



# Safety Statement

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Product Name: ABS Orange Polyphenols PBF

Code: 16734

INCI Name: Water & Propylene Glycol & Citrus Aurantium Amara (Bitter Orange) Flower Extract

ABS Orange Polyphenols PBF is manufactured by first processing via mechanical grinding/milling of *Citrus aurantium amara* flowers. The flowers are then extracted in water under controlled conditions before diluting with propylene glycol and filtering.

The Cosmetic Ingredient Review (CIR) conducted a safety assessment of propylene glycol, tripropylene glycol, and PPGs as used in cosmetics. This study determined that propylene glycol is safe for use in cosmetic products at concentrations up to 50%. Propylene glycol was determined to be non-toxic in acute oral toxicity and repeated-dose oral toxicity studies. Undiluted propylene glycol was less than marginally irritating to rabbit eyes, and it was minimally irritating to mice in a dermal irritation study. Oral administration of propylene glycol did not have any adverse effects on mice or rats. Propylene glycol can act as a penetration enhancer for some compounds under certain conditions, which formulators should keep in mind for finished products.<sup>1</sup>

*Citrus aurantium amara* is of natural origin. It is a fruit used commonly in food and nutritional wellness products. Its oil is often used as a flavoring agent, and its juice has a wide variety of culinary applications. Therefore it may be classified as GRAS (Generally Recognized as Safe) 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>

ABS Orange Polyphenols PBF 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 Orange Polyphenols PBF in cosmetic applications at use levels of 1-10%. No further testing is required at this time.

1. "Safety Assessment of Propylene Glycol, Tripropylene Glycol, and PPGs as Used in Cosmetics". Cosmetic Ingredient Review.  
2. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. [www.fda.gov](http://www.fda.gov).