



## Safety Statement

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Product Name: ABS Apple AHA's

Code: 10286

INCI Name: Water & Propylene Glycol & Malic Acid & Pyrus Malus (Apple) Fruit Extract & Glycolic Acid & Lactic Acid & Citric Acid

ABS Apple AHA's is manufactured by first processing *Pyrus malus* fruit via mechanical grinding or milling. The fruit is then extracted in water before blending propylene glycol. Glycolic, lactic, citric and malic acids are added, then the resulting mixture is filtered.

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>

The CIR also conducted a safety assessment of malic acid and sodium malate. The study found that oral consumption of malic acid in a chronic study did not cause any adverse effects, and malic acid did not cause reproductive toxicity in mice, rats, or rabbits. Malic acid is moderately irritating to rabbit skin and is an irritant to guinea pigs. Malic acid can cause ocular irritation in rabbit eyes. It is not mutagenic in plate tests, Ames tests, or a suspension test. Malic acid proved to be not toxic in clinical testing. This data led the CIR to conclude that malic acid is safe for use in cosmetics as a pH adjuster at use levels of roughly 1%.<sup>2</sup> ABS Apple AHA's contains 20.5% malic acid, so even at the highest recommended use level, there would be 1% malic acid in a final product. Malic acid is also included on the FDA's GRAS (Generally Recognized as Safe) list.<sup>3</sup>

*Pyrus malus* is of natural origin. It is used commonly in food and nutritional wellness products. Therefore it may be classified as GRAS according to the FDA's Federal Food, Drug and Cosmetic Act.<sup>4</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

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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>4</sup>

Glycolic acid and lactic acid were reviewed by the CIR as part of a report focusing on the safety of alpha hydroxyl acids (AHAs). Acute toxicity studies demonstrated that these acids are of a low order of toxicity when applied either dermally or orally. No significant toxicity was seen in subchronic oral studies after lactic acid was orally administered to animals. Chronic oral studies using glycolic acid showed some adverse effects in male rats, but none were lethal. Dermal irritation testing of products with 15-50% glycolic acid in rabbits concluded that the products were nonirritating. Dermal exposure to undiluted 60% aqueous lactic acid resulted in negligible irritation. RIPTs and maximization tests using AHAs were negative, and they were not considered photosensitizers or phototoxins. Both lactic and glycolic acids were nonmutagenic in Ames testing. These tests, among others included in the report, supported the CIR's conclusion that both lactic and glycolic acids are safe as used in cosmetics at a use level of less than or equal to 10%.<sup>5</sup> Lactic acid is also listed on the FDA's GRAS database.<sup>3</sup>

Citric acid is included on the FDA's GRAS list, and the CIR published a safety assessment of it as used in cosmetics.<sup>3</sup> The CIR report concluded that citric acid is safe as presently used in cosmetics. This conclusion was supported by test data, including oral and inhalation toxicity tests which showed that citric acid did not indicate any notable toxic effects in animals. Citric acid had negative results for in vitro and in vivo genotoxicity tests. Thirty percent citric acid was not a primary irritant in rabbit irritation studies, while undiluted citric acid is irritating. It was minimally irritating to rabbit eyes at a 10% concentration.<sup>6</sup>

ABS Apple AHA's 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.

A cellular viability assay was conducted for ABS Apple AHAs, and found that it is capable of increasing cell metabolism and viability.

The above information supports the safety of ABS Apple AHA's in cosmetic applications at use levels of 1-5%. 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.

<http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR560.PDF>

2. "Final Report on the Safety Assessment of Malic Acid and Sodium Malate". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr330.pdf>

3. "Alphabetical List of SCOGS Substances". U.S. Food and Drug Administration. <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm084104.htm>

4. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. [www.fda.gov](http://www.fda.gov).

5. "Final Report on the Safety Assessment of Glycolic Acid, Ammonium, Calcium, Potassium, and Sodium Glycolates, Methyl, Ethyl, Propyl, and Butyl Glycolates, and Lactic Acid, Ammonium, Calcium, Potassium, Sodium, And TEA-Lactates, Methyl, Ethyl, Isopropyl, and Butyl Lactates, and Lauryl, Myristyl, and Cetyl Lactates". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr34.pdf>

6. "On the Safety Assessment of Citric Acid, Inorganic Citrate Salts, and Alkyl Citrate Esters as Used in Cosmetics". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR590.pdf>

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