matrihealth

Product Specifications

matripure®

Cosmetics-grade soluble elastin

INCI: HYDROLYZED ELASTIN

1. Identity

Parameter	Specification	Method
Protein fraction[1)]	≥ 90 %	SEC
Desmosine[1)]	≥ 0.5 w%	Amino acid analysis
Isodesmosine[1)]	≥ 0.5 w%	Amino acid analysis
Elastin content in protein fraction[1)]	≥ 90 %	HPLC-MS/MS, Spectral counting

2. Physical and Chemical Properties

Parameter	Specification	Method
Appearance	Powder	Organoleptic
Color	Yellow to orange	Organoleptic
Odor	Odorless	Organoleptic
Water content	≤ 10 w%	LOD: 10 g, 100 °C, 5 h
Active water (a_w)[1)]	< 0.6	PV-AC-135, Sensor measurement at 20 °C
Conductivity	< 1 mS/cm	Conductivity electrode: 20 °C, 1 w% solution
Mean molecular weight (M_w)[1)]	10-30 kDa	SEC
pH	6-8	pH electrode: 20 °C, 1 w% solution
Clarity of solution	FIO[2)], LOT-specific	OD_{600}: 20 °C, 1 w% solution

3. Microbiological Purity

Parameter	Specification	Method
Total Aerobic Mesophilic Microorganisms (bacteria + yeast + molds)	≤ 100 CFU/g	Calculated according to ISO 17516:2014-10
Total Aerobic Mesophilic Bacteria	≤ 100 CFU/g	ISO 21149:2022-08
Yeast and Mold	≤ 100 CFU/g	ISO 16212:2022-08
Pseudomonas aeruginosa	Absence	ISO 18415:2022-08
Staphylococcus aureus	Absence	ISO 18415:2022-08
Escherichia coli	Absence	ISO 18415:2022-08
Candida albicans	Absence	ISO 18415:2022-08
Aspergillus niger	Absence	ISO 18415:2022-08
Salmonella	Absence	BAV-IM-5.4-09-01:2020-05 validated against ISO 6579

4. Heavy Metals

Parameter	Specification	Method
Arsenic	≤ 1 mg/kg (ppm)	PV-SA-337, ICP-MS
Antimony	≤ 1 mg/kg (ppm)	PV-SA-337, ICP-MS
Cadmium	≤ 1 mg/kg (ppm)	PV-SA-337, ICP-MS
Lead	≤ 1 mg/kg (ppm)	PV-SA-337, ICP-MS
Mercury	≤ 1 mg/kg (ppm)	PV-SA-337, ICP-MS

1) This parameter is monitored through periodic validation and is not part of routine batch release testing.

2) For information only. Parameter measured per batch but not part of specification.

Regulatory Information Sheet
matripure®

Allergens EU Regulation 1169/2011 Consumer Protection Act of 2004 Latex	*matripure*® is not derived from or does contain any of the products and substances listed in EU Regulation 1169/2011 ANNEX II. This product is not derived from the following materials identified in the Food Allergen Labeling and Consumer Protection Act of 2004 as major food allergens: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybeans. *matripure*® is not derived from or does contain latex.
Animal derived ingredients **BSE/TSE**	*matripure*® contains animal-derived ingredients, as it is produced from porcine sources. In relation to EU Regulation 999/2001 and U.S. regulations 21 CFR 189.5 and 21 CFR 700.27, *matripure*® is not associated with Transmissible Spongiform Encephalopathies (TSE) or Bovine Spongiform Encephalopathy (BSE), as these are only known to originate from bovine products.
Animal Testing EU Regulation 1223/2009	*matripure*® complies with Chapter V, Article 18 'Animal testing' of EU Regulation 1223/2009.
California Proposition 65	*matripure*® is not specifically analysed for the presence of the substances listed in Proposition 65. Based on our knowledge of the raw materials and manufacturing process, we have no reason to expect that this product would contain substances at levels which would require warning as required by Proposition 65.
Contaminants	*matripure*® is analysed on microbiological contaminants and heavy metals by an independent accredited laboratory (DIN EN ISO/IEC 17025/2018). More detailed information is to find in the certificate of analysis (CoA).
Country of origin	*matripure*® is produced in Germany. The animal-derived ingredients were also obtained from a German supplier.
Ethylene oxide	*matripure*® is not produced with ethylene oxide, nor is it treated with ethylene oxide during transport and storage.
Forbidden substances	*matripure*® is not produced with or does contain any toxic, narcotic, psychotropic or other forbidden substances.
GMO EU Directive 2001/18 and EU Regulations 1829/2003 and 1830/2003	For *matripure*® no source materials containing Genetically Modified Organisms are used and the product is neither derived from Genetically Modified Organisms, nor does it contain Genetically Modified Organisms based on the current knowledge.

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Good manufacturing practice DIN EN ISO 22716	*matripure*® is produced according to the Good Manufacturing Practices (GMP) standards of DIN EN ISO 22716.
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Irradiation	*matripure*® was not treated with irradiation during or after manufacturing.
Metal catalysts	*matripure*® is produced without the use of metal catalysts or metal reagents.
Natural Cosmetics ISO 16128 Cosmos Natrue	*matripure*® is considered 'ingredient of natural origin' according to ISO 16128. *matripure*® is currently not Natrue or Cosmos certified.
Others Phthalates Fructose	*matripure*® is not derived from or does contain phthalates or fructose.
Palm oil	*matripure*® is not derived from or does contain any palm oil.
Raw materials and production	*matripure*® is produced from porcine-derived elastin via hydrolysis.
REACH	To our knowledge *matripure*® does not contain any substance of very high concern (SVHC) with concentrations exceeding 0.1 mass percentage according to the REACH regulation, Article 7(2) and Article 33, respectively and does not contain any substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A, 1B or 2, under Part 3 of Annex VI to EU Regulation 1272/2008.
Residual solvents	During the production of *matripure*® no organic solvents are used.
Viral safety	*matripure*® is unlikely to carry any risk of viral contamination. The porcine-derived raw material is classified as 'Category III' according to EU Regulations 1069/2009.