

RAW MATERIAL IDENTIFICATION DATA

SEPIGEL 305™

Preamble

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of SEPPIC's knowledge, but might be updated. SEPPIC does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers.

The Product, as defined in this document is the product supplied by SEPPIC, which can be composed of one or several ingredients/components.

The information contained in this document and related to the Product is communicated by SEPPIC to its prospects and/or customers for their own development and/or the manufacturing of their formulations.

The information contained in this document cannot be communicated by SEPPIC's prospects and/or customers to any third party without the prior written agreement of SEPPIC, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers.

This document complements information communicated in SDS, CoA and other statements issued by SEPPIC.





RAW MATERIAL IDENTIFICATION DATA

SEPIGEL 305™

Summary

GENERAL INFORMATION	3
COSMETIC COMPOSITION	4
CHEMICAL COMPOSITION	5
MPURITIES	6
FLOWCHART	8
MANUFACTURING OPERATIONS	ç
STARTING MATERIALS	11
LABELS AND CERTIFICATIONS	12
CHEMICAL REGULATORY STATUS	14
COSMETIC REGULATORY STATUS	16
REGULATORY COMMITMENT	18
TOXICOLOGICAL DATA	22
ECOTOXICOLOGICAL DATA	24





GENERAL INFORMATION

SEPIGEL 305™

Product information

Commercial name: SEPIGEL 305™

Supplier

Headquarter and contact for correspondence

Seppic - Etablissement de Paris

50 Boulevard National, 92250 La Garenne-Colombes, France

Tel.: +33 (0)1 42 91 40 00

www.seppic.c

Function and use level

Fields of application: Cosmetics

Function of the Product: Thickening / Emulsifying agent / Stabilizer

Description of the Product:

-INCI name: Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7

-Physico-chemical data (color (range), state): Translucent to Opaque, White to yellowish / Liquid

Recommended use concentration: 0.1 - 5 %

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 17.02.2023 Version N°: 2







COSMETIC COMPOSITION

SEPIGEL 305™

INCI Name: Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7

PCPC registered

The INCI composition has been defined in accordance with PCPC INCI naming rules.

The additives are not included in the INCI name of the Product ingredient(s). As a common solvent present in the finished products, water is not always included in the INCI name of the above Product ingredient(s).

INCI composition

INCI NAME	CONCENTRATION RANGE (%)	TYPICAL CONCENTRATION* (%)
Polyacrylamide	35-45	40
C13-14 Isoparaffin	15-25	24
Laureth-7	3-8	6

^{*}given as indicative value

Additional information on composition

ADDITIVES**	NAME	CONCENTRATION RANGE (%)	TYPICAL CONCENTRATION* (%)
Solvents	Water	22-47	30
Preservatives	none		
Other	none		

^{*}given as indicative value

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 15.02.2023 Version N°: 2





^{**}intentionally added to the Product during or after the manufacturing



CHEMICAL COMPOSITION

SEPIGEL 305™

To achieve the most accurate description of our Product, we may make reference to multiple CAS numbers.

COMPONENT	CAS NUMBER	CONCENTRATION RANGE (%)	TYPICAL CONCENTRATION (%)
1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-propenyl)ami no]-,monosodium salt, polymer with 2-propenamid (9Cl)	38193-60-1	35-45	40
Distillates (petroleum), hydrotreated light	246538-78-3 and / (or 64742-47-8)	15-25	24
3,6,9,12,15,18,21-Heptaoxatritriac ontan-1-ol	3055-97-8	3-8	6
Water	7732-18-5	22-47	30

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 18.03.2022 Version N°: 1







IMPURITIES

SEPIGEL 305™

The following information is given, at the date of this document, to the best of our knowledge and/or according to our suppliers' statements.

The impurities listed in this statement are technically unavoidable in good manufacturing practice.

SUBSTANCE	ORIGIN	RESIDUAL CONCENTRATION	ANALYSIS/COMMENT
Acrylamide	Residual monomer	≤1ppm	Product specification
Ethylene oxide	Laureth-7 residual raw material	< 0.1 ppm	Estimated from data obtained on Laureth-7
1,4-dioxane	Laureth-7 by-product	<1 ppm (test limit)	Internal analysis
Monoethylene glycol	Laureth-7 by-product	<1ppm	Estimated from data obtained on Laureth-7
Diethylene glycol	Laureth-7 by-product	<1ppm	Estimated from data obtained on Laureth-7
Heavy metals (global)	Contaminants	< 10 ppm	External analysis
Heavy metals: - Lead - Cadmium - Mercury - Arsenic - Nickel - Chromium - Cobalt - Antimony	Contaminants	< 0.20 ppm < 0.010 ppm < 0.020 ppm < 0.10 ppm < 0.20 ppm < 0.30 ppm < 0.20 ppm < 0.050 ppm	External analysis tested on 3 batches







Based on our knowledge of the raw materials used and the manufacturing process, the following substances are not intentionally used in the manufacturing process and are not expected to be present in the Product:

-Acetone

-Alkylphenol and alkylphenol ethoxylates

-Antibiotics

-Antineoplastic agent

-Asbestos

-BHT, BHA

-1,4-Butanediol

-Camphre and derivatives

-Ethanol

-Eucalyptol

-Formaldehyde

-Glycol ethers

-Glycidol

-Growth promoter

-Hormones

-IARC & NTP listed substances

-Isopropyl alcohol

-Lactose

-Latex

-3-MPCD

-Melamine

-Menthol

-Methanol

-Methyl ethyl ketone

-Narcotics

-Nitrosamines

-Parabens

-Per- and polyfluoroalkyl substances (PFASs)

-Phenol

-Phthalates

-Polycyclic Aromatic Hydrocarbons (PAH)

-Psychotropic agents

-Residual metal catalysts

-Silicone

-Steroids

-Terpenes

SEPPIC does not perform any analysis for the above non-exhaustive list of impurities.

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 17.03.2023 Version N°: 2

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.

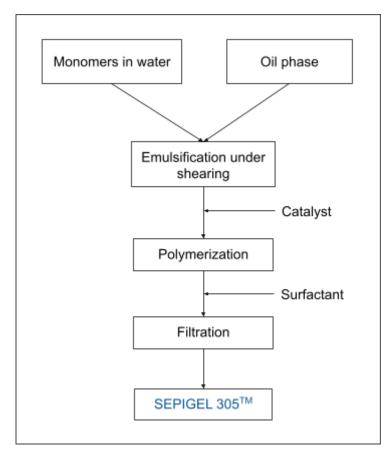




FLOWCHART

SEPIGEL 305™

Manufacturing process: Inverse emulsion polymerization



Monomers: Acrylamide, 2-Acrylamido-2-methylpropane sulfonic acid

Oil: C13-14 isoparaffin Surfactant: Laureth-7

Catalyst: Confidential (SEPPIC property)

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 18.03.2022 Version N°: 1







MANUFACTURING OPERATIONS

SEPIGEL 305™

Manufacturing* location

France

*EFfCI defines as a manufacturer: A company holding the trademark for the cosmetic ingredient or that performs the final release of the cosmetic ingredient. Seppic, as designer, manufacturer of ingredients in healthcare, assumes that manufacturing is defined as at least one of operations covering receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release and storage.

labeling, relabeling, quality control, release and storage.			
Quality assurance of the manufacturer □ ISO 9001 □ ISO 14001 □ ISO 45001			
For further information on the manufacturer site quality systems, please refer to the quality manual of the manufacturing plant(s).			
Manufacturing standards of the Product □ IPEC □ GMP* □ Others:			
The manufacturing plant has been inspected by local authority: \Box Yes \Box No The manufacturing plant has been inspected by the US FDA: \Box Yes \Box No			
*according to EFfCI GMP guidelines (European Federation for cosmetic Ingredients-2010)			
Production The Product is made by a: ⊠ Batch process □ Continuous process			
Decontamination or sterilization			
Is the Product decontaminated or sterilized? $\ \square$ Yes $\ \boxtimes$ No			
Batch numbering and labelling For definition of batch and general information on batch and label for SEPPIC products (batch numbering system, traceability of raw materials, labeling of finished products), please refer to the quality manual of the manufacturing plant(s).			
Packaging Batch separation is maintained during packaging?			

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.





Storage

Does the Product request special conditions before manipulation and / or for storage? Please refer to the SDS.

For other information regarding storage practices, please refer to the quality manual of the manufacturing plant(s).

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 17.02.2023 Version N°: 2

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*'s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.





STARTING MATERIALS

SEPIGEL 305™

The following information is provided without prejudice and reproduces information obtained, at the date of this document, from our current suppliers. This information is not included to the Product specifications.

COMPONENTS OF SEPIGEL 305™	MANUFACTURING PROCESS(ES)	STARTING MATERIAL / ORIGIN*	
Polyacrylamide	Polymerization	Acrylamide / Petrochemical 2-Acrylamido-2-methylpropane sulfonic acid / Petrochemical	
C13-14 Isoparaffin	Multi-step chemical process from petrochemical feedstock		
Laureth-7	Multi-step chemical process from petrochemical feedstock		

^{*}vegetal, biotechnology, mineral, animal, petrochemical

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 18.03.2022 Version N°: 1

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.





LABELS AND CERTIFICATIONS

SEPIGEL 305™

		ı
U	ГΙ	I

If you need any information for your certification, please ask your usual contact about CFI ingredient criteria.

COSMOS	\square approved	□ certified
Ecocert	□ approved	

EU and Nordic Swan Ecolabel

If you need any information for your certification, please ask your usual contact about **Ecolabel EU** and **Nordic Swan ingredient criteria**.

Halal ⊠ certified (standard) □ s	suitable*
----------------------------------	-----------

Seppic Halal certificate available upon request.

Information for Vegan assessment

The Product:

- -is not manufactured using animal derived raw materials;
- -is not produced using animal derived processing aids;
- -does not come into direct contact with material from animal origin at any stage of the manufacturing process;
- -is not tested on animals in terms of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products Chapter V Art. 18. The animal testing bans requirements of article 18 (1) became fully applicable to cosmetic ingredients on March 11th, 2013.

Please note that our analysis takes into account all the manufacturing steps at Seppic production facilities. The Product covered in this statement is not certified to any Vegan Labels. The vegan end-product certification or associated claim are under responsibility of the cosmetic product manufacturer.







ISO 16128

Natural/Natural origin index/content calculated according to ISO 16128 standard:

NI:-/NOI:-/NC (%): 30 / NOC (%): 30

NI: Natural index

NOI: Natural origin index NC: Natural content

NOC: Natural origin content

If you need further information on ISO 16128, please ask your usual contact

ii you i	leed fulfiller information of 150 16126, please ask your usual contact.
Kosher	⊠ suitable*
-is not	of animal origin and does not contain any animal origin constituents; of grape or wine origin and does not contain grape or wine constituents; mal, grape or wine source was present during the manufacture of the Product.
Natrue	□ approved
RSPO	☐ mass balance certified (standard)
	ns that no independent certification is available for our products and the suitability assessment by SEPPIC of the criteria expressly mentioned under this expression.

conclusion

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 17.02.2023 Version N°: 2







CHEMICAL REGULATORY STATUS

SEPIGEL 305™

REACH-like regulations

COUNTRY OR REGION	IDENTIFIER UNDER SPECIFIC REGULATION		
	CHEMICAL NAME	IDENTIFICATION NUMBER	STATUS UNDER SPECIFIC REGULATION
	Acrylamide (2-acrylamido-2-methylpropane sulphonic acid, sodium salt polymer)	EC: / CAS: 38193-60-1	Exempted As polymer (all monomers are registered or exempted)
Europe	Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	EC: 920-901-0 CAS: 246538-78-3	Registered Id: 01-2119456810-40-XXXX Seppic status: Downstream user
(REACH)	Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	EC: 927-676-8 CAS: /	Registered Id: 01-2119456377-30-XXXX Seppic status: Downstream user
	3,6,9,12,15,18,21-heptaoxatritria contanol	EC: / CAS: 3055-97-8	Exempted As polymer (all monomers are registered or exempted)
Korea (K-REACH)	1	1	Excluded Pharmaceutical, food and cosmetic uses are out of the scope
	Acrylamide (2-acrylamido-2-methylpropane sulphonic acid, sodium salt polymer)	EC: / CAS: 38193-60-1	Exempted As polymer (all monomers are pre-registered, registered or exempted)
Türkiye	Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	EC: 920-901-0 CAS: 246538-78-3	Pre-registered Id: 05-0000215391-15-0000
(KKDIK)	Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	EC: 927-676-8 CAS: /	Pre-registered Id: 05-0000215409-15-0000
	3,6,9,12,15,18,21-heptaoxatritria contanol	EC: / CAS: 3055-97-8	Exempted As polymer (all monomers are pre-registered, registered or exempted)
United Kingdom (UK-REACH)	Acrylamide (2-acrylamido-2-methylpropane	EC: / CAS: 38193-60-1	Exempted As polymer (all monomers are

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*'s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.







sulphonic acid, sodium salt polymer)		notified, registered or exempted)
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	EC: 920-901-0 CAS: 246538-78-3	Exempted Restriction volumes: <1T/yr
Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	EC: 927-676-8 CAS: /	Exempted Restriction volumes: <1T/yr
3,6,9,12,15,18,21-heptaoxatritria contanol	EC:/ CAS: 3055-97-8	Exempted As polymer (all monomers are notified, registered or exempted)

Other regulations

Australia (AIIC): Authorized. All CAS numbers used for this country are listed or exempted.

Canada (DSL/NDSL/R-ICL): Authorized. All CAS numbers used for this country are listed or exempted.

China (IECSC): Authorized. All CAS numbers used for this country are listed or exempted.

Japan (ENCS): Authorized. Restriction uses: Only for pharmaceutical, food and cosmetic uses. ISHL compliance should be ensured by the importer.

New-Zealand (NZIoC): Authorized. All CAS numbers used for this country are listed or exempted.

Philippines (PICCS): Not authorized. Some CAS numbers used for this country are not listed.

Taiwan (TCSI): Authorized. All CAS numbers used for this country are listed or exempted.

United States (TSCA): Authorized. All CAS numbers used for this country are listed or exempted.

If any questions on restrictions, please come back to your Seppic contact.

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 18.03.2022 Version N°: 1







COSMETIC REGULATORY STATUS

SEPIGEL 305™

COUNTRY / ZONE	IDENTIFIER	REGULATION / TEXT OF REFERENCE	COMPLIANCE (RESTRICTION)
Australia	INCI PCPC: Polyacrylamide C13-14 Isoparaffin Laureth-7	Classical cosmetic: Industrial Chemicals (notification and Assessment) Act 2019 Schedules (Poisons Standard)	Yes
	AAN: Polyacrylamide C13-14 Isoparaffin Laureth-7	Therapeutic Good: Therapeutic Goods Act 1989	Yes (as excipient): restrictions of use may apply
Canada	INCI PCPC: Polyacrylamide C13-14 Isoparaffin Laureth-7	Classical cosmetic: The Food and Drug Act, Cosmetic Regulations (C.R.C., ch. 869) Cosmetic Ingredient Hotlist	Yes
	NHP ingredient Database: Polyacrylamide C13-14 Isoparaffin Laureth-7	Natural Health Product & Non-prescription Drugs: Category IV Monographs & Natural Health Products regulation (SOR/2003-196)	Yes (as excipient): restrictions of use may apply
China	INCI (Chinese translation): 聚丙烯酰胺 C13-14 异链烷烃 月桂醇聚醚-7	Cosmetic Supervision and Administration Regulation (CSAR) including Safety and technical standard for cosmetics IECIC list 2021	Yes
Europe	INCI: Polyacrylamide C13-14 Isoparaffin Laureth-7	Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.	Yes (Polyacrylamide is listed in annex III/66 as restricted ingredient)
Japan	INCI (PCPC Japanese translation): ポリアクリルアミド (C13,14)イソパラフィン ラウレス - 7	Classical cosmetic: Japanese Standards of Cosmetics (Notification No.331 of 2000)	Yes
	QD monograph n°: All the components are JSQI listed	Quasi Drug: Pharmaceutical Affairs Law of Japan (PAL)	Yes

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*'s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.







South Korea	INCI (Korean translation): ポリアクリルアミド C13-14 아이소파라핀 ラウレス - 7	Classical cosmetic: Cosmetic Act 17250 Safety Standard for Cosmetics	Yes
	QD monograph n°: No data available on QD monograph	Cosmeceutical/ Quasi Drug according to the definition of functional cosmetics in the Korean Cosmetics Act	No
UK	INCI PCPC: Polyacrylamide C13-14 Isoparaffin Laureth-7	Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019	Yes
USA	INCI PCPC: Polyacrylamide C13-14 Isoparaffin Laureth-7	Classical cosmetic: Federal Food, Drug and Cosmetic (FD&C) Act. 21 CFR 700 to 740	Yes
	UNII: RHA9LWJ494 (Crosslinked; 0.01-0.2 Mole percent bisacrylamide) E4F12R0E70 Z95S6G8201	OTC: 21 CFR Part 3xx - OVER-THE-COUNTER DRUG PRODUCTS	Yes (as excipient)

To the best of our knowledge, the Product is also compliant with the local cosmetic regulations of the following countries / geographical areas:

Taiwan
New Zealand
Hong Kong
Asean
Gulf countries
Saudi Arabia
Morocco
Andean community - CAN
Mercosur
CACM
India
Russia

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 17.02.2023 Version N°: 2

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.





REGULATORY COMMITMENT

SEPIGEL 305™

Animal testing

Last revision date: 18.03.2022

Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, Article (18), Animal testing

SEPIGEL 305[™] has not been the subject of animal testing after March 11, 2013, in order to meet the requirements of Regulation (EC) No. 1223/2009.

Allergens (Fragrance)

Last revision date: 18.03.2022

Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, Annex III

Based on information supplied to us concerning the raw materials and our knowledge of the manufacturing process, the fragrance allergens within the scope of EU Regulation 1223/2009 (Annex III) are not expected to be present in SEPIGEL 305^{TM} .

BSE/TSE

Last revision date: 18.03.2022

SEPIGEL 305TM has neither been produced with raw materials from animal or human origin nor come into contact with any animal or human material during its manufacturing process. Therefore this Product is not concerned by BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible spongiform encephalopathy) and related regulations.

California Proposition 65

Last revision date: 18.03.2022

California Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986

Based on information supplied to us concerning the raw materials and our knowledge of the manufacturing process, no substances (other than those possibly disclosed in the impurities table) listed under Proposition 65 State Drinking Water and Toxic Enforcement Act are expected to be present in SEPIGEL 305^{TM} .

CITES and IUCN Red List

Last revision date: 18.03.2022

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and IUCN Red List

Based on information supplied to us concerning the raw materials and our knowledge of the manufacturing process, SEPIGEL 305[™] does not contain any substance derived from species listed in CITES or listed in IUCN Red list.

CMR

Last revision date: 18.03.2022

CLP Regulation (EC) 1272/2008, Annex VI

Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, Article (15), Substances classified as CMR substances and Article (17), Traces of prohibited substances

Based on information supplied to us concerning the raw materials and our knowledge of the manufacturing process, substances meeting the CMR criteria in accordance with Annex VI of the CLP Regulation (EC) 1272/2008 are not expected to be present in SEPIGEL 305[™]. This Product complies with the provision of Article 15 of Regulation (EC) 1223/2009 about CMR substances, as amended.







The potential presence of technically unavoidable traces of CMR substances is covered by the provision of Article 17 of Regulation (EC) No 1223/2009.

Conflict Minerals

Last revision date: 18.03.2022

Conflict minerals, as defined in the Dodd–Frank Wall Street Reform and Consumer Protection Act, are not intentionally added as constituent components for the manufacturing of SEPIGEL 305^{TM} .

Contaminants

Last revision date: 18.03.2022

Commission Regulation (EC) \mbox{N}° 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, as amended

SEPIGEL 305TM is in compliance with the above mentioned regulation for the following contaminants: Nitrates, Mycotoxines including aflatoxines, 3-MCPD, Dioxins and PCBs, PAH, Melamin and analogues, Plant toxins, Glycidol/Glycidyl fatty acid esters listed in the above mentioned regulation.

GMO

Last revision date: 18.03.2022

Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003 as amended

SEPIGEL 305[™] is manufactured with petroleum-based raw materials. Therefore the presence of GMO is not expected in the Product.

Irradiation

Last revision date: 18.03.2022

Directive 1999/2/EC of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation and Directive 1999/3/EC of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation

SEPIGEL 305TM is not submitted to ionising radiation and does not contain any components submitted to ionising radiation in compliance with the above mentioned regulations.

Mineral hydrocarbons

Last revision date: 18.03.2022

Cosmetics Europe recommendation No. 14 (17-09-2018) on mineral hydrocarbons in cosmetic lip care products

SEPIGEL 305[™] does not correspond to any monograph of the above recommendation. Therefore the restrictions related to the use of mineral hydrocarbons in cosmetic lip care's applications according to this recommendation do not apply to this Product.

Nanomaterials

Last revision date: 18.03.2022

Commission Recommendation (EC) No. 2011/696/EU of 18 October 2011 on the definition of nanomaterial and French Decree n° 2012-232 of 17 February 2012 on the annual declaration on substances at nanoscale in application of article R. 523-4 of the Environment code

SEPIGEL 305[™] is not considered as a nanomaterial according to the above definitions as not all parameters of the definitions are fulfilled.







Pesticides MRL

Last revision date: 18.03.2022

Regulation 2005/396/EC of the European Parliament and of the Council of 23 February 2005 on maximum residue level pesticides in or on food and feed of plant or animal origin and amending Council directive 91/414/EEC and amendments and European Pharmacopoeia monograph <2.8.13> Pesticide residues

SEPIGEL 305[™] is manufactured with petroleum-based raw materials. Therefore the presence of pesticides is not expected in the Product.

Residual solvent

Last revision date: 17.02.2023

Guidelines ICH Q3C: Residual solvents

USP General methods <467>: Residual solvents

Based on information supplied to us concerning the raw materials and our knowledge of the manufacturing process, the following solvent(s) listed in the guidelines ICH Q3C (class 1, class 2 or class 3) are expected to be

present in SEPIGEL 305^{TM} : 1,4-dioxane (class 2) < 1 ppm

Monoethylene glycol (class 2) < 1 ppm Both solvents are below the option 1 limit.

SVHC (Substances of Very High Concern)

Last revision date: 18.03.2022

VOC

Last revision date: 18.03.2022

SEPIGEL 305TM contains no substance identified as "SVHC" (Substances of Very High Concern which are referred to in the "candidate list" published by ECHA in the context of the REACh Regulation (EC) No. 1907/2006) above the 0.1% w/w threshold.

Swiss Ordinance SR 814.018 of 12 November 1997, Annex 1 (Art 2, a), exemption from tax (Article 8) and amendments

Based on information supplied to us concerning the raw materials and our knowledge of the manufacturing process:

-C13-14 Isoparaffin is a VOC according to the SR 814.018 VOC definition.
-None of the substances listed in Annex 1 (Art 2, a) of SR 814.018 are expected to be present in SEPIGEL 305™ above the threshold of 3% defined in Article 8 for exemption from tax.

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 17.02.2023 Version N°: 2







TOXICOLOGICAL DATA

SEPIGEL 305™

Data available on the Product:

TOXICITY ENDPOINT	METHOD	REFERENCE	RESULT
Mutagenicity	Bacterial Reverse Mutation Test (Ames' Test - OECD 471)	SAFEPHARM 1190-055 LCE01072 a confidential.PDF	Non (Pro)mutagenic tested up to 5000 µg/plate

Data available on the Product at use dosage (or level):

TOXICITY ENDPOINT	METHOD	REFERENCE	RESULT
Eye Irritation	HETCAM test based on the Official Journal of the Republic of France (N° 300), December 26th, 1996	Tox HETCAM SEPPIC 298 – SEPIGEL 305 2% a confidential.PDF	Non irritant at 2% in water (score = 0)
	RBCA test adapted from INVITTOX protocol n°37	Tox RBCA SEPPIC 862 - SEPIGEL 305 3% a confidential	Not irritant at 3% (L/D > 100)
Skin Irritation	Patch test 48h (10 volunteers, occlusive patches)	Tox Patch test 48 h - IEC R50216D - CN50210 SEPIGEL 305 5% a confidential	Non irritant at 5% (4% Isostearyl isostearate and 15% ethanol, <i>qs</i> water) (index = 0)
	Use test (12 volunteers) forearms application twice daily for 42 days	Tox Use test ISPE 27992 SE23707 SE23708 - SEPIGEL 305 5% a confidential	Not induced any cutaneous redness phenomena at 5% in water
Skin Sensitization	Human Repeated Insult Patch Test (HRIPT) according to the Marzulli & Maybach method (50 volunteers, occlusive patches)	Tox M&M IEC R41131D - SEPIGEL 305 5% a confidential.PDF	Non Irritant (M.I.I. = 0,06) and non sensitizing at 5% (10% paraffin oil qs water)

For additional toxicological information: please refer to the SDS and Safety Complementary Data (available only upon request).







This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 18.03.2022 Version N°: 1

The information contained in each statement is deemed to be valid up until the date of its last version, to the best of Seppic*s knowledge, but might be updated. Seppic does not commit itself to automatically updating this document and to automatically communicating the updated document to its customers. The Product, as defined in this document, is the product supplied by Seppic, which can be composed of one or several ingredients/components. The information contained in this document and related to the Product is communicated by Seppic to its prospects and/or customers for their own development and/or the manufacturing of their formulations. The information contained in this document cannot be communicated by Seppic's prospects and/or customers to any third party without the prior written agreement of Seppic, with the exception of communication to legal authorities, which remains the sole responsibility of the said prospects and/or customers. This document complements information communicated in SDS, CoA and other statements issued by Seppic.





ECOTOXICOLOGICAL DATA

SEPIGEL 305™

Data available on the component(s) of the Product:

 Acrylamide-sodium acrylamidomethyl propanesulfonate copolymer is included at 35-45% in SEPIGEL 305™:

ECOTOXICOLOGICAL DATA	METHOD	REFERENCE	RESULT
Inherent biodegradability	OECD 302 B	OCDE 302B décanté Eurofins TOX20011 TOX20012_116684 3A01-1	inherently ultimately biodegradable, 90% in 28 days

Distillates (petroleum), hydrotreated light is included at 15-25% in SEPIGEL 305[™] (REACH data):

The component "Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics" included in the component Distillates (petroleum), hydrotreated light is not classified for the environment according to (EU) n°1272/2008 (CLP regulation) on the basis of available ecotoxicological data (based on aquatic acute assays EL/LL50 > 1000 mg/L freshwater, marine water, and aquatic chronic assays NOEL = 1 (Read-across OECD 211)- 1000 mg/L).

This substance is not expected to be bioaccumulative (BCF of representative substances range between 144.3 L/kg to 962.6 l/kg, based on QSAR calculation) and is readily biodegradable (77 to 83% in 28 days based on oxygen consumption and meeting the 10-day window).

The component "Hydrocarbons, C11-C13, isoalkanes, <2% aromatics" included in the component Distillates (petroleum), hydrotreated light is not classified for the environment according to (EU) n°1272/2008 (CLP regulation) on the basis of available ecotoxicological data (based on aquatic acute assays EL/LL50 > 1000 mg/L freshwater, marine water, and aquatic chronic assays NOEL = 0.316-1000 mg/L).

This substance is not expected to be bioaccumulative (BCF of representative substances range between 144.3 L/kg to 962.6 l/kg, based on QSAR calculation) and is readily biodegradable (77 to 83% in 28 days based on oxygen consumption and meeting the 10-day window).

For additional ecotoxicological information: please refer to the SDS and Safety Complementary Data (if existing, available only upon request).

This statement is valid without signature as of the "Last revision date" provided below.

Creation date: 18.03.2022 Last revision date: 18.03.2022 Version N°: 1



