



Safety Statement

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Product Name: ProCutiGen® Vegan Thermal Shield

Code: 20830

INCI Name: Saccharomyces Cerevisiae Extract

ProCutiGen® Vegan Thermal Shield is manufactured by growing *Saccharomyces cerevisiae* cells in nutrient-rich media. The *Saccharomyces* cells are then crushed using high pressure homogenization followed by filtration.

Saccharomyces cerevisiae is a yeast of natural origin used by bakers and brewers globally. Section 184.1983 of the Federal Food & Drug Administration (FDA) affirms that any *Saccharomyces cerevisiae* extract is Generally Recognized as Safe (GRAS).¹ *Saccharomyces Cerevisiae* Extract is commonly used as a flavoring agent in food, reiterating the GRAS status of the material.

The GRAS 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.²

ProCutiGen® Vegan 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® Vegan 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® Vegan Thermal Shield was considered to be nonmutagenic to the *Salmonella typhimurium* tester strains under the conditions of this assay.

ProCutiGen® Vegan 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® Vegan 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® Vegan Thermal Shield is not classified and therefore not harmful to aquatic organisms.

Furthermore, ProCutiGen® Vegan Thermal Shield was assessed for ready biodegradability in an aerobic aqueous medium via the OECD 301 B Ready Biodegradability: CO2 Evolution (Modified Sturm Test). ProCutiGen® Vegan Thermal Shield achieved 89.5% 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® Vegan Thermal Shield are attached for reference.

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

1. "CFR-Code of Federal Regulations Title 21". Federal Food & Drug Administration.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1983>
2. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.

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