



Safety Statement

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Product Name: AC Moisture-Plex Advanced PF

Code: 16503PF

INCI Name: Glycerin & Water & Sodium PCA & Urea & Trehalose & Polyquaternium-51 & Sodium Hyaluronate

AC Moisture-Plex Advanced PF is manufactured by first dispersing sodium PCA, urea, trehalose, polyquaternium-51, and sodium hyaluronate in a combination of water and glycerin. After dispersing for a specific duration, the mixture is filtered.

The glycerin used to manufacture AC Moisture-Plex Advanced PF is derived from coconuts (*Cocos nucifera*) and is commonly used as an ingredient in food products. Glycerin is therefore considered a Generally Recognized As Safe (GRAS) ingredient according to the FDA's Federal Food, Drug and Cosmetic Act.¹ 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.¹

The Cosmetic Ingredient Review (CIR) conducted a safety assessment for PCA and sodium PCA. It concluded that sodium PCA is not a dermal or ocular irritant, nor is it a skin sensitizing agent. No evidence of phototoxicity was observed, and the compound was proven to be non-comedogenic. Sodium PCA was not mutagenic when tested in a *Salmonella* mutagenicity assay, with and without metabolic activation. These test results, among others in the report, led the CIR to conclude that sodium PCA is safe as presently used in cosmetic formulations.²

Urea is classified as a GRAS substance according to the FDA.³ The CIR's safety assessment of urea proved that urea is not carcinogenic. There are also very few occurrences of skin sensitization among the many clinical studies that use urea in the treatment of diseased skin. Acute, short-term and chronic animal toxicity studies demonstrate little evidence of adverse effects of urea, and reproductive and developmental toxicity studies in animals raised no concerns. Urea can increase the percutaneous absorption of other chemicals, which should be noted by cosmetic formulators. Based on the available data, the CIR concluded that urea is safe as used in cosmetic products.⁴

The CIR published a safety assessment of monosaccharides, disaccharides, and related ingredients as used in cosmetics in 2014. This includes trehalose, a disaccharide, among 24 other compounds. Trehalose was specifically tested for genotoxicity, for which it was negative. The report concluded that the 25 compounds tested were safe in cosmetics as they're presently being used.⁵

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Manufacturers of polyquaternium-51 solutions report that the product is not irritating to the skin or eye, and it is not a skin sensitizer. The substance is not listed on any carcinogenic compound databases, and its LD₅₀ value is >2,000 mg/kg.⁶ While an official safety assessment has not been conducted on polyquaternium-51, there is no data available that suggests it is harmful at its typical use levels in cosmetic products.

The CIR's safety assessment of sodium hyaluronate concluded that it is safe for use in cosmetics. This conclusion was based on studies proving that sodium hyaluronate is not a concern for dermal or ocular irritation, UV absorption, photosensitization, or photoirritation. While adverse reactions to injections of hyaluronic acid and its related compounds have been reported in other industries, there are no reported reactions to topically applied hyaluronic acid. Finally, the source of the sodium hyaluronate may be a concern to some, as rooster combs are a traditional source of this compound. Sourcing sodium hyaluronate from rooster combs was thought to be risky due to the risk of exposure to avian flu. However, the heat from the manufacturing process consistently kills the avian flu virus, therefore negating any concern.⁷ The sodium hyaluronate in AC Moisture-Plex Advanced PF is from a biotechnology/fermentation source, so there are no animal ingredients involved in its manufacture.

AC Moisture-Plex Advanced PF 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 AC Moisture-Plex Advanced PF in cosmetic applications at use levels of 1-10%. No further testing is required at this time.

1. "Federal Food, Drug and Cosmetic Act (FD&C Act)". US Food & Drug Administration. <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>
2. "Final Safety Assessment for PCA and Sodium PCA". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr47.pdf>
3. "Alphabetical List of SCOGS Substances". US Food & Drug Administration. <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm084104.htm>
4. "Final Report of the Safety Assessment of Urea". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr310.pdf>
5. "Safety Assessment of Monosaccharides, Disaccharides, and Related Ingredients as Used in Cosmetics". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR657.pdf>
6. "Safety Data Sheet-Lipidure PMB". Presperse. http://www.presperse.com/assets/documents/msds/Lipidure-PMB_MSDS.pdf
7. "Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr450.PDF>

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