federal judge denied A.H. Robins' request to consolidate thousands of punitive-damage claims related to the Dalkon Shield, despite the Judge's concern that repeated punitive awards might force the company into bankruptcy-law proceedings. This ruling continues Robins' facing separate claims for damages attributed to the intrauterine birth-control device, which, since the 1970's, has been blamed for causing in women uterine perforations, pelvic inflammatory disease, sterility, spontaneous abortions and, in some cases, death. Extensive litigation and punitive-damage claims have resulted in financial uncertainty for Robins. Robins lost 32 of the 59 Dalkon shield cases that have gone to trial and 11 juries have awarded a total of \$24.8 million in punitive damages.

were former employees of Revlon's Armour Pharmaceutical Co., Ayerst Laboratories Division of American Home, and some leading wholesalers.

In a move to crack down on illegal trade in discount prescription drugs, Federal authorities charged three small companies and 43 people last month with wire and mail fraud, drug adulteration and misbranding, and other offenses. The arrests and indictment followed the two-year operation of an FBI "sting" op-

eration in Atlanta called Pharmacy Services Co., and included seizure of about \$620,000 of drugs in Georgia, Tennessee, Mississippi, Alabama, Florida, and California. The companies indicted included two drug wholesalers and one pharmacy management firm in Georgia and Mississippi. Among the 43 arrested

Process Validation will be the subject of a seminar co-sponsored by the Food, Drug & Cosmetic and the Biomedical Divisions of the American Society for Quality Control, in cooperation with the FDA, at Stouffer's Crystal City Hotel in Arlington, Va. Oct. 21-22. Keynote speaker will be John Villforth, director of the FDA Center for Devices & Radiological Health. Information can be had by calling Joyce Stecker at Parke-Davis, (201) 540-4308.