



# Safety Statement

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Product Name: Phyto-Biotics Quercus

Code: 16588

INCI Name: Quercus Alba Bark Extract

Phyto-Biotics Quercus is manufactured by mechanically grinding/milling *Quercus alba* bark, then inoculating bark cells with *Leuconostoc*. The mixture is then filtered and extracted in water.

*Leuconostoc* is a genus of microorganisms used to produce a variety of food products. Most commonly, it is one of the types of microorganisms used to convert cabbage into sauerkraut. *Leuconostoc* is a type of Lactic Acid Bacteria (LAB) and converts various sugars into lactic acid. Any existing LAB in Phyto-Biotics Quercus is removed by filtration. Since *Leuconostoc* species are intentionally used in food, they may be classified as Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.<sup>1</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>1</sup>

*Quercus alba*, a type of oak, has been used in various topical and oral applications in the past. Tea made from oak bark may be ingested to treat colds, fever, cough, or bronchitis, among other uses. Oak bark has been used in topical compresses to treat inflammation and pain. While there is limited clinical safety data for topical applications of oak bark, it appears to be safe if used according to suggested use levels.<sup>2</sup>

Phyto-Biotics Quercus was tested for its effect on cell viability and metabolism. The assay found that it had a positive effect on viability and metabolism.

Phyto-Biotics Quercus 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 Phyto-Biotics Quercus in cosmetic applications at use levels of 1.0 – 10.0%. No further testing is required at this time.

1. "Federal Food, Drug, and Cosmetic Act." FDA. <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactFDCA/default.htm>
2. "Oak Bark". WebMD. <http://www.webmd.com/vitamins-supplements/ingredientmono-498-OAK%20bark.aspx?activeIngredientId=498&activeIngredientName=OAK%20bark>

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