SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

RAW MATERIAL IDENTIFICATION DATA

CHEMICAL INGREDIENTS

SIMULGEL™ EG
C/9331/GB/02/October 2019

Procedure N° GRRAF004

- CTFA - Raw Material Information Form (RMIF updated version July20-2010)
- Fragrance Product Information Form Version 2.5 - FPIF 07/11/2011
- The French ingredients questionnaire, published on the Ministry of Industry and Economy's website on 7 July 2010.

PREAMBLE

This document aims to facilitate the information exchanges related to SEPPIC's chemical raw materials (herein after referred to as the "Raw Materials"). Such exchanges shall occur between SEPPIC, supplier of the Raw Materials, and its customers.
In the framework of these exchanges, SEPPIC offers to sale such Raw Materials for the preparation of cosmetic formulations. The final use of the Raw Materials supplied by SEPPIC remains the sole responsibility of SEPPIC's customers.
SEPPIC complies with chemical regulations (as CLP, REACH, 29 CFR 1910.1200, Order 7, etc.) in countries where SEPPIC assumes the role of manufacturer / importer. In this situation, as downstream user, SEPPIC's customers must comply with some obligations under these chemical regulations, if applicable.
In case of direct importation, SEPPIC's customers are responsible for the compliance of the imported chemicals with the local chemical regulations.
The final use of the Raw Material supplied by SEPPIC and the compliance with associated regulations remains the sole responsibility of the customer. SEPPIC commits to supply Raw Materials that are in conformity with the application claimed. According to the European Cosmetic Regulation, SEPPIC's customers are solely responsible for the safety evaluation of the cosmetic formulations containing Raw Materials supplied by SEPPIC.
Each Raw Material is associated to a commercial reference, to a packaging unit, and to contractual specifications, to which the data supplied in this document are linked. The information provided in this document cannot be taken as specifications. The only specifications on the Raw Material are information included in its certificate of analysis.
This document is equivalent to a statement. No other statement will be prepared for data available in the present document.
The data comprised in this document are deemed to be valid at the date of its signature, at the best of SEPPIC's knowledge, but might be updated. SEPPIC does not commit itself to automatically update this document and to automatically communicate the updated document to its customers.
The information comprised in this document and related to the Raw Material are submitted by SEPPIC to his prospects and/or customers for their own development and/or the manufacturing of its cosmetic formulations.
The information contained in this document cannot be communicated by SEPPIC's prospects and/or customers to a third party without the prior written agreement of SEPPIC, at the exception of the communication to legal authorities which remains of the prospects and/or customers' sole responsibility.

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

A. PRODUCT IDENTITY AND GENERAL INFORMATION

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

GENERAL INFORMATION

1. Commercial name

SIMULGEL™ EG (CODE: 38190L)

2. INCI name

Sodium Acrylate / Sodium Acryloyldimethyl Taurate Copolymer & Isohexadecane & Polysorbate 80

3. Supplier

Head office
75, Quai d'Orsay –75321 Paris Cedex 07 – France
Tel.: +33 (0)1 40 62 55 55 Fax: +33 (0)140 62 52 53

Head quarter
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41
www.seppic.com

4. Quality status of SEPPIC

All of SEPPIC's business areas are described in a documentation system compliant with the regulations in force, the certification gained and the standards listed below:

- Is SEPPIC ISO 9001 certified (Quality Management System)?

☒ Yes ☐ No

SEPPIC (commercial and administrative offices) and its plants, SEPPIC-SA (Castres, France plant), BIOTECHMARINE (Pontrieux, France plant) and SEPPIC-SSCS (Qing Pu, China plant) are ISO 9001 certified.

- Is SEPPIC Plant ISO 14001 certified (Environment Management System)?

☒ Yes ☐ No

SEPPIC-SA (Castres's plant) is ISO 14001:2004 certified.

- Is SEPPIC plant OHSAS 18001 certified (Health and Safety at work Management System)?

☒ Yes ☐ No

SEPPIC-SA (Castres plant) is OHSAS 18001 certified.

- Is SEPPIC plant GMP certified (Good Manufacturing Practices)?

☒ Yes ☐ No

SEPPIC-SA (Castres) received a certificate of external audit from INTERTEK for main of its cosmetic ingredients, according to EFfCI GMP guidelines (European Federation for cosmetic Ingredients-2010).

SEPPIC-SA (Castres) received a certificate of inspection from ANSM (French Health Products safety Agency) for all the pharmaceutical materials, according to ICH Q7a guideline (annex 18 as European GMP for active pharmaceutical ingredient).

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Other guidelines have been implemented for pharmaceutical excipients, such as IPEC GMP:2006.

- Is SEPPIC plant ISO 22000 certified (Food Safety management System)?

☐ Yes ☒ No

For SEPPIC-SEPIPROD (Castres), risk analysis according to HACCP method have been realised for the food ingredients.

- Is SEPPIC SA8000 certified (Social Accountability Norm)?

☐ Yes ☒ No

SEPPIC is respecting the general rules contained in the SA8000 Standard.

- Is SEPPIC RSPO member (Roundtable on Sustainable Palm Oil)?

☒ Yes ☐ No

SEPPIC is approved as an Ordinary member by the Executive Board of the RSPO since October 2009.

See Reference 1 (For References, see at the end of the document)

5. Function and use level

- Function of the ingredient: Polymer - Thickening - emulsifying agent
- Recommended use concentration: 0.1 - 5 % (depending on the formulation)
- Fields of application: Cosmetic

See Reference 2

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

COMPOSITION

1. Composition

See composition's statement attached

The whole composition of the substance has been taken into account in the INCI name according to PCPC naming rules.

2. Chemical structure of main components

	CAS number	CAS name	Synonym
1	77019-71-7	2- Propenoic acid, polymer with 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid, sodium salt (9Cl)	2-Acrylamido-2-methylpropanesulfonic acid-acrylic acid copolymer sodium salt
2	93685-80-4 for EU 4390-04-9 for other countries	Nonane, 2,2,4,4,6,8,8-heptamethyl-(6Cl,7Cl,8Cl,9Cl)	2,2,4,4,6,8,8-Heptamethylnonane
3	9005-65-6	Sorbitan, mono-9-octadecenoate,poly(oxy-1,2-ethanediyl) derivs.	Polyethylene glycol sorbitan monooleate

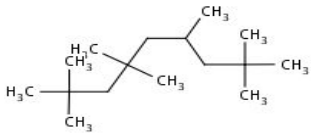
Chemical structure of main components:

Component 1: Sodium Acrylate / Sodium Acryloyldimethyl Taurate Copolymer:

$(C_7H_{13}NO_4S.C_3H_4O_2)x.Na2x$

Component 2: Isohexadecane:

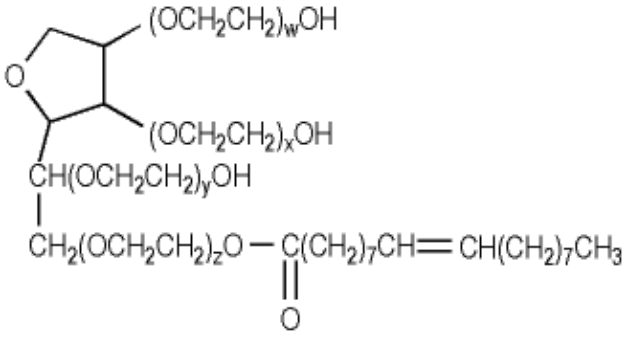
$C_{16}H_{34}$



Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Component 3: Polysorbate 80 is a mixture of oleate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 20 moles of ethylene oxide



where w + x + y + z has an average value of 20.

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

3. Residues, impurities and additives

The following information is given, at the date of this document, to the best of our knowledge and/or according to our suppliers' statements.	
Residues and additives	Comments
Solvant: Water Additive: Sorbitan Oleate Residual monomers: Sodium acrylate Sodium acryloyldimethyltaurate	22.5-37.5 % 0-5% < 260 ppm* (acid form quantified) < 600 ppm*
Impurities	Comments
Methanol	Not expected
Ethanol	Not expected
Isopropyl alcohol	Not expected
1,4-butanediol	Not expected
Acetone	Not expected
Monoethylene glycol	<310 ppm**
Diethylene glycol	<0.1%**
Acetaldehyde	< 3 ppm in the formulation of a finished product at maximal recommended use concentration (5%)
Phenol	Not expected
Alkyl phenols	Not expected
Ethylene oxide	< 0.2 ppm**
Other oxide (OP, OB, …)	Not expected
1,4-dioxane *(see Reference 3)*	< 1 ppm**
Volatile Organic Compounds *(see Reference 4)*	Isohexadecane: 20 - 25%
Other residual Solvents *(see Reference 5)* according to ICH Q3C Guidelines, USP <467> & EP 5.4	See above MEG, 1,4 dioxane and ethylene oxide

*Statistical analysis (1 in 5 batch).
**Estimated by calculation. Technically unavoidable traces in ethoxylated products, Technically unavoidable traces are permitted according to provisions of Chap IV-Art 17 of European Cosmetic Product Regulation 1223/2009/EC
A warning about listed chemicals known to cause cancer ("carcinogens") is not required because we can demonstrate that the exposure occurs at a level that poses "no significant risk" or because we can demonstrate that the discharge will not cause a "significant amount" of the listed chemical to enter any drinking water source, and complies with all other applicable laws, regulations, permits, requirements, or orders http://oag.ca.gov/prop65/faqs-view-all

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Impurities	Comments
Heavy metals:	<10 ppm**
- Lead Pb*	< 5 ppm*
- Cadmium Cd*	< 1 ppm*
- Mercury Hg*	< 0.3 ppm*
- Arsenic As*	< 1 ppm*
- Nickel Ni*	< 5 ppm*
- Chromium Cr (esp. Cr VI+)*	< 1 ppm*
- Cobalt Co*	< 5 ppm*
- Other (copper Cu, silver Ag...)	Antimony*: < 5 ppm* Silver*: < 1 ppm* Copper*: < 5 ppm* Titane: 10 ppm max
Residual metal catalysts 10 *(see Reference 6)* and environmental contaminants or Conflict minerals US law 11 *(see Reference 7)*	Not expected
Proposition 65 and bill 484 listed substances*** *(see Reference 8)*	See above Ethylene oxide and 1,4 dioxane
Glycol ethers	Not expected
Phthalates	Not expected
Terpenes	Not expected
Free amines	Not expected
Alcanol amines: MEA, DEA, TEA….	Not expected
Nitrosamines	Not expected
EDTA (Ethylenediaminetetraacetic acid) and its salts	Not expected
Silicone and latex	Not expected

* Tested on batch T52631 By ICP/AAFG/FAVF. These values are not included in specifications. Technically unavoidable traces from raw materials, Technically unavoidable traces are permitted according to provisions of Chap IV-Art 17 of European Cosmetic Product Regulation 1223/2009/EC

** Tested on polymer with similar structure according to the test limit of the European Pharmacopea method 2.4.8

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Impurities	Comments
Preservatives	Not expected
Polycyclic Aromatic Hydrocarbons (PAH): benzopyrenes & DMSO…	Not expected
Hydroquinone; Methyletherhydroquinone (MEHQ) Other hydroquinone dérivatives	Not expected
Nitrates	Not expected
Nitrites	Not expected
Oxydants: H2O2…	Not expected
Proteins	Not expected
Pesticides *(see Reference 9)*	Not expected
IARC & NTP listed substances *(see Reference 10)*	Not expected
Dioxin, PCB	Not expected
BHT/BHA (butylated hydroxytoluene/butylated hydroxyanisole)	Not expected
Cytotoxic agents	Not expected
Aflatoxines	Not expected
Mycotoxins	Not expected
Ochratoxins	Not expected
Mycoplasma	Not expected
Antineoplastic agent	Not expected
Asbestos	Not expected
Fungi	Not expected
Camphre & derivatives	Not expected
Menthol	Not expected
Eucalyptol	Not expected

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Impurities	Comments
Halogens (Iodine and derivatives and others)	Not expected
Melamine	Not expected
Psychotropic agents	Not expected
Narcotics	Not expected
Antibiotics	Not expected
Steroids, hormones, growth promoter	Not expected

Type of substance	Specific regulation	Compliance (Y/N)
Allergen *(see Reference 11)*	Regulation (EC) No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products	Y See Allergenic Substances Statement
CMR *(see Reference 12)*	Regulation (EC) No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products, CHAPTER IV, Article 15 Substances classified as CMR substances. Guideline on the limits of genotoxic impurities CPMP/SWP/5199/02 Directives 67/548/CEE and 1999/45/CE (classification and labeling of dangerous substances and preparations) Regulation CLP 1272/2008	Y See CMR Statement

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

4. Microbiological data

Microorganism	Result	Method	Monitoring
Total bacterial Aerobies	<100CFU/g	PE 2.6.12	☐ Each batch ☐ Statistical analysis ☒ Qualified batch only ☐ Not applicable*
Total Yeasts and moulds	<100CFU/g	PE 2.6.12	☐ Each batch ☐ Statistical analysis ☒ Qualified batch only ☐ Not applicable*
Specific pathogens -Enterobacteries & other Gram- -Escherichia Coli -Salmonella -Pseudomonas aeruginosa -Staphylococcus aureus;	Absence/g	PE 2.6.13	☐ Each batch ☐ Statistical analysis ☒ Qualified batch only ☐ Not applicable*

* tested on batches T 90830, T 90840 and T 90850

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

B. MANUFACTURING, ORIGIN AND SUSTAINABLE DEVELOPMENT

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

INFORMATION ON MANUFACTURING

Country of Manufacturing: FRANCE

Plant Address: SEPPIC - Usine Lacaze Basse - BP 228 - 81105 CASTRES CEDEX France

In the market since: 1998

Quality assurance of the manufacturing site:

For further information on the manufacturing site quality systems, see the Quality manual of the manufacturing plant

Manufacturing standards of the material:

These standards or guidelines are followed for the manufacturing of the material:

☒ ISO 9001
☒ ISO 14001
☒ OHSAS 18001
☒ GMP (Good Manufacturing Practices) according to EFfCI standards
☐ ISO 22000
☐ Hazard Analysis & Critical Control Point (HACCP) defined by Codex Alimentarius

The material is made by a: ☒ Batch process ☐ Continuous process

Stage of decontamination or sterilization

Is the ingredient decontaminated or sterilized? ☐ Yes ☒ No

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

ORIGIN OF STARTING MATERIALS

The following information comes from data obtained, at the date of this document, from our current suppliers.

Declaration of origin

Are the starting materials from:

- Animal ☐ Yes ☒ No
- Vegetal origin ☒ Yes ☐ No
- Mineral origin ☐ Yes ☒ No
- Synthetic origin ☒ Yes ☐ No
- Other origin (fermentation, biotechnology, culturing cells) ☐ Yes ☒ No

In case of vegetable origin

Details of origin:

Starting materials	Name of the plant	Part of the plant	Origin of the plant
Oleic acid	olive tree	fruit	Europe
Sorbitol	wheat or corn	seed	Europe

Are starting materials listed on CITES, Annexes I, II or III and/or regulation n°338/97, annexes A, B, C, D?

☐ Yes ☒ No *See Reference 13*

Are the starting materials derived from Palm Oil?

☐ Yes ☒ No

The material contains or consists of GMO's and is produced from or contains ingredients produced from GMO's according to Regulation (EC) 1829/2003:

☐ Yes ☒ No

The manufacturing process includes recombinant technologies:

☐ Yes ☒ No

There is a system to check the PCR negative status:

☐ Yes ☒ No

See GMO certificate

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

In case of synthetic origin:

Raw materials of synthetic origin:

Sodium acrylate/Acryloyldimethyl taurate copolymer
Isohexadecane
Ethylene oxide (used to produce Polysorbate 80)

Are the starting materials concerned by the nanotechnology or contain nanomaterials?

According to the definition of Regulation (EC) N° 1223/2009 on Cosmetic Products
☐ Yes ☒ No

According to EU Commission Recommendation 2011/696/EU of 18 October 2011
☐ Yes ☒ No

According to 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
☐ Yes ☒ No

See Reference 15

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

SUSTAINABLE DEVELOPMENT

1. Principles of green chemistry

The 12 principles of green chemistry give means of environmental improvement for any chemical reactions.
These 12 principles were theorized by American researchers (Anastas, P. T.; Warner, J. C.; Green Chemistry: Theory and Practice, Oxford University Press: New York, 1998, p.30.):

1. Prevention
2. Atom Economy
3. Less Hazardous Chemical Syntheses
4. Designing Safer Chemicals
5. Safer Solvents and Auxiliaries
6. Design for Energy Efficiency
7. Use of Renewable Feedstocks
8. Reduce Derivatives
9. Catalysis
10. Design for Degradation
11. Real-time analysis for Pollution Prevention
12. Inherently Safer Chemistry for Accident Prevention

At SEPPIC, from the R&D step to the process down streaming, we committed to implement these principles as far as possible. For the processes of new products, prevention of waste, energy saving, use of raw materials with renewable origin and ecotoxicological properties are key elements. For the existing processes, improvements are made to make them cleaner.

Bio-based content of the product:

- Natural origin index according to ISO 16128 standard: 32,5%

2. Labels

Organic and natural labels
Does the ingredient comply with an organic or natural label?

☐ Yes ☒ No

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

PACKAGING, LABELING & STORAGE

1. Packaging

Nature/type of packaging: Plastic drum

OTP 30

	Primary packaging*	Pallet**
Type of Material	Plastic Drum (HDPE)	Wood
Size (cm)	Ø31.5, h=51.7	114 x 114
Specifications (weight, …)	30 Kg	794.400 Kg 24 plastic drum / pallet

Or

CT800

	Primary packaging*	Pallet**
Type of Material	Plastic Drum (HDPE)	Wood
Size (cm)	100 x 120 x 99	100 x 120
Specifications (weight, …)	800 Kg	862 Kg (Gross weight) 1 plastic drum / pallet

* The primary packaging means that the product is in direct contact with the packaging

** Standard packaging. This packaging could be changed without any prejudice to the material

Regulatory informations:

The packaging material complies with the following regulations or directives:

Legal text	Yes/No
Commission Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and later amendments	Yes
Commission Regulation 1935/2004/EC and later amendments	Yes
Commission Directive 94/62/CE on packaging and packaging waste and later amendments	Yes
Commission Regulation 10/2011/CE on Plastic materials and Articles intended to come into contact with food and later amendments	Yes

The packaging contains substances on the candidate list (SVHC) as defined by the REACH regulation with a concentration greater than 0.1% (w/w): ☐Yes ☒No

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

2. Batch & Label

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.

3. Storage

Does the ingredient request special conditions before manipulation and / or for storage?

See SDS

For other information regarding storages practices, please refer to the quality manual of the manufacturing plant.

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

C. REGULATORY AND INTRINSIC DATA

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

REGULATORY INFORMATION

1. Chemical inventories and regulatory status

EUROPE

Chemical name	Synonym	N°CAS	N°EC	Status in the supply chain	REACH status
2-propenoic acid, polymer with 2-methyl 2-[(1-oxo-2-propenyl) amino]-1-propanesulfonic acid, sodium salt	Sodium acrylate / Sodium Acryloyldimethyl Taurate copolymer	77019-71-7	Polymer, not concerned	manufacturer	Yes as polymer. Our suppliers preregistered monomers
Hydrocarbons, C4, 1,3-butadiene-free, polymd., tetraisobutylene fraction, hydrogenated	Isohexadecane	93685-80-4 (similar CAS 4390-04-9)	297-628-2	downstream user	01-2119486102-45-XXXX
Sorbitan monooleate, ethoxylated	Polysorbate 80	9005-65-6	Polymer, not concerned	manufacturer	Yes as polymer. Our supplier pre-registered ethylene oxide and sorbitan oleate is exempted according to annex IV (EEC 1907/2006)
Sorbitan oleate	Sorbitan Oleate	1338-43-8	215-665-4	manufacturer	Yes, annex IV (EEC 1907/2006)

For Sodium acrylate / Sodium Acryloyldimethyl Taurate copolymer, list of monomers

Chemical name	N°CAS	N°EC	Status in the supply chain	REACH status
acrylic acid (sodium acrylate)	79-10-7	201-177-9	downstream user	01-2119452449-31-XXXX
sodium 2-methyl-2-[(1-oxoallyl)amino]propanesulphonate	5165-97-9	225-948-4	confidential	01-2119495270-39-XXXX

For polysorbate 80, list of monomers:

Chemical name	N°CAS	N°EC	Status in the supply chain	REACH status
ethylene oxide	75-21-8	200-849-9	downstream user	01-2119432402-53-XXXX
sorbitan oleate	1338-43-8	215-665-4	manufacturer	Yes, annex IV (EEC 1907/2006)

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

The ingredient or one of its components is:	Yes/No if Yes, which component?
Persistent, Bioaccumulative and Toxic (PBT)	No
Very Persistent, Very Bioaccumulative (vPvB)	No
Included in the candidate list (SVHC)	No
Subject to authorization (annex XIV of REACH)	No
Subject to restriction (annex XVII of REACH)	No

See Reference 17

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

OTHER COUNTRIES

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

	USA	JAPAN	AUSTRALIA	CANADA
	TSCA	ENCS/ISHL	AICS	DSL/NDSL
2-Acrylamido-2-methylpropanesulfonic acid-acrylic acid copolymer sodium salt CAS: 77019-71-7	Not listed	Listed under 1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propenyl)amino]-, polymer with 2-propenoic acid, sodium salt Japanese ENCS Number: (6)-2151 and ISHL Number: 9-793	Listed under 2-Propenoic acid, polymer with 2-methyl-2-[(1-oxo-2-propenyl) amino]-1-propanes-ulfonic acid, sodium salt	Listed DSL under 2-Propenoic acid, polymer with 2-methyl-2-[(1-oxo-2-propenyl) amino]-1-propanes-ulfonic acid, sodium salt
2,2,4,4,6,8,8-Heptamethylnonane CAS: 93685-80-4 for EU 4390-04-9 for other countries	Listed under Nonane, 2,2,4,4,6,8,8-heptamethyl-	Listed under Nonane, 2,2,4,4,6,8,8-heptamethyl- ENCS-ISHL Number : (2)-10	Listed under 2,2,4,4,6,8,8-Heptamethyl-nonane	Listed DSL under Nonane, 2,2,4,4,6,8,8-heptamethyl-
Polyethylene glycol sorbitan monooleate CAS: 9005-65-6	Listed under Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	Listed under Sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs., (Z)- ENCS Number : (8)-55	Listed under Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	Listed DSL under Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

	CHINA	KOREA	NEW-ZEALAND	PHILIPPINES	TAIWAN
	IECSC	KECI	NZIoC	PICCS	TCSI
2-Acrylamido-2-methylpropanesulfonic acid-acrylic acid copolymer sodium salt CAS: 77019-71-7	Listed under 2-丙烯酸基醯胺-2丙烷磺酸与丙烯酸的共聚物	Not listed	Listed under 2-Propenoic acid, polymer with 2-methyl-2-[(1-oxo-2-propenyl) amino]-1-propanes-ulfonic acid, sodium salt	Not listed	Listed under 2-Propenoic acid, polymer with 2-methyl-2-[(1-oxo-2-propenyl) amino]-1-propane sulfonic acid, sodium salt
2,2,4,4,6,8,8-Heptamethylnonane CAS: 93685-80-4 for EU 4390-04-9 for other countries	Listed under 2,2,4,4,6,8,8-七甲基壬烷	Listed under 2,2,4,4,6,8,8-Heptamethyl-nonane (2,2,4,4,6,8,8-헵타메틸노난 KE-18266	Listed under Nonane, 2,2,4,4,6,8,8-heptamethyl-	Not listed	Listed under Hydrocarbons, C4, 1,3-butadiene-free, polymd., tetraisobutylene fraction, hydrogenated
Polyethylene glycol sorbitan monooleate CAS: 9005-65-6	Listed under 脱水山梨醇单油酸酯聚氧乙烯醚	Listed under (Z)-Mono-9-octadecenoate sorbitan poly(oxy-1,2-ethanediyl) derivs.; Polyoxyethylene sorbitan monooleate KE-25511	Listed under Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	Listed under Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs.	Listed under Sorbitan monooleate, ethoxylated

See Reference 18

Other regulations

Microplastics

Regulation updates statements related to the microplastics topic are available by country/area upon request. (see appendix)

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

2. Regulatory status according to the final applications

Cosmetic applications

All the intentional components of the ingredient as mentioned in statement 10 139 have been audited.

Country or region	Identifier (if available)	Compliance with specific regulation?	
Europe	European INCI name: a) Sodium acrylate/sodium Acryloyldimethyl Taurate Copolymer b) Isohexadecane c) Polysorbate 80	Regulation EC N° 1223/2009	Y
USA	PCPC INCI name (ID Monograph): a) Sodium acrylate/sodium Acryloyldimethyl Taurate Copolymer Monograph ID: 17390 b) Isohexadecane Monograph ID: 4032 c) Polysorbate 80 Monograph ID: 2457	**Classical cosmetic:** Federal Food, Drug and Cosmetic (FD&C) Act. 21 CFR 700 to 740	Y
	UNII: a) 1DXE3F3OZX b) 918X1OUF1E c) 6OZP39ZG8H	**OTC :** 21 CFR Part 3xx - OVER-THE-COUNTER DRUG PRODUCTS	Y (as excipient)
Japan	J-INCI name (PCPC Japanese translation): a) （アクリル酸Ｎａ／アクリロイルジメチルタウリンＮａ）コポリマー b) イソヘキサデカン c) ポリソルベート８０	**Classical cosmetic:** Japanese Standards of Cosmetics (Notification No.331 of 2000)	Y
	Approved as QD additive Monograph code: 99 Ingredient name: Sodium Acrylate・Sodium Acryloyldimethyltaurate Copolymer / Isohexadecane / Polysorbate 80	**Quasi Drug**: Pharmaceutical Affairs Law of Japan (PAL)	Y(Only the grade SIMULGEL EG QD is provided with QD monograph compliant COA)
Australia	See chemical status above	**Classical cosmetic:** Industrial Chemicals (notification and Assessment) Act 1989	Y
	AAN : a) Not available b) Isohexadecane c) Polysorbate 80	**Therapeutic Good:** Therapeutic Goods Act 1989	N

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Canada	See chemical status above	**Classical cosmetic:** The Food and Drug Act, Cosmetic Regulations (C.R.C., c. 869)	Y
	NHP ingredient Database: a) Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer listed as non medicinal ingredient. Topical use only b) 918X1OUF1E Isohexadecane Listed as non medicinal ingredient-Topical use only c) Polysorbate 80 listed	**Natural Health Product &** Non-prescription Drugs: Category IV Monographs **&** Natural Health Products regulation (SOR/2003-196)	Y (as excipient)
China	Chinese INCI names: a) Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (Chinese translation: 丙烯酸钠/丙烯酰二甲基牛磺酸钠共聚物) for INCI name PCPC is listed IECIC 2015 Final version* b) Isohexadecane (Chinese translation: 异十六烷) is listed IECIC 2015 Final version* c) Polysorbate 80 (Chinese translation: 聚山梨醇酯-80) is listed IECIC 2015 Final version*	**Cosmetics (functional and non-functional):** Safety and Technical Standard for Cosmetics (2015 - Notice 2015-268)	Y
	* The IECIC 2015 list published by CFDA on December 2015 is the official list of existing cosmetic ingredients for Chinese authorities.		
Taiwan	/	Law for the control of cosmetic hygiene (Dec 28th, 1972)-TFDA	Yes
New Zealand	/	Hazardous Substances and New Organisms Act 1996 & Cosmetic Product Group Standard	Yes
HONG KONG	/		Yes
Korea	/	Classical cosmetic: Korean Cosmetic Products Act	Yes
	No data available on cosmeceutical or QD Monographs	Cosmeceutical/ Quasi Drug according definition of functional cosmetics in Cosmetics Act Korea	No
Asean	/	ASEAN Harmonized Cosmetic Regulatory Scheme	Yes
Gulf Countries	/	Cosmetic Products Safety Requirements (GSO 1943:2009)	Yes

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

Saudi Arabia	/	Guidance for products classification & the Gulf Standard GSO 1943/2009	Yes
Morocco	/	Circulaire N°48 DMP/20	Yes
Andean community-CAN	/	Decision 516 Harmonizing Legislation in the Area of Cosmetic Products	Yes
Mexico	/	Ley General de Salud, 7 de Mayo 1997 : Capitulo IX y X	Yes
Mercosur	/	Mercosur resolutions for cosmetics (GMC)	Yes
Central American Common Market (CACM)	/	Reglamento technico centroamericano 2008	Yes
India	/	**Classical cosmetic:** The Drugs and Cosmetics Act, 1940 & The Drugs and Cosmetics Rules, 1945-Standard IS 4011(BSI)	Yes
Russia	/	**Classical cosmetic:** Federal Law N 289 076-4 - Technical regulation of cosmetics and perfumes (Sept. 2010)	Yes

See Reference 19

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

PHYSICO-CHEMICAL DATA

- Other physico-chemical data: *see SDS and CoA of the product*
- Stability data: *see attached CoA*
- Analytical data: *see attached CoA*

The analytical specifications warranted are only those mentioned on the certificate of analysis supplied with each delivery of the product.

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

TOXICOLOGICAL DATA

Acute and repeated toxicity

The different components included in **SIMULGEL™ EG** are well characterized in terms of toxicity (REACH dossiers, CIR, public and private data). No significant adverse effect is expected at the recommended dose level.

The copolymer, "2-Acrylamido-2-methylpropanesulfonic acid-acrylic acid copolymer sodium salt" is considered safe in cosmetics according to the available data (CIR, NICNAS, internal data). In addition, the residual monomers are well characterized in term of toxicity; Sodium acryloyldimethyltaurate (*i.e.* < 600 ppm) and sodium acrylate (*i.e.* < 260 ppm) are not classified for human health according to REACH dossier.
Isohexadecane (*i.e.* 2,2,4,4,6,8,8-Heptamethylnonane) may be fatal if swallowed and enters airways, it is harmful if inhaled according to REACH dossier, no other significant effect was observed based on available data (CIR, US EPA, ECHA). However, due to its physico-chemical properties (*i.e.* low vapour pressure, high boiling point) it is unlikely expected to be Inhaled in normal condition of use.
Polyethylene glycol sorbitan monooleate is not classified for human health according to the majority of notifications provided by companies to ECHA in CLP notifications, in addition no other significant effect has been reported in the available data (EFSA, CIR, FDA).
Sorbitan oleate are not classified for health according to GHS, based on data published (CIR, US EPA, ECHA).

Please refer to REACH identification numbers in Chapter : Regulatory Information 1. EUROPE.

In addition, toxicity tests were performed on the commercial product **SIMULGEL™ EG:**

In vitro tests:

Toxicity endpoint	Method	Reference	Result
Mutagenicity	Bacterial Reverse Mutation Test (Ames' Test - OECD 471).	Tox AMES SAFEPHARM 1190 016 - SIMULGEL EG a confidential.	Not mutagenic
Skin Irritation	In Vitro Skin Irritation (RHE Test Method - OECD 439) on Episkin™.	Tox_In vitro Skin irritation OECD439_IPL_FSR-IPL 160907_SIMULGEL EG_LCE16063_a_confidential.pdf	Not Irritant.
Eyes irritation	HETCAM test based on the Official Journal of the Republic of France (N° 300), December 26th, 1996	Tox HETCAM SEPPIC 1603 - SIMULGEL EG 5% a confidential.PDF	Not irritant at 5% (score =0)
	RBCA Test (INVITTOX protocol n°37)	Tox RBCA SEPPIC 653 - SIMULGEL 5% a confidential.PDF	Not irritant at 5% (L/D ratio > 100)

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Human tests:

Toxicity endpoint	Method	Reference	Result
Skin Irritation	Patch test 24 h (60 volunteers, occlusive patches)	Tox Patch test 24 h BIO HC - SIMULGEL EG 3% and 5% a & f confidential.PDF	Not irritant at 3% and 5% (HICV index = 0.02 and 0.07 respectively)
Skin sensitization	Human Repeated Patch Test (HRIPT) according to the Marzulli & Maybach method (50 volunteers, semi-occlusive patches)	Tox M&M EVIC CEBA IF 037 99 0237 - SIMULGEL EG a confidential.PDF M&M	No significant induction of skin irritation and no induction of allergic contact dermatitis at 6% in water.

For other information: see SDS and safety evaluation and SCD

Animal testing

Does this ingredient comply with the requirements 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?

☒ Yes ☐ No

See SEPPIC "alternative methods statement"

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

ECOTOXICOLOGICAL DATA

No experimental data was performed with SIMULGEL™ EG .

Ecotoxicity data are available on a close structure (compounds belonging to the same chemical families in similar quantities) which is considered suitable for read-across:

Ecotoxicological data	Method	Reference	Result
Biodegradability	OECD 301B	Biodegradability OCDE 301B LAUS AB07112801G605 - SIMULGEL SMS 88 a confidential	Not readily biodegradable
Algae acute toxicity	OECD 201	ECOTOX OCDE 201 LAUS 07112801G301 LCE07096 SIMULGEL SMS88 GB confidential.pdf	NOEC (72h) = 100 mg/L ErC50 (72h) > 100 mg/L
Daphnia acute toxicity	OECD 202	ECOTOX OCDE 202 LAUS 07112801G201 LCE07096 SIMULGEL SMS88 GB confidential.pdf	EC50 (48h) > 100 mg/L NOEC (48h) = 100 mg/L
Fish acute toxicity	OECD 203	ECOTOX OCDE 202 LAUS 07112801G201 LCE07096 SIMULGEL SMS88 GB confidential.pdf	96h NOEC = 100 mg/L 96h LC50> 100 mg/L

Based on literature data (read-across), the acute toxicity (EC50) on micro-organisms from activated sludge (according to OECD 209) is higher than 100 mg/L.

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

HAZARD CLASSIFICATION

EUROPE

According to the physico-chemical, toxicological and ecotoxicological data, is this ingredient classified as dangerous according to Regulation CLP EC 1272/2008?

See SDS for Europe

GERMANY

Water hazard class (WGK): *See German SDS*

See Reference 20

USA (national standards)

NFPA & HMIS rates: *See US SDS*

See Reference 21

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

APPENDICES

Please find attached the following documentation:

- SDS : Safety Data Sheet ☒
- Composition File : Statement 10 139 SIMULGEL EG Composition ☒
- COA : Certificate of Analysis (Specifications: batch 1) ☒
- SCD : Safety Complementary Data ☐
- Process : Flow chart 18 018 01 SIMULGEL EG ☐
- Technical Data Sheet ☐

Chemical regulation

Europe - REACH

- SEPPIC and the REACH regulation - S 3946 GB - ☒
- Regulation on substances of very high concern under Reach - Statement 08 234 - ☒
- Regulation update polymers in form of emulsion (EUROPE) 19 267 ☒

Other countries

- Chemical regulation ECN in Taiwan S 4625 GB ☒
- Chemical regulation in TURKEY S 4983 GB ☐
- Regulation update polymers in form of emulsion (USA) 19 257 ☒
- Regulation update polymers in form of emulsion (UK) 19 258 ☒
- Regulation update polymers in form of emulsion (TAIWAN) 19 259 ☒
- Regulation update polymers in form of emulsion (SWEDEN) 19 260 ☒
- Regulation update polymers in form of emulsion (NZ) 19 261 ☒
- Regulation update polymers in form of emulsion (ITALY) 19 262 ☒
- Regulation update polymers in form of emulsion (GERMANY) 19 263 ☒
- Regulation update polymers in form of emulsion (FRANCE) 19 264 ☒
- Regulation update polymers in form of emulsion (CANADA) 19 265 ☒
- Regulation update polymers in form of emulsion (KOREA) 19 266 ☒
- Regulation update polymers in form of emulsion (SWITZERLAND) 19 268 ☒

QHSE

- SEPPIC Management Manual – S4083 GB ☐
- Quality Manual of manufacturing plants (including ISO 9001 ; ISO 14001 ; OHSAS 18001 certificates) ☒
  - Castres (S3563/GB) ☐
  - Qing Pu ☐
- SEPPIC Handbook ☐
- ISO 9001 certificate by AFAQ
  - Certificate N° 1992/745 (AFAQ) ☐
- ISO 14001 certificate by AFAQ
  - Certificate N° 2000/14894 for Castres (AFAQ) ☐
  - Certificate N°2009/36161 for Qing Pu (AFAQ) ☐
- OHSAS 18001 certificate by AFAQ
  - Certificate N° 2009/36114 for Castres (AFAQ) ☐
  - Certificate N°2009/36161 for Qing Pu (AFAQ) ☐
- GMP certificates for pharmaceutical ingredients
  - Certificate N° 24/03/2006 for Castres (ANSM). ☐

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

- GMP certificates for cosmetic ingredients
  - o GMP cosmetic EFfCI guideline Certificate compliance of SEPPIC CASTRES ☐

- Seppic Management Commitment - S 4193 GB ☒
- Seppic Assessment for Health and Beauty Ingredients – S 4404 GB ☒
- RSPO Roundtable on Sustainable Palm Oil SEPPIC Statement S 4392 GB ☒
- RSPO Letter of Intent-Palm Oil – S 4397 GB ☐
- RSPO acceptance letter on 8 March 2010 ☐
- Carbon footprint - S 4489 GB ☒
- Kosher Certificate 4699/GB ☐

<u>General Certificates only for cosmetic uses:</u>

- Statement 01 020 no BSE Cosm gb ☒
- Statement 01 023 no BSE animal derivatives Cosm Ing. gb ☐
- Statement 13 004 Cosm Ing. Animal origin Global attestation gb ☐
- Statement 01 024 GMO free Cosm gb ☒
- Statement 12 091 GMO Policy gb ☒
- Statement 03 032 Alternative methods gb ☒
- Statement 04 053 Allergenic substances Cosm gb ☒
- Statement 04 065 Gluten free Cosm gb ☒
- Statement 05 050 Glycols ethers and Phthalates Cosm gb ☒
- Statement 06 007 CMR Cosm gb ☐
- Statement 08 088 Latex free Cosm gb ☒
- Statement 08 111 US and EU Cosm allowed gb ☒
- Statement 09 109 Dioxin free Cosm gb ☒
- Statement 10 033 nanomaterials Cosm gb ☒
- Statement 11 257 WHEAT free Cosm gb ☒
- Statement 12 029 Production annuelle psychotrope fr ☐
- Statement 08 001 Paraben free Cosm ingredients gb ☒
- Statement 09 002 ADM free HALAL Cosm gb ☒
- Statement 09 155 VOC Cosm gb ☐
- Statement 10 165 CITES Cosm gb ☒
- Statement 11 200 Alkylphenol derive. Cosm gb ☒
- Statement 13 002 Health certificate Cosm Ingredients gb ☒
- Statement 13 033 Conflict miménals Cosm Ingredients gb ☒
- Statement 13 045 Acrylamide free Polymers gb ☒
- Statement 13 094 Prop. 65 Cosm Ingredients gb ☒
- Statement 13 103 Metal Catalysts Cosm Ingredients gb ☒
- Statement 14 076 Nagoya Protocol Cosm Ingredients gb ☒
- Statement 15 032 Green palm Active ingredients gb ☐
- COSMOS/ECOCERT & NaTrue approvals ☐

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Document approved at Castres on September 17, 2019

By Matthieu BOUFFARTIGUE
Cosmetic regulatory affairs Manager

This information constitutes the knowledge of Seppic at this date.

It remains the customer's responsibility to assess the freedom to operate the material within the formulation it intends to develop and/or place onto the market.

UPDATES

Version (date)	Type of update	Responsible person
August, 98	1113V1/GB/AUGUST 98	A. GILLIO
September, 98	1113V2/GB/SEPTEMBER 98	A. GILLIO
January, 99	1113V3/GB/JANUARY 99	A. GILLIO
July, 1999	1113V4/GB/JULY 1999	C. PITZ
April, 2000	1113V5/GB/april 2000	C. PITZ
May, 2001	1113V6/GB/may 2001	C. PITZ
September, 2010	1113/GB/V7/September 2010	C. PITZ
March, 2006	1113/GB/07/ March 2006	C. PITZ
September, 2001	1113/GB/07/September 2001	C. PITZ
June, 2007	1113/GB/08/ June 2007	A. ROSO
December, 2001	1113/GB/08/December 2001	C. PITZ
August, 2008	1113/GB/09/ August 2008	A. ROSO
August, 2003	1113/GB/09/august 2003	C. PITZ
January 2009	1113/GB/10/ January 2009	A. ROSO/C. PITZ
February, 2004	1113/GB/10/February 2004	C. PITZ

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

October, 2004	1113/GB/11/October 2004	C. PITZ
September, 2010	1113/GB/11/September 2010	C. PITZ
November, 2005	1113/GB/12/november 2005	C. PITZ
May, 2006	1113/GB/14/may 2006	C. PITZ
October, 2019	9331/GB/01/October 2019	M. BOUFFARTIGUE
November, 2019	9331/GB/02/October 2019 Regulation update Microplastics	M. BOUFFARTIGUE

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

REFERENCES AND NOTES

Reference number	Details and links
Reference 1	Check our progress at: http://www.rspo.org/file/ACOP2012-OM_CGM%20Submitters.pdf SEPPIC is approved as an Ordinary member by the Executive Board of the RSPO. Request for Information regarding Company status on segregated palm and palm kernel derivatives. As a committed RSPO member since 2009, SEPPIC sources 100% of its palm oil from certified sustainable sources. SEPPIC status: SEPPIC membership to RSPO Convinced that Green palm certificates constitute a workable interim option during the transition period to physical use of certified oil for derivatives also, today we go on with a proactive communication to our palm-based derivatives suppliers towards fully physically segregated palm / palm kernel derivatives.
Reference 2	For fields of application see Article 13 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. See cosing website http://ec.europa.eu/consumers/cosmetics/cosing/
Reference 3	The SFDA (China)'s Public Notice N°4, 2012 limits the concentration of 1, 4-Dioxane in cosmetic product no more than 30mg/kg. ICCR Working Group on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products (Final report of January 2017) recommends a target level of trace 1,4-Dioxane in cosmetics less than or equal to 10 ppm in finished cosmetic products. http://www.iccr-cosmetics.org/files/2414/8717/1555/ICCR_14-Dioxane_Final_2017.pdf
Reference 4	VOC according directive 1999/13/EC amended 2004/42/EC & Switzerland Ordonance RS 814.018-Method: ISO 11890-2 http://www.admin.ch/ch/f/rs/814_018/app1.html
Reference 5	Residual Solvents in ANDAs: Question and Answers (FDA Office of Generic Drugs on October 28, 2008) and Guidelines CPMP/ICH/283/95 amended by CPMP/ICH/1940/00 and EMEA/CVMP/423/01 –FINAL on residual solvents (ICH Q3C guidelines). http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000742.jsp&mid=WC0b01ac0580028e8c USP General methods <467>: residual solvents European Pharmacopoeia chapt 5.4: residual solvents
Reference 6	For residual metal catalysts definition see Guideline EMEA/CPMP/SWP/4446/2000 USP GENERAL CHAPTER <232> : http://www.usp.org/usp-nf/official-text/revision-bulletins/elemental-impurities-limits-and-elemental-impurities-procedures-0
Reference 7	Environmental contaminants :Toxic metal impurities -> list defined by ICH Q3D draft guidelines of Europe and America http://ipecamericas.org/sites/default/files/PreliminaryDraftQ3Dv6.0Ref.Info_.pdf Conflict minerals law according On July 21, 2010 Congress enacted Section 1502 of the Dodd–Frank Wall Street Reform and Consumer Protection Act. Companies whose take their social responsibility seriously, disclose any products that contain following substances: tin, tungsten, tantalum, gold from the Democratic Republic of the Congo and adjoining countries which includes most of central Africa.
Reference 8	USA – CALIFORNIA: http://www.oehha.ca.gov/prop65.html
Reference 9	Limits are given by the European Pharmacopeia chapt 2.8.13 pesticides residues
Reference 10	Substances carcinogenic on the International Agency for Research on Cancer (IARC) list: http://monographs.iarc.fr/ Substances carcinogenic on the National Toxicology Program (NTP) list. http://ntp.niehs.nih.gov/?objectid=03C9F0A4-B1C2-31DE-ABA8508AE9949C57#A

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Reference 11	SCCS Final opinion on Fragrance allergens in cosmetic products: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf
Reference 12	Classification of carcinogens [edit] **International Agency for Research on Cancer** [edit] The International Agency for Research on Cancer (IARC) is an intergovernmental agency established in 1965, which forms part of the World Health Organization of the United Nations. It is based in Lyon, France. Since 1971 it has published a series of *Monographs on the Evaluation of Carcinogenic Risks to Humans*[20] that have been highly influential in the classification of possible carcinogens. • Group 1: the agent (mixture) is definitely carcinogenic to humans. The exposure circumstance entails exposures that are carcinogenic to humans. • Group 2A: the agent (mixture) is probably carcinogenic to humans. The exposure circumstance entails exposures that are probably carcinogenic to humans. • Group 2B: the agent (mixture) is possibly carcinogenic to humans. The exposure circumstance entails exposures that are possibly carcinogenic to humans. • Group 3: the agent (mixture or exposure circumstance) is not classifiable as to its carcinogenicity to humans. • Group 4: the agent (mixture) is probably not carcinogenic to humans. Approximate equivalences between classification schemes IARC / GHS / NTP / ACGIH / EU Group 1 / Cat. 1A / Known / A1 / Cat. 1 Group 2A / Cat. 1B / Reasonably suspected / A2 / Cat. 2 Group 2B / Cat. 2 / A3 / Cat. 3 Group 3 / A4 Group 4 / A5
Reference 13	CITES annexes: http://www.cites.org/fra/app/F-Apr27.pdf Regulation (CE) n°338/97, as amended, on the protection of species of wild fauna and flora by regulating trade therein http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0338:20100815:FR:PDF
Reference 14	WHO Category (1-4): http://www.who.int/en/ http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/form_at-toa_e.html classified as Category 3 according to the European Commission regulation 1069/2009 : http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:300:0001:0033:EN:PDF
Reference 15	EU Commission Recommendation 2011/696/EU of 18 October 2011 http:\ec.europa.eu/health/scientific_committees/opinions_layman/nanomaterials/en/index.htm Publication on Nanomaterials by the SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) of the European Commission: http://ec.europa.eu/health/scientific_committees/opinions_layman/nanomaterials2012/en/index.htm#il1 According to 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 http://www.developpement-durable.gouv.fr/spip.php?page=article&id_article=30578
Reference 16	EU ECOLABELs: According to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel. http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html
Reference 17	List of substances subject to authorization (annex XIV of REACH): http://www.echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp List of substances of Substances of Very High Concern (candidate list) http://echa.europa.eu/fr/candidate-list-table List of substances subject to restrictions (annex XVII of REACH): https://echa.europa.eu/fr/substances-restricted-under-reach REACH amendments regarding restrictions: https://echa.europa.eu/fr/regulations/reach/legislation
Reference 18	USA: TSCA => Toxic Substances Control Act https://www.epa.gov/tsca-inventory JAPAN: ENCS => Existing and New Chemical Substances http://www.nite.go.jp/en/chem/index.html AUSTRALIA: AICS => Australian Inventory of Chemical Substances https://www.nicnas.gov.au/ CANADA:

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

	DSL => Domestic Substance List NDSL => Non-Domestic Substance List https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/domestic.html CHINA: IECSC => Inventory of Existing Chemical Substance Control http://cciss.cirs-group.com/ KOREA: KECI => Korean Existing Chemicals Inventory http://ncis.nier.go.kr/main/Main.jsp NEW-ZEALAND: NZIoC => New Zealand Inventory of Chemicals http://www.epa.govt.nz/search-databases/Pages/nzioc-search.aspx PHILIPPINES: PICCS => Philippine Inventory of Chemicals and Chemical Substances. The PICCS inventory has been made available through the EMB website: http://chemical.emb.gov.ph/?page_id=138 MEXICO: INSQ => Mexican National Chemicals Inventory published first on November 2012 by National Institute of Ecology and Climate Change (INECC) VIETNAM : Published by CECHEDAR on September 15, 2016 http://vcerc.com/ TAIWAN: NECI=> National Existing Chemical Inventory (draft) Supplementary Existing Chemical Substance Nomination (SECN). Inventory published on 1st May 2012 Seppic has followed the ECN process (nomination on August 2010) For Taiwan NECI, you could search and find CAS numbers on NECI website: https://csnn.osha.gov.tw/content/home/Substance_Home.aspx The updated Existing chemical substances inventory (ECSI) is now available on CSNN website: https://csnn.osha.gov.tw/content/home/Substance_Home.aspx Users are able to identify the substances in search fields by entering CAS No., serial number(for substances without CAS number or substances with data protection), or exact chemical substances names in Chinese or English. The inventory was last updated on Dec. 22, 2012. Link search on inventories: http://www.cirs-reach.com/Inventory/National_Existing_Chemical_Inventory_NECI_Taiwan.html
Reference 19	The Asia Pacific Zone covers the following countries: South Korea, Japan, China, Taiwan, Thailand, Vietnam, Cambodia, Lao, Myanmar, Indonesia, Malaysia, Philippines, Singapore, Brunei, Australia, New Zealand, India, Pakistan, Sri Lanka, Bangladesh, and Nepal. The Gulf Countries covers: U.A.E (Sharjah, Ajman, Dubai, Abu Dhabi, Fujairah, Ras Alkhaymah, Um-Alquwain), Kuwait, Saudi Arabia, Bahrain, Qatar and Oman Asean Member Countries: Brunei Darussalam; Cambodia ; Indonesia ; Laos ; Malaysia ; Myanmar-Birmania ; Philippines ; Singapore ; Thailand ; VietNam Andean community- CAN Current members: Bolivia, Chile, Colombia, Ecuador; Associate members: Argentina, Brazil, Paraguay and Uruguay. ; Observer countries: Mexico, Panama; Former full members: Venezuela, Chile

	Mexico (Observer country of CAN & MERCOSUR). Prohibited & Restricted Substances in Perfumes & Cosmetics, List 3, Restricted Substances (Official Gazette, May 21, 2010) Mercosur (Full members: Argentina, Brazil, Paraguay, Uruguay, Venezuela; Associate members: Bolivia, Chile, Colombia, Ecuador, Peru; Observers: Mexico) Central American Common Market (CACM) Members: Salvador, Panama, Guatemala, Honduras, Nicaragua, Costa Rica
Reference 20	http://webrigoletto.uba.de/rigoletto/public/language.do?language=english
Reference 21	NFPA: http://www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=704 HMIS : http://www.paint.org/programs/hmis.html

Société d'Exploitation de Produits Pour les Industries Chimiques
Siège social / head office : 75, quai d'Orsay – 75321 Paris Cedex 07, FRANCE
S.A. à Directoire et Conseil de Surveillance au capital de 3 050 640 € – Siret 552 016 487 00407 – N° TVA UE / EU VAT Number : FR 95 552 016 487

SEPPIC PARIS
Paris La Défense, 50 Boulevard National, CS 9002
92257 La Garenne Colombes Cedex, France
Tél. +33 (0)1 42 91 00 00 Fax +33 (0)1 42 91 41 41

Air Liquide Healthcare is a world leader in medical gases, home healthcare, hygiene products and healthcare specialty ingredients. It aims to provide customers in the continuum of care from hospital to home with medical products, specialty ingredients and services that contribute to protecting vulnerable lives.

* SEPPIC being:
SEPPIC SA and its subsidiaries (addresses available on www.seppic.com)