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Safety Statement

Product Name: AC Sebum Control Enzyme PF

Code: 20395PF

INCI Name: Butylene Glycol & Water & Spiraea Ulmaria Extract

AC Sebum Control Enzyme PF is manufactured by processing (grinding/milling) *Spiraea ulmaria*, which is then extracted in water. The extract is blended with butylene glycol before filtration.

Butylene glycol is a synthetic compound commonly used as a solvent. In 1985, the Journal of the American College of Toxicology published a report entitled "Final Report on the Safety Assessment of Butylene Glycol, Hexylene Glycol, Ethoxydiglycol, and Dipropylene Glycol".¹

This report concluded that butylene glycol is safe for topical use in cosmetic products. This claim was substantiated by the results of several toxicity and irritation tests. Butylene glycol tested at 100% caused minimal to mild irritation of skin and eyes in test animals. Human skin patch tests on undiluted butylene glycol produced a very low order of primary skin irritation. An RIPT (Repeated Insult Patch Test) produced no evidence of skin sensitization.¹

Spiraea ulmaria, more commonly known as meadowsweet, is of natural origin. It is also used in some food and beverage preparations. It is specifically used to flavor herbal beers or produce herbal teas.² Therefore it may be classified as Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.³

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.³

AC Sebum Control Enzyme 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 Sebum Control Enzyme PF in cosmetic applications at use levels of 2.0 – 5.0%. No further testing is required at this time.

1. "Final Reports on the Safety Assessment of Butylene Glycol, Hexylene Glycol, Ethoxydiglycol, and Dipropylene Glycol". Journal of the American College of Toxicology. Volume 4, Number 5. 1985.
2. "Meadowsweet". Botanical.com. <http://www.botanical.com/botanical/mgmh/m/meadow28.html>
3. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.

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