



## Safety Statement

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Product Name: ProCutiGen® Thermal Shield  
Code: 20828  
INCI Name: Hydrolyzed Keratin

ProCutiGen® Thermal Shield is manufactured by enzymatic hydrolysis of keratin. The hydrolyzed keratin is then filtered.

The Cosmetic Ingredient Review (CIR) conducted a safety assessment of plant- and animal-derived amino acids as used in cosmetics. Since the keratin in ProCutiGen® Thermal Shield is hydrolyzed, its composition is comprised of amino acids, so this safety assessment is applicable to the product in question.

The conclusion of the safety assessment was that all of the amino acids tested, including keratin amino acids, are safe as currently used in cosmetics. This conclusion was based on irritation, sensitization, toxicology, and phototoxicity studies.<sup>1</sup>

ProCutiGen® Thermal Shield was tested using *in vitro* dermal and ocular irritation models, including phototoxicity irritation (EpiDerm™ EPI-200-SIT). This product was found to be non-irritating in all models, including non-phototoxic for the *in vitro* dermal model. The full reports are attached for reference.

A *Salmonella typhimurium* reverse mutation standard plate incorporation study was conducted to evaluate whether ProCutiGen® Thermal Shield would cause mutagenic changes in the average number of revertants for histidine-dependent *Salmonella typhimurium* strains in the presence and absence of S9 metabolic activation. This study was conducted to satisfy, in part, the Genotoxicity requirement of the International Organization for Standardization: Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity. ProCutiGen® Thermal Shield was considered to be nonmutagenic to the *Salmonella typhimurium* tester strains under the conditions of this assay.

ProCutiGen® Thermal Shield Complete was also tested via the OECD TG 442C Direct Peptide Reactivity and OECD TG 442D In Vitro Skin Sensitization Assays in accordance with the EURL ECVAM and UN GHS guidelines. This product was determined to be a non-skin sensitizer in both *in chemico* and *in vitro* models.

An OECD 202 *Daphnia* spp. Acute Immobilization Test was conducted to determine the toxicity of ProCutiGen® Thermal Shield by exposing *Daphnia* spp. to the test substance for 48 hours and measuring the immobilization rate against the control. Under the conditions of this assay according to the EU Directive 93/67/EEC, ProCutiGen® Thermal Shield is not classified and therefore not harmful to aquatic organisms.

Furthermore, ProCutiGen® Thermal Shield was assessed for ready biodegradability in an aerobic aqueous medium via the OECD 301 B Ready Biodegradability: CO<sub>2</sub> Evolution (Modified Sturm Test). ProCutiGen® Thermal Shield achieved 91.0% biodegradation after 28 days of testing, indicating that the product meets method requirements for the Ready Biodegradable classifications.

The full reports for each safety study analyzing ProCutiGen® Thermal Shield are attached for reference.

The above knowledge combined with the CIR assessment supports the safety of ProCutiGen® Thermal Shield in cosmetic applications at use levels of 1.0 – 10.0%. No further testing is required at this time.

1. "Safety Assessment of Animal- and Plant-Derived Amino Acids as Used in Cosmetics". Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR625.pdf>