



## Safety Statement

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Product Name: ABS Acai Sterols EFA

Code: 10414

INCI Name: Euterpe Oleracea Sterols & Linoleic Acid & Oleic Acid & Linolenic Acid

ABS Acai Sterols EFA is manufactured by first pressing *Euterpe oleracea* seeds for oil. The oil is then fractionated to isolate the sterol rich fraction. Linoleic acid, oleic acid, and linolenic acid are blended with the oil.

The Cosmetic Ingredient Review (CIR) analyzed the safety of phytosterols as used in cosmetics, including *Euterpe oleracea* (acai) sterols. Acai sterols did not contain any detectable levels of allergens. The phytosterol class as a whole tested negative for genotoxicity and were not irritating to scarified skin in a repeat irritation assay. The CIR concluded that all phytosterols tested, including *Euterpe oleracea*, are safe for use in cosmetics.<sup>1</sup>

Linoleic and linolenic acids are both essential fatty acids, meaning the body cannot synthesize the compounds from other sources. Food products containing these acids must be consumed in order for the body to contain them. Due to their natural origin and use in food and nutritional products, they may be classified as Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.<sup>2</sup>

The act states:

Any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.<sup>2</sup>

The CIR reviewed oleic acid, along with several other related fatty acids, and determined it to be safe in present practices in cosmetics. Oleic acid caused no signs of toxicity when fed to chicks at 5%. Topically applied oleic acid caused no toxicity until a use level of 25% was reached, at which point there was some inflammation reported. In carcinogenicity studies, no malignant tumors were induced by repeated injections of oleic acid. In clinical irritation studies, oleic acid was nonirritating. Cosmetic formulations containing 1-13% oleic acid produced no photosensitization.<sup>3</sup>

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ABS Acai Sterols EFA was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models. The full report is attached for reference.

The above information supports the safety of ABS Acai Sterols EFA in cosmetic applications at use levels of 0.5-5.0%. No further testing is required at this time.

1. "Safety Assessment of Phytosterols as Used in Cosmetics". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR651.pdf>
2. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. [www.fda.gov](http://www.fda.gov)
3. "Final Report on the Safety Assessment of Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, and Stearic Acid". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr161.pdf>

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