



# Safety Statement

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Product Name: Active.Lite<sup>®</sup>

Code: 22040

INCI Name: Saccharomyces/Grape Ferment Extract

Active.Lite<sup>®</sup> is manufactured by macerating *Vitis vinifera*, then fermenting it with *Saccharomyces cerevisiae*. The ferment is then extracted in butylene glycol and filtered.

*Saccharomyces cerevisiae* is a yeast of natural origin used by bakers and brewers globally. Section 184.1983 of the Federal Food & Drug Administration (FDA) declares that any *Saccharomyces cerevisiae* extract is Generally Recognized as Safe (GRAS).<sup>1</sup>

Grape (*Vitis vinifera*) is widely used in the food, beverage, and nutritional wellness industries. Therefore it may be classified as 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>

Active Concepts, LLC conducted extensive safety testing on Active.Lite<sup>®</sup>, summarized below:

- Cellular Viability: Active.Lite<sup>®</sup> does not inhibit cellular viability. Therefore, it may be considered nontoxic to cells.
- Acute *Daphnia*: Active.Lite<sup>®</sup> is not harmful to aquatic organisms.
- AMES: Active.Lite<sup>®</sup> is non-mutagenic.
- Ready Biodegradability: Active.Lite<sup>™</sup> is readily biodegradable.
- RIPT: Active.Lite<sup>®</sup> is not an irritant/sensitizer.

Active.Lite<sup>®</sup> was also 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 Active.Lite<sup>®</sup> in cosmetic applications at use levels of 1.0 – 10.0%. No further testing is required at this time.

1. "CFR-Code of Federal Regulations Title 21". Federal Food & Drug Administration. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1983>
2. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. [www.fda.gov](http://www.fda.gov).

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