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Matrixyl® 3000



English

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Product Information File

MATRIXYL® 3000

(Item code: SE26770)

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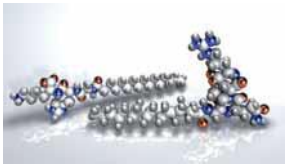
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1. PRODUCT INFORMATION

Description

MATRIXYL® 3000 supports the activation of the cutaneous repair process, and in particular at the level of the fragile and UV-damage prone papillary dermis. **MATRIXYL® 3000** promotes wrinkle smoothing and improves tone and elasticity.



MATRIXYL® 3000 is an association of 2 palmitoylated matrikines: Pal-Gly-His-Lys and Pal-Gly-Gln-Pro-Arg.

INCI Name

Glycerin (and) Water (Aqua) (and) Butylene Glycol (and) Carbomer (and) Polysorbate 20 (and) Palmitoyl Tripeptide-1(1) (and) Palmitoyl Tetrapeptide-7.

(1): Previous INCI Name Palmitoyl Oligopeptide which has been revised in Palmitoyl Tripeptide-1 in September 2013.

Proven cosmetic activity

In vitro

Study on senescence markers

Study of *de novo* matrix synthesis by human fibroblasts

Gene activation study (DNA Array method)

In vivo

Tests on female panelists

Tests on male panelists

Tests on female panelists (High resolution ultrasound and confocal laser microscopy)

Ex vivo

Study on skin explants

Formulation guidelines

Appearance: whitish opalescent gel

Solubility: water soluble

Recommended use level: 3%

Storage

Conditions: Long term storage recommended at 4-7°C.

Re-evaluation date: 24 months from the date of manufacturing, if the storage conditions are respected.

Specifications

See selling specifications or contact your local sales representative.

Patents and publications

WO 2005/048968; WO 2012/164488; FR 2 975 904; EP 1 686 957; US 6,974,799; JP 4256389; CN 1893911; KR 20060122844.

For further information, please contact your local sales representative or refer to our technical dossier available upon request.

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2. MANUFACTURER / SUPPLIER INFORMATION

Supplier and/or Manufacturer

SEDERMA SAS

29 rue du Chemin Vert

78612 Le Perray en Yvelines cedex

France

Certifications

SEDERMA is certified ISO 14001:2004, ISO 9001:2008, OHSAS 18001-2007 and EFfCI GMP.

Good Manufacturing Practices

SEDERMA realizes their activities according to Good Manufacturing Practices for Cosmetic Ingredients and makes sure they are correctly implemented thanks to external audits.

Sustainability

According to its policy, SEDERMA is in favor of sustainable development based on the following objectives:

- decrease of energy and water consumption,
- respect of protected species (according to Washington's convention),
- promotion of recycling of waste,
- use of cell plant culture to minimize the impact on the environment,
- use of renewable and sustainable raw materials whenever possible.

SEDERMA's ambition is to raise awareness about social and environmental responsibility of every actor along the value chain and to favor shared commitments to progress. In particular:

- to pursue traceability of raw materials, their processing, and of all those involved in these domains,
- to encourage sustainable partnerships between all those involved in the supply chain.

SEDERMA, as part of CRODA International Plc, is a member of the RSPO: Roundtable on Sustainable Palm Oil (**www.rspo.org/en/member/82/croda-international-plc**).

Moreover, SEDERMA respects the Corporate Social Responsibility (C.S.R.) policy developed by CRODA and has also signed the "Cosmetic Valley Charter for Sustainability" (please visit our website **www.sederma.fr**).

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3. COMPOSITION AND MANUFACTURING PROCESS

Composition

INCI Name (PcPc)	CAS Nr	%	Origin*	Function
Glycerin	56-81-5	qsp 100	V	Solvent
Water	7732-18-5	≈ 25		Solvent
Butylene Glycol	107-88-0	≈ 20	S	Solvent
Carbomer	9003-01-4	≈ 1	S	Viscosity increasing agent
Polysorbate 20	9005-64-5	≈ 0.5	S,V	Surfactant
Palmitoyl Tripeptide-1[(1)]	147732-56-7	≈ 0.01	S	Skin conditioning agent
Palmitoyl Tetrapeptide-7	221227-05-0	≈ 0.005	S	Skin conditioning agent
Manufacturing additive: Sodium Lactate	72-17-3	max 1	B	pH buffer
Preservative: /				

* V: vegetable, S: synthetic, B: biotechnology, Mi: mineral

(1): Previous INCI Name Palmitoyl Oligopeptide which has been revised in Palmitoyl Tripeptide-1 in September 2013.

Country of origin

France

Simplified manufacturing process

MATRIXYL® 3000 is a mixture of Glycerin, Water, Butylene Glycol, Carbomer, Polysorbate 20, Palmitoyl Tripeptide-1 and Palmitoyl Tetrapeptide-7.

Palmitoyl Tripeptide-1 (Pal GHK) and Palmitoyl Tetrapeptide-7 (Pal GQPR) are obtained by chemical synthesis: for each peptide, coupling of aminoacids followed by a last coupling with palmitic acid.

The both peptides are solubilized in a jellified excipient.

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4. REGULATORY INFORMATION

Note: This information is based on the knowledge of our raw materials and of the manufacturing process of the product. It is not part of the product's specifications and thus is likely to change.

Chemical Inventory Status / REACH

		Chemical Inventory							REACH		
INCI Name (PcPc)	**CAS Nr**	**Europe** EINECS Nr	**US** TSCA	**Canada** DSL/NDSL /ICL	**China** IECSC	**Korea** KECI/K-REACH	**Japan** ENCS /ISHL	**Australia** AICS	**Exemption if any**	**Pre-registered**	**Registered**
Glycerin	56-81-5	200-289-5	X	DSL	X	X	X	X	Annex V.9		
Water	7732-18-5	231-791-2	X	DSL	X	X	X	X	Annex IV		
Butylene Glycol	107-88-0	203-529-7	X	DSL	X	X	X	X		Yes	01-2119455875-25
Carbomer	9003-01-4	n/a	X	DSL	X	X	X	X	Polymer		
Polysorbate 20	9005-64-5	n/a	X	DSL	X	X	X	X	Polymer		
Palmitoyl Tripeptide-1	147732-56-7	n/a	X	ICL	-	-	-	X	<1t/year		
Palmitoyl Tetrapeptide-7	221227-05-0	n/a	X	ICL	-	-	-	-	<1t/year		
Sodium Lactate	72-17-3	200-772-0	X	DSL	X	X	X	X	Annex V.4		

X: listed or exempt

-: unknown

Cosmetic use covered according to the Cosmetics Europe (formerly COLIPA) use mapping.

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Cosmetic Status

- Europe: MATRIXYL® 3000 complies with the Regulation (EC) No 1223/2009 of the European Parliament and of the Council.
- United States of America: MATRIXYL® 3000 complies with the Code of Federal Regulation (CFR) title 21.
- Canada: MATRIXYL® 3000 complies with the Cosmetic Regulation C.R.C., c 869.
- MERCOSUR (Argentina, Brazil, Paraguay, Uruguay and Venezuela): MATRIXYL® 3000 complies with cosmetic regulation in force.
- CAN (Bolivia, Colombia, Ecuador and Peru): MATRIXYL® 3000 complies with cosmetic regulation in force.
- ASEAN (Indonesia, Malaysia, the Philippines, Singapore, Thailand, Brunei, Burma (Myanmar), Cambodia, Laos and Vietnam): MATRIXYL® 3000 complies with the ASEAN Cosmetic Directive.
- South Korea: MATRIXYL® 3000 complies with the Korean Cosmetic Products Act (KCPA).
- Japan: MATRIXYL® 3000 complies with the Standards for Cosmetics.
- China: MATRIXYL® 3000 complies with the Hygienic Standard 2007. All the ingredients of MATRIXYL® 3000 are listed IECIC 2014.

Biodiversity

RSPO: MATRIXYL® 3000 contains ingredients which may be obtained from palm or palm kernel.

We confirm that our suppliers are members of recognized voluntary schemes in favour of sustainability (RSPO, ISCC…).

CITES: MATRIXYL® 3000 does not contain ingredient obtained from endangered species listed on Annexes I, II and III of the Convention on International Trade in Endangered Species of wild fauna and flora (CITES).

IUCN: The plant raw materials used are not derived from threatened species according to the International Union or Conservation of Nature (IUCN) red list.

Nanomaterial

MATRIXYL® 3000 is not a nanomaterial and does not contain nanomaterial, according to the Cosmetic Regulation (EC) No 1223/2009 definition of a nanomaterial:

'Nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

GMO

MATRIXYL® 3000 does not contain and is not produced from genetically modified organisms (GMO).

BSE / TSE

None of the ingredients used for the production of MATRIXYL® 3000 are of bovine, ovine, equine or porcine origin. Therefore, Bovine Spongiform Encephalopathy (BSE) / Transmitting Spongiform Encephalopathy (TSE) risk, as defined in the European Commission Decision 97/534/EC and EMEA/410/10, does not concern this product.

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5. IMPURITIES AND OTHER RESIDUES

Note: This information is based on the knowledge of our raw materials and of the manufacturing process of the product. Analyses are not part of the product's specifications and are thus not performed in routine.

Allergens

According to its composition and its manufacturing process, MATRIXYL® 3000 does not contain any of the 26 allergenic substances as defined in the Annex III of the Cosmetics Regulation (EC) No 1223/2009 (analysis not performed).

Pesticides

According to its composition and its manufacturing process, MATRIXYL® 3000 does not contain any pesticides (analysis not performed).

Heavy metals

Elements		**Results (mg/kg)** ICP-MS
Arsenic	(As)	<0.20 (1)
Cadmium	(Cd)	<0.10 (1)
Lead	(Pb)	<0.10 (1)
Mercury	(Hg)	<0.10 (1)
Chromium	(Cr)	<0.20 (1)
Antimony	(Sb)	<0.50 (1)
Molybdenum	(Mo)	<0.50 (1)
Tin	(Sn)	<0.50 (1)
Nickel	(Ni)	<0.50 (1)
Cobalt	(Co)	<0.10 (1)
Barium	(Ba)	<0.50 (1)

(1) *Quantification limit*

CMR

MATRIXYL® 3000 does not contain any ingredients classified CMR category 1A, 1B or 2 (Carcinogen, Mutagen, toxic for the Reproduction) according to the Regulation (EC) No 1272/2008 and adaptations. Nevertheless, potential traces of these substances are technically unavoidable due to the presence of Polysorbate 20.

MATRIXYL® 3000 fulfils the requirements of the article 15 of the Cosmetics Regulation (EC) No 1223/2009 and its amendments.

Residual Solvents

MATRIXYL® 3000 complies with ICH guideline for residual solvents CPMP/ICH/283/95 and Chapter <467> of USP/NF: Residual Solvents Limits.

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VOC

MATRIXYL® 3000 does not contain one or more intentionally added Volatile Organic Compounds (VOC) in compliance with the Swiss ordinance and the definition of California. Nevertheless, potential traces of Ethyl Acetate and Cyclohexane are technically unavoidable due to the presence of Carbomer.

SVHC

No Substances of Very High Concern (SVHC) listed in annex 14 of the Regulation (EC) 1907/2006, or listed in candidate list published by ECHA of which we regularly follow the updates, are intentionally added in the manufacturing process of MATRIXYL® 3000. Therefore, MATRIXYL® 3000 would not be expected to contain these substances.

Proposition 65

The ingredients constituting MATRIXYL® 3000 are not known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act of which we regularly follow the updates.

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Phthalates

The following Phthalates are not intentionally added in the manufacturing process of MATRIXYL® 3000. Therefore, MATRIXYL® 3000 would not be expected to contain these substances:

Substances		CAS Nr
Dibutyl Phthalate	(DBP)	84-74-2
Diethylhexyl Phthalate	(DEHP)	117-81-7
Benzyl Butyl Phthalate	(BBP)	85-68-7
Di-n-pentyl Phthalate	(DnPP)	131-18-0
Dimethylglycol Phthalate	(DMEP)	117-82-8
Diisopentyl Phthalate	(DIPP)	605-50-5
Diisobutyl Phthalate	(DIBP)	84-69-5
n-Pentyl-isopentyl Phthalate	(PIPP)	776297-69-9
Dihexyl Phthalate	(DHP)	84-75-3

Glycol Ethers

The following Glycol Ethers are not intentionally added in the manufacturing process of MATRIXYL® 3000. Therefore, MATRIXYL® 3000 would not be expected to contain these substances:

Substances		CAS Nr
2-Methoxyethanol / Ethylene Glycol Monomethyl Ether	(EGME)	109-86-4
2-Methoxyethyl Acetate / Methylglycol Acetate	(EGMEA)	110-49-6
2-Ethoxyethanol	(EGEE)	110-80-5
2-Ethoxyethyl Acetate	(EGEEA)	111-15-9
1,2-Dimethoxyethane / Ethylene Glycol Dimethyl Ether	(EGDME)	110-71-4
Oxybis(2-Methoxyethyl) / Dimethoxydiglycol	(DEGDME)	111-96-6
1,2-bis(2-Methoxyethoxy)ethane / Triethylene Glycol Dimethyl Ether	(TEGDME)	112-49-2
2-Butoxyethanol	(EGBE)	111-76-2
2-(2-Butoxyethoxy)ethanol	(DEGBE)	112-34-5
2-(2-Ethoxyethoxy)ethanol	(DEGEE)	111-90-0

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Glycerin

Glycerin used for the production of MATRIXYL® 3000 meets specifications of accepted pharmacopoeias with respect to Diethylene Glycol impurity (DEG content NMT 0.1%).

Formaldehyde

Formaldehyde and Formaldehyde releasers (as described by the SCCNFP opinions 586/02 and 587/02) are not intentionally added in the manufacturing process, and so are not expected in MATRIXYL® 3000.

Packaging

The packaging of MATRIXYL® 3000 is in compliance with Regulation (EC) No 1935/2004 of the European parliament and of the Council of October 27th, 2004 on materials and articles intended to come into contact with food.

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6. MICROBIOLOGICAL INFORMATION

Specifications

Total aerobic microbial count <100 cfu/g
Total combined yeasts / moulds count <10 cfu/g

Challenge Test

Strains	D7 (cfu/g)	D14 (cfu/g)	D28 (cfu/g)
Bacteria	<10	<10	<10
Yeast/mould	<10	<10	<10
Aspergillus. niger	100	<10	<10

Internal test method

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7. TOXICOLOGICAL INFORMATION

Animal testing

MATRIXYL® 3000 has not been tested on animals to fulfil the requirements of the European Cosmetics Regulation (EC) No 1223/2009 and its amendments, by or on behalf of SEDERMA.

Since 1998 and according to CRODA's policy, SEDERMA has decided not to perform any animal testing on its products (except for other specific regulatory purposes).

Toxicological tests results

Local toxicity	
Cutaneous primary tolerance (Patch-test) October 31st, 2003 Dilution to 50%	Non irritant
Ocular irritation (HETCAM) October 24th, 2003 Dilution to 50%	Slightly irritant
Ocular irritation (Neutral Red Release Method) October 24th, 2003	Slightly cytotoxic
Allergenicity	
Sensitization (HRIPT) December 12th, 2003 Dilution to 50%	Non sensitizing
Systemic toxicity	
Mutagenicity (Ames test) November 4th, 2003	Non mutagenic

Complete reports and Expert's certificates are available upon request.

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NOAEL

INCI Name (PcPc)	DA µg/cm² (%)	NOAEL[(a)] / NOEL[(b)] (mg/kg/day)	Read accross
Glycerin	100	8000 [(b)] [1]	No
Water	n/a	n/a	No
Butylene Glycol	100	3000 [(a)] [2]	No
Carbomer	100	Safe for use [3]	No
Polysorbate 20	100	1000 [(a)] [4]	Polysorbates
Palmitoyl Tripeptide-1[(1)]	10	Safe for use [5]	No
Palmitoyl Tetrapeptide-7	100	0.96 [(a)] [5] [6]	Tuftsin [7]

[1] EFSA Panel on Contaminants in the Food Chain (CONTAM) (2010) Scientific Opinion on the abiotic risks for public and animal health of glycerine as co-product from the biodiesel production from Category 1 animal by-products (ABP) and vegetable oils. EFSA Journal; 8(12), p. 1934.

[2] 1,3-Butanediol USEPA - HPV Challenge Program Submission- December 17, 2002.

[3] Cosmetic Ingredient Expert Review Panel (1982) Final Report on the Safety Assessment of Carbomers-934, -910, -934P, -940, -941, and -962. International Journal of Toxicology (1982), Vol. 1, No. 2, pp. 109-141.

[4] Food Safety Commission (2007) Evaluation Report of Food Additives Polysorbates (Polysorbates 20, 60, 65 and 80).

[5] Cosmetic Ingredient Expert Review Panel (2014). Final Report on the Safety Assessment of Tripeptide-1, Hexapeptide-12, their Metal Salts and Fatty Acyl Derivatives, and Palmitoyl Tetrapeptide-7 as Used in Cosmetics.

[6] Catane *et al*, (1983). Toxicology and antitumor activity of tuftsin, Annals of New York Academy of Science, 419(1), pp. 251-260.

[7] Veretennikova NI, Chipens GI, Nikiforovich GV, Betinsh YR. (1981) Rigin, another phagocytosis-stimulating tetrapeptide isolated from human IgG. Confirmations of a hypothesis. Int J Pept Protein Res. 17 (4), pp. 430-435.

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Date	Rev #	Description
October 21st, 2015	3	Structural change, additional information
April 29th, 2015	2	Impurities and other residues updated
February 12th, 2015	1	Biodiversity updated
July 3rd, 2014	0	Creation

Signed by:
Brice LECLERC
Regulatory Affairs Manager



For further information, don't hesitate to contact your local sales representative or to visit our website: **www.sederma.fr**

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Cosmetic
ACTIVE INGREDIENTS

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SEDERMA SAS
29 rue du Chemin Vert
F-78612 Le Perray en Yvelines cedex
tel ++ 33 1 34 84 10 10 fax ++ 33 1 34 84 11 30
sederma@sederma.fr www.sederma.com

SEDERMA Inc
300 Columbus Circle
Edison NJ 08837 USA
tel ++ (732) 692 1652 fax ++ (732) 417 0804
sederma-usa@croda.com www.sederma.com

SEDERMA GmbH
Herrenpfad-Süd 33
41334 Nettetal Germany
tel ++ 49 21 57 817318 fax ++ 49 21 57 817361
sederma@sederma.de www.sederma.com

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