

# ProCutiGen® Thermal Shield Certificate of Compliance

**Code:** 20828  
**INCI Name:** Hydrolyzed Keratin  
**INCI Status:** Conforms  
**CAS #:** 69430-36-0  
**EINECS #:** 274-001-1  
**China NMPA #:** N/A

**Below is a list of processing aids used, but not declared on the ingredient label:**

INCI Name	CAS#	EINECS#	Percentage (%)	Function
Leuconostoc/Radish Root Ferment Filtrate	1686112-10-6 (or) 9015-54-7	N/A (or) 295-635-5	2.00%	Natural Antimicrobial

The following information on regulatory clearances is believed to be accurate and is given in good faith as a guide to a global use of our ingredients in cosmetic applications. No representation or warranty as to its competences or accuracy is made. Information is offered for use in general cosmetic applications and may vary in particular applications. Users are responsible for determining the suitability of these products for their own particular use. All regulatory decisions should be made on the advice of your regulatory group or legal counsel.

Country / Regulatory Body	Status of Product
EU (CosIng)	Compliant
USA (TSCA)	Compliant
Australia (AICS)	Compliant
Japan (METI)	Complaint
Canada (DSL)	Compliant
China (IECIC)	Compliant
Brazil (ANVISA)	Compliant
Korea (KECI)	Compliant
Philippines (PICCS)	Compliant
Mexico (COFEPRIS)	Compliant

## ProCutiGen® Thermal Shield Code: 20828

Attention must be paid to the use of ProCutiGen® Thermal Shield in the equivalent of OTC formulations (eg. quasi-drugs in Japan, or therapeutic goods in Australia). Some countries maintain restricted inventories of raw materials that can be used in those applications so more detailed guidance may be required.

ProCutiGen® Thermal Shield and its components and impurities are in compliance with the rules governing cosmetic products in the European Union (Directive 76/768/ECC & Regulation No. 1223/2009). The recommended use levels for ProCutiGen® Thermal Shield is 1.00 – 10.00%.

ProCutiGen® Thermal Shield is in compliance with the standardized set of rules developed and approved by the NPA (Natural Products Association).

The Nagoya Protocol provides a scheme for the fair and equitable sharing of benefits derived from Genetic Resources. Information regarding the Nagoya Protocol and Access and Benefit Sharing (ABS) is available at <https://www.cbd.int/abs/>. The agreement focusses on wild taxa and excludes most commercially cultivated crops. For the signatories to the agreement, responsibility for Benefit Sharing falls on the entity exporting or extracting the resource from the signatory country. Active Concepts audits its suppliers to conform compliance with the Nagoya Protocol where applicable.

ProCutiGen® Thermal Shield is considered a non-hazardous material. All significant toxicological routes of absorption have been considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL). Due to the restriction placed on animal testing of cosmetic raw materials, and Active Concepts, LLC's internal non-animal testing policy, this product was not tested for NOAEL.

ProCutiGen® Thermal Shield was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models.

To our knowledge the above material is free of CMR (\*) substances, as defined according to Regulation (EC) No 1272/2008 and Cosmetic Regulation (EC) No 1223/2009 as amended. Products supported for Personal Care applications will not be classified as CMR (\*), as defined by (EC) 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures, unless supported by a positive SCCS opinion.

(\*) Carcinogenic, Mutagenic, toxic for Reproduction

Active Concepts, LLC certifies that to the best of our knowledge our product does not contain any material listed on California Proposition 65.

Active Concepts, LLC certifies that ProCutiGen® Thermal Shield does not contain any materials prohibited by Halal laws.

As of November 4, 2022, ProCutiGen® Thermal Shield does not contain any substances present on the so called "candidate list" provided by the European Chemicals Agency (ECHA). We further certify that this material has not been manufactured using any of the species listed in the CITES Appendices as of November 4, 2022.

ProCutiGen® Thermal Shield is REACH Compliant and free of the following:

- Butylphenyl methylpropional (Lilial)
- Formaldehyde or formaldehyde donors
- Glycol ethers
- Gluten
- Lactose
- Nanoparticles
- Nitrosamines
- Palm oil/palm kernel oil (or derivatives)
- Parabens
- Paraffin/petroleum products
- Phthalates
- Polyethylene glycol (PEG)
- Residual solvents
- Sulfates
- Volatile organic compounds