Vitamin C-- Ascorbyl stearate

Ascorbyl stearate ($C_{24}H_{42}O_7$) is an ester formed from ascorbic acid and stearic acid. In addition to its use as a source of vitamin C, it is used as an antioxidant food additive in margarine. The USDA limits its use to 0.02% individually or in conjunction with other antioxidants.

Evaluation

Level causing no toxicological effect

2500 ppm (0.25%) in the diet equivalent to 125 mg/kg body weight

Estimate of acceptable daily intake for man

0-1.25 mg/kg bodyweight

Ascorbyl Palmitate, Ascorbyl Dipalmitate, Ascorbyl Stearate, Erythorbic Acid, and Sodium Erythorbate are related ingredients that function as antioxidants in cosmetic formulations. Ascorbyl Palmitate, Ascorbyl Dipalmitate, and Ascorbyl Stearate are esters and di-esters of ascorbic acid with long-chain fatty acids.

Erythorbic Acid is a stereoisomer of ascorbic acid and Sodium Erythorbate is the sodium salt of Erythorbic Acid. Although all of these ingredients are used, uses of Ascorbyl Palmitate and Erythorbic Acid predominate, with combined uses in over a thousand cosmetic formulations at low concentrations.

Ascorbyl Palmitate is used at concentrations between 0.01 and 0.2%, and Erythorbic Acid is used at concentrations of 0.5-1%. Ascorbyl Palmitate has vitamin C activity approximately equal to that of L-ascorbic acid, whereas Erythorbic Acid has only 5% activity. The esters are likely to penetrate the skin readily, but the acid and its salt are not likely to penetrate.

These ingredients exhibit low acute oral toxicity in animals. In chronic feeding studies, decreased body weight gain, the formation of oxalate stones in the bladder, and hyperplasia were seen in rats fed high levels of Ascorbyl Palmitate.

Ascorbyl Palmitate (10%) and Ascorbyl Dipalmitate (100%) were not irritating to the intact skin of albino rabbits.

Ascorbic Acid (30%) itself caused barely perceptible erythema and Sodium Erythorbate powder caused no irritation to the intact and abraded skin of rabbits.

In animal studies, Ascorbic acid was not a sensitizer, and Erythorbic Acid (10%) applied topically to porcine skin reduced ultraviolet B (UVB)-induced phototoxicity. In clinical studies, Ascorbyl Palmitate caused no dermal irritation or sensitization.

These ingredients are minimally irritating to the eye. Sodium Erythorbate did not cause fetal or maternal toxicity or developmental toxicity in rats and mice fed high levels. Although these ingredients were generally negative in a wide range of genotoxicity tests, Erythorbic Acid and Sodium Erythorbate did produce isolated positive genotoxicity test results.

As antioxidants, these ingredients have been studied in animals after initiation with various carcinogens. In some cases reductions in tumor incidence were seen, in others no effect was noted. In no case did treatment with these ingredients increase tumor incidence.

The highest use concentrations of Erythorbic Acid and Sodium Erythorbate are in oxidative hair dyes, where they are completely consumed in the chemical reaction that takes place at mixing. The fatty acid esters of ascorbic acid are used at lower concentrations in leave-on formulations.

In consideration of these uses and based on the available safety test data, Ascorbyl Palmitate, Ascorbyl Dipalmitate, Ascorbyl Stearate, Erythorbic Acid, and Sodium Erythorbate are safe for use as cosmetic ingredients in the present practices of use.