



B. TOXICOLOGY



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**APPENDIX B: TOXICOLOGY
OVERVIEW**

The most comprehensive safety overview conducted to date on HCA, is the study by the Burdock group published in Food and Chemical Toxicology in 2004.

The most salient conclusions of this study are:

- i. Dried fruit rind of *Garcinia Cambogia* (containing 10-30%HCA) has been used for centuries throughout Southeast Asia as a food preservative, flavouring agent and carminative
- ii. That a 50% Calcium Salt of HCA has a low acute oral toxicity
- iii. That the average administration of 2500mg/kg/day for a period of 90 days caused a significant decrease in body weight and reduction in feed consumption without any adverse effects
- iv. That the structure, mechanism of action, long history of use of HCA, and other toxicity studies indicate that HCA is unlikely to cause reproductive or developmental effects
- v. In several, placebo-controlled, double blind trials employing up to 2800 mg/day HCA, no treatment-related adverse effects were reported. This level of supplementation is considered to be safe in humans

In 2003, researchers at Creighton University conducted acute oral toxicity, acute dermal toxicity, primary dermal irritation and primary eye irritation in animals using a HCA extract. Results of this study indicated that the LD50 of HCA-SX (a calcium/potassium salt of 60% HCA extract) is greater than 5,000 mg/kg when administered once orally via gastric intubation to fasted male and female Albino rats. No gross toxicological findings were observed under the experimental conditions.

In 2002, the same researchers also conducted a chronic safety study of HCA. The conclusion of this study was that HCA supplementation did not alter hepatic and testicular lipid peroxidation or DNA fragmentation. The study noted that feed intake was significantly reduced in HCA supplemented rats, demonstrating appetite suppression.

Previous toxicity tests have been conducted to verify the absence of possible side effects or acute/chronic toxicity of the HCA isolate. The results showed that the acute LD50 (Lethal dose for 50% of the animals tested) was greater than 2000 mg/kg for intraperitoneal administration and greater than 4000 mg/kg for oral administration. Researchers at Hoffmann LaRoche achieved very similar results using simple citrate and considered the two compounds almost identical in safety. Acute oral toxicity studies performed at Wil Research Laboratories, Ashland, OH, showed that 5000 mg/kg of Citrimax (brand leader in HCA products) resulted in no toxicity or deaths in rats. This is equivalent to 350 grams, or 233 times the recommended dosage of 1.5grams/day consumed by an average size human. The Merck Index lists the LD50 of citrate used intraperitoneally as 975 mg/kg, which would indicate that Hca is actually safer than citrate.

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SAFETY THE RELEVANT POINTS

1. HCA and citrate are very close in terms of their degree of safety, and the latter is now mostly produced synthetically and widely used in commercial food production.
2. Citrate is, of course, the primary acid in oranges, lemons and other citrus fruits
3. Garcinia Cambogia, the main source of naturally- occurring HCA, has a long history of common use as a flavouring, preservative and herbal tonic. A typical daily dose of HCA in humans for the purpose of losing weight is roughly the equivalent to the rind of half a fruit, which is not out of proportion of its common use
4. Reports of toxicity do not appear in the literature regarding the traditional use of the extract, so it is highly unlikely that there is any danger from regular consumption
5. The most likely negative effect from excess intake of the isolate would be bowel intolerance, and this problem would be reversible through a simple reduction in dosage. This problem was not seen in animal or human studies at the levels of intake, which was necessary to reduce appetite.

Despite its inherent safety, there are individuals who should not use HCA, just as they should not use any other diet product. HCA has been shown to influence the body's own production of cholesterol, and therefore it may influence indirectly the production of sterols. The hormones made from sterols include oestrogen, progesterone, testosterone and so forth. For the great majority of Americans, the diet is so rich in fats and calories in general that a lack of building blocks for fat-dependent hormones within the body is simply not an issue. Nevertheless, some instances do require caution.

Pregnancy is a time of extreme sensitivity to steroid hormones, and therefore products, which contain HCA, should not be used during pregnancy. HCA should be avoided during lactation. Similarly, HCA should not be given in large amounts or for extended periods to young children. Although long human experience with fruit sources of HCA does not indicate any danger to these groups, it must be remembered that fruit sources consist almost totally of the less active lactone of HCA.