

Alka-Plex[®] Compound Safety and Use Overview

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Note: Alka-Plex[®] is the active ingredient in all products

Introduction

This is a general safety statement regarding the use of Alka-Plex[®] as a dietary supplement. Many dietary supplements are marketed with little or no scientific studies on their impact with regard to human physiology and with no sound basis for expecting any beneficial result. The active ingredient in our products, Alka-Plex – has undergone extensive testing, has been reviewed by the USDA and approved for various structure/function claims. The World Anti-Doping Agency (WADA) recently completed testing on Acid Zapper and found the sample lot to be free of anabolic androgenic steroids and stimulants. We guarantee that all lots are produced with the highest quality ingredients and production standards. Ed.

Alka-Plex is a mineral based crystalline composition that has localized and systemic alkalizing effects in the body. Cellulose gum and gel binders bond the minerals together to make free flowing granules utilizing a patented damp agglomeration process.

1. All ingredients, in the amounts delivered in **Alka-Plex**, are recognized by law to be generally recognized as safe (GRAS) according to 21CFR 184.1191/1428/1622/1631. GRAS status is reached only after thorough scientific review by the American Academy of Sciences.
2. The Food and Drug Administration (FDA) has reviewed data regarding **Alka-Plex** uniformity and safety. It recognizes **Alka-Plex** as a New Dietary Ingredient (NDI), a regulatory requirement for dietary supplement safety and uniformity that few supplements can achieve.
3. Cyto-toxicity tests of **Alka-Plex** showed no negative reactions with live cell cultures.
4. Stanford Research Institute lab animal tested a single dose of **Alka-Plex** at about 100 times the advertised human dosage and found no negative effects on the animals.
5. An independent researcher interviewed fifteen human subjects after an 18-month trial taking about 1000mg of **Alka-Plex** for each 50 pounds of body weight per day. The researcher found no adverse events during the entire 18 month trial.
6. We monitor serious adverse events (SAE) using FDA drug reporting standards and have never had an SAE report even with thousands of consumers using the product over a period of ten years as a food additive.
7. Product uniformity and composition is reviewed by an independent laboratory with each batch. **Alka-Plex** exceeds FDA's pharmaceutical drug product uniformity requirements.
8. Our previous test had two athletes taking up to eleven 1000mg tablets per day under medical supervision. Blood chemistry data of the athletes was collected and monitored during the tests. All physiological and blood chemistry was within normal limits.
9. **Alka-Plex** has been sold as a food and beverage additive for over 10 years and in 2006 the Acid Zapper product line was launched that focuses on athletes.
10. The United States Anti-Doping Agency's (USADA's) doctor reviewed the ingredient list for **Alka-Plex** and stated that each of them was acceptable for use.
11. The World Anti-Doping Agency (WADA) completed testing on Acid Zapper and found the sample to be free of anabolic androgenic steroids and stimulants.

Alka-Plex is a physical composition, not a chemical composition. It derives much of its characteristics from its structure. Chemists often do not appreciate the difference. This is explained in over simplified terms by contrasting pure carbon (a chemical concept) with graphite, diamond, and buckminsterfullerene i.e. "bucky-balls" (which are structurally different but are all pure carbon). **Alka-Plex** contains GRAS ingredients in amounts that are safe and holds them in a precisely structured, slow-release composition.