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RAW MATERIAL IDENTIFICATION DATA

CHEMICAL INGREDIENTS

SEPIPLUS™ 400
2626/GB/11/June 2015

Procedure N° 11 – DT – 002

- 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.

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A. PRODUCT IDENTITY AND GENERAL INFORMATION

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GENERAL INFORMATION

1. Commercial name (Product code)

SEPIPLUS 400 (37490A)

2. INCI name

Polyacrylate-13 and Polyisobutene and Polysorbate 20

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
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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-SEPIPROD (Castres, France plant) and SEPPIC-SSCS (Qing Pu, China) are ISO 9001:2008 certified.

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

☒ Yes ☐ No

SEPPIC-SEPIPROD (Castres's plant) and SEPPIC-SSCS (Qing Pu's plant) are ISO 14001:2004 certified.

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

☒ Yes ☐ No

SEPPIC-SEPIPROD (Castres plant) and SEPPIC-SSCS (Qing Pu plant) are OHSAS 18001:2007 certified.

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

☒ Yes ☐ No

SEPPIC-SEPIPROD (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-SEPIPROD (Castres) received a certificate of inspection from ANSM ex AFSSAPS (French Health Products safety Agency) for all the pharmaceutical materials, according to ICH Q7a guideline (annex 18 as

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European GMP for active pharmaceutical ingredient).
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. Patent

- Has SEPPIC filed patent applications relating to this ingredient and/or its preparation process and/or its use?

☒ Yes ☐ No

SEPPIC owns industrial property related to this product. According to the continuous enlargement of this industrial property and the regular evolution of associated examination procedures, SEPPIC will provide patents application and/or patent publication numbers upon request

6. Codes

Customs: HS code 390690

7. Function and use level

- Function of the ingredient: Thickening agent, rheology modifier
- Recommended use concentration: 1-5%
- Fields of application: Cosmetic

See Reference 2

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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

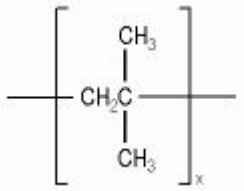
	CAS number	CAS name	Synonym
1	152728-72-8	2-Propenoic acid, polymer with 2-methyl-2[(1-oxo-2propenyl)amino]-1-propanesulfonic acid monosodium salt, 2-propenamide and sodium 2-propenoate	Copolymer of acrylamide, sodium acrylate and sodium acryloyldimethyltaurate
2	9003-27-4	1-propene, 2-methyl-, homopolymer	○ 2-methyl-1-propene homopolymer ○ Isobutene homopolymer ○ Polyisobutene
3	9005-64-5	Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	○ Polyoxyethylene (20) sorbitan monolaurate ○ Poly(oxyethylene)sorbitan monolaurate ○ Polysorbate 20

Chemical structure of main components:

Component 1: 2-Propenoic acid, polymer with 2-methyl-2[(1-oxo-2propenyl)amino]-1-propanesulfonic acid monosodium salt, 2-propenamide and sodium 2-propenoate

Component 2: Polyisobutene

$[CH_2C(CH_3)_2]_x$



Component 3: Polysorbate 20
Mixture of laurate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 20 moles of ethylene oxide.

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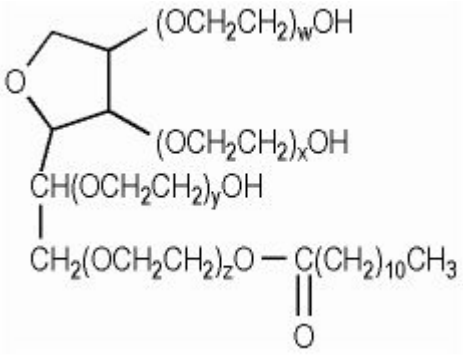

Where w + x + y + z has an average value of 20

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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
Residual Monomers: Acrylamide Acrylic acid Acryloyldimethyltaurate	 Max 2 ppm Max 100 ppm Max 600 ppm
Sorbitan isostearate	3-5%
Impurities	**Comments**
Methanol	Not expected
Ethanol	Not expected
Isopropyl alcohol	Not expected
1,4-butanediol	Not expected
Acetone	Not expected
Methylene Glycol	Not expected
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)*	No VOC higher than the pertinent level (0.1%)
Other residual Solvents *(see Reference 5)* ICH Pharmacopae method USP <467> & EP 5.4	No residual solvents higher than the applicable level
Glycol ethers	Not expected
Phthalates	Not expected
Terpenes	Not expected
3-dimethylaminopropylamine (DMAPA)	Not expected
Cocamidopropyldimethylamine	Not expected

* based on calculation according to the percentage of ethoxylated materials in the ingredient.

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Impurities	Comments
Heavy metals: according EP method 2.4.8.C	
- Lead Pb	< 5 ppm*
- Cadmium Cd	< 2 ppm*
- Mercury Hg	< 0.3 ppm*
- Arsenic As	< 1 ppm*
- Nickel Ni	< 2 ppm*
- Chromium Cr (esp. Cr VI+)	< 2 ppm*
- Cobalt Co	< 2 ppm*
- Other (copper Cu, silver Ag...)	Cu < 2 ppm* Sb < 5 ppm* Ag < 2 ppm*
Residual metal catalysts 10 *(see Reference 6)* and environmental contaminants or Conflict minerals US law 11 *(see Reference 7)*	See above
Proposition 65 and bill 484 listed substances** *(see Reference 8)*	See above acrylamide, ethylene oxide and 1,4-dioxane
Monochloroacetic acid	Not expected
Dichloroacetic acid	Not expected
Chloroacetamide	Not expected
Free amines	Not expected
Alcanol amines: MEA, DEA, TEA….	Not expected
Nitrosamines	Not expected
EDTA (Ethylenediaminetetraacetic acid) and its salts and its impurities as NTA	Not expected
Silicone and latex	Not expected
Preservatives Parabens (salts and esters of 4-hydroxybenzoic acid) Other antimicrobiological agents (fungicides, biocides…)	Not expected
Polycyclic Aromatic Hydrocarbons (PAH): benzopyrenes & DMSO…	Not expected
Proteins	Not expected

* performed on batch T44041 by ICP-MS, GFAA or CVAFS.

** 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-al

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Impurities	Comments
Soy & soybeans, nuts (peanuts, Tree nuts), cereals, yeast, corn, milk, eggs, seeds, fish, shellfish.	Not expected
Pesticides *(see Reference 9)*	Not expected
Endocrine pertubators	Not expected
Dioxin, PCB	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
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	YES See SEPPIC 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	YES See SEPPIC CMR Statement

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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/10g	PE 2.6.13	☐ Each batch ☒ Statistical analysis ☐ Qualified batch only ☐ Not applicable

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B. MANUFACTURING, ORIGIN AND SUSTAINABLE DEVELOPMENT

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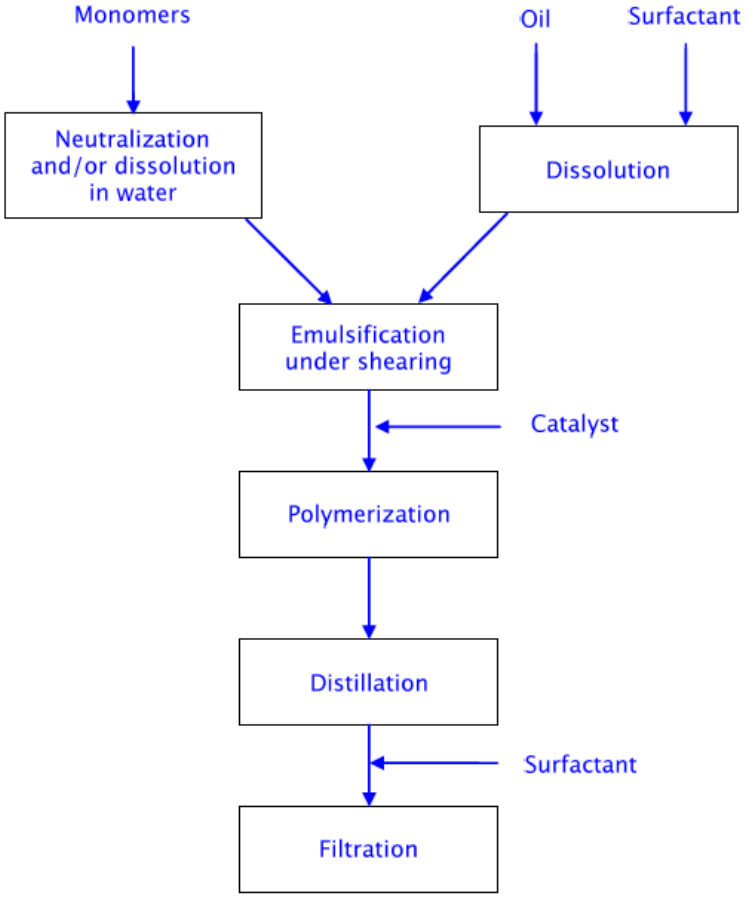
INFORMATION ON MANUFACTURING

Description of the manufacturing process

SEPIPLUS 400 is obtained by polymerization in inverse emulsion followed by a distillation.

Flow Chart:



Component	Identity
Monomers	2-acrylamido-2-methylpropane sulfonic acid Acrylamide Acrylic acid
Oil	Polyisobutene
Surfactants	Sorbitan isostearate Polysorbate 20
Catalyst	Confidential

Country of Manufacturing: FRANCE

SEPPIC - Usine Lacaze Basse - BP 228 - 81105 CASTRES CEDEX France

In the market since: 2004

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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

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

Details on origin

Starting materials	Source
Acrylamide	Synthetic
Acrylic acid	Synthetic
Acryloyldimethyl taurate	Synthetic
Polyisobutene	Synthetic
Polysorbate 20	Vegetal (sorbitol and lauric acid)
Sorbitan isostearate	Vegetal (sorbitol and isostearic acid)

In case of vegetal origin

Details of origin:

Starting materials	Name of the plant	Part of the plant	Origin of the plant
Sorbitol	Wheat or corn	Seeds	Europe
Lauric acid	Coconut	Meat	Not communicated by our suppliers
Isostearic acid	non palm oil (rapeseed or other)	Not communicated by our suppliers	Not communicated by our suppliers

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

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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 SEPPIC GMO certificate

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

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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.

- During the manufacturing of your chemically transformed ingredient, are there intermediary reactions?

☐ Yes ☒ No

2. Labels

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

☐ Yes ☐ No Not applicable

EU Ecolabel
Ecotoxicological data available on the ingredient for the calculation of the CDV (Critical Dilution Volume) of the finished product according to the EU ECO-LABEL to soaps, shampoos and hair conditioners (Commission Decision 2007/506/EC)

☐ Yes ☐ No Not applicable

See Reference 16

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PACKAGING, LABELING & STORAGE

Packaging

Nature/type of packaging:

OTP30

	primary packaging*	Pallet**
Type of Material	Plastic drum	Wood
Size (cm)	Ø 31,5 ; h=51,7	114 x 114
Specifications (weight, …)	Net weight: 30 kg	794 kg 24 boxes/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 information:

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

Other information:

Batch separation is maintained during packaging: ☒Yes ☐No

Silica Gel Desiccant is used during packaging: ☐Yes ☒No

The air cleanliness class in final processing and packaging rooms is:
☐ Class 100 ☐Class 10 000 ☐ Class 100 000 Not applicable

Appropriate controls & measures taken on containers & closures of sterile drug substances are: Not applicable. We are producer of chemical additives.

There is a quarantine system for final material: ☐Yes ☒No

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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.

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.

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C. REGULATORY AND INTRINSIC DATA

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REGULATORY INFORMATION

1. Chemical inventories and regulatory status

EUROPE

Component (usual name)	N°CAS	N°EINECS/ ELINCS/NLP	REACH registration number
2-propenoic acid, polymer with 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt and sodium 2-porpenoate	152728-72-8	Not applicable	Exempted (polymer)
Sorbitan monolaurate, ethoxylated	9005-64-5	Not applicable	Exempted (polymer)
Hydrogenated polyisobutene	9003-27-4	Not applicable	Exempted (polymer)
Sorbitan isooctadecanoate	71902-01-7	276-171-2	Pre-registered. Deadline: 2018

Detailed REACH status of each component: see Reach Statement

The ingredient or one of these 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

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OTHER COUNTRIES

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

	USA	JAPAN	AUSTRALIA	CANADA	MEXICO
	TSCA	ENCS/ISHL	AICS	DSL/NDSL	INSQ
2-Propenoic acid, polymer with 2-methyl-2[(1-oxo-2propenyl)amino]-1-propane-sulfo-nic acid monoso-dium salt, 2-propen-amide and sodium 2-propenoate CAS: 152728-72-8	Not listed	Not listed	Listed Under 2-Propenoic acid, polymer with 2-methyl-2[(1-oxo-2propenyl)amino]-1-propane-sulfo-nic acid monoso-dium salt, 2-propen-amide and sodium 2-propenoate Meet PLC criteria in Australia (Reference dossier: PLC/652)	Listed DSL Under 2-Propenoic acid, polymer with 2-methyl-2[(1-oxo-2propenyl)amino]-1-propane-sulfo-nic acid monoso-dium salt, 2-propen-amide and sodium 2-propenoate	Not listed
1-propene, 2-methyl-, homopolymer CAS: 9003-27-4	Listed Under 1-propene, 2-methyl-, homopolymer	Listed 1-propene, 2-methyl-, homopolymer ENCS/ISHL: (6)-774	Listed Under 1-propene, 2-methyl-, homopolymer	Listed DSL Under 1-propene, 2-methyl-, homopolymer	Listed DSL Under 1-propene, 2-methyl-, homopolymer
Sorbitan, monododecanoate,poly(oxy-1,2-ethanediyl) derivs. CAS: 9005-64-5	Listed Under Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	Listed Under Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs. ENCS/ISHL: (8)-55	Listed Under Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	Listed Under Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	Listed Under Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.
Sorbitan, isooctadecanoate CAS 71902-01-7	Listed Under Sorbitan, isooctadecanoate	Listed Under Sorbitan, isooctadecanoate ENCS/ISHL: (8)-63	Listed Under Sorbitan, isooctadecanoate	Listed Under Sorbitan, isooctadecanoate	Listed Under Sorbitan, isooctadecanoate

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	CHINA	KOREA	NEW-ZEALAND	PHILIPPINES
	IECSC	KECI	NZIoC	PICCS
2-Propenoic acid, polymer with 2-methyl-2[(1-oxo -2propenyl)amino] -1-propane- sulfo-nic acid monoso-dium salt, 2-propen-amide and sodium 2-propenoate CAS: 152728-72-8	Registered*	Not listed	Not listed	Not listed
1-propene, 2-methyl-, homopolymer CAS: 9003-27-4	Listed Under 聚异丁烯的均聚物	Listed under 1-propene, 2-methyl-, homo-polymer KE-28918	Listed Under 1-propene, 2-methyl-, homopolymer	Listed Under 1-propene, 2-methyl-, homopolymer
Sorbitan, monododecan oate,poly(oxy-1,2-ethanediyl) derivs. CAS: 9005-64-5	Listed Under 聚氧乙烯脱水山梨醇单月桂酸酯	Listed Under Sorbitan, monododecan oate, poly(oxy-1,2-etha nediyl) derivs. KE-31681	Listed Under Sorbitan, monododecan oate, poly(oxy-1,2-etha nediyl) derivs.	Listed Under Sorbitan, monododecan oate, poly(oxy-1,2-etha nediyl) derivs.
Sorbitan, isooctadecanoate CAS: 71902-01-7	Listed Under 异十八烷酸山梨醇酯	Listed Under Sorbitan, isooctadecanoate	Listed Under Sorbitan, isooctadecanoate	Listed Under Sorbitan, isooctadecanoate

** Simplified registration for import quantities up to 10000kg/y of the polymer has been done on May 2011 and approved on 22 July 2011 by CRC-MEP. Certificate Xin Jian Deng T-112318.*
Chinese chemical substance name: 2-丙烯酸与2-丙烯酰胺、2-甲基-2-[(1-氧-2-丙烯基) 氨基]-1-丙烷磺酸单钠盐和2-丙烯酸钠的聚合物

See Reference 18

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Other regulations

Microplastics

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

2. Regulatory status according to the final applications

Cosmetic applications

All the intentional components of the ingredient as mentioned in statement 11 214 have been audited.

Country or region	Identifier (if available)	Compliance with specific regulation?	
Europe	European INCI name: a) Polyacrylate-13 b) Polyisobutene c) Polysorbate 20 d) Sorbitan Isostearate	Regulation EC N° 1223/2009	Y
USA	PCPC INCI name (ID Monograph): a) Polyacrylate-13 (ID: 18900) b) Polyisobutene (ID: 2436) c) Polysorbate 20 (ID: 2451) d) Sorbitan Isostearate (ID: 2983)	**Classical cosmetic:** Federal Food, Drug and Cosmetic (FD&C) Act. 21 CFR 700 to 740	Y
	UNII: a) Not available b) Not available c) 7T1F30V5YH d) 01S2G2C1E4	**OTC :** 21 CFR Part 3xx - OVER-THE-COUNTER DRUG PRODUCTS	Y (as excipient)
Japan	J-INCI name (PCPC Japanese translation): a) ポリアクリレート - １３ b) ポリイソブテン c) ポリソルベート２０ d) イソステアリン酸ソルビタン	**Classical cosmetic:** Japanese Standards of Cosmetics (Notification No.331 of 2000)	Y
	No data available on QD monograph	**Quasi Drug**: Pharmaceutical Affairs Law of Japan (PAL)	N
Australia	See chemical status above	**Classical cosmetic:** Industrial Chemicals (notification and Assessment) Act 1989	Y
	AAN : a) Not available b) Not available c) Polysorbate 20 d) Sorbitan isostearate	**Therapeutic Good:** Therapeutic Goods Act 1989	N

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Canada	See chemical status above	**Classical cosmetic:** The Food and Drug Act, Cosmetic Regulations (C.R.C., c. 869)	Y
	NHP ingredient Database: a) listed as non medicinal ingredient b) listed as non medicinal ingredient c) listed as non medicinal ingredient d) listed as non medicinal ingredient	**Natural Health Product &** Non-prescription Drugs: Category IV Monographs **&**Natural Health Products regulation (SOR/2003-196)	Y (as excipient)
China	Chinese INCI names: a) 聚丙烯酸酯-13 for INCI name PCPC Polyacrylate-13 - Is listed IECIC 2015 Final version* b) 聚异丁烯 for INCI name PCPC Polyisobutene - Is listed MoH 2003 - Is listed SFDA 2007 - Is listed IECIC 2015 Final version* c) 聚山梨醇酯-20 for INCI name PCPC Polysorbate 20 - Is listed MoH 2003 - Is listed SFDA 2007 - Is listed IECIC 2015 Final version* d) 山梨坦异硬脂酸酯 for INCI name PCPC Sorbitan Isostearate - Is listed MoH 2003 - Is listed SFDA 2007 - Is listed IECIC 2015 Final version*	**Cosmetics (functional and non-functional):** Hygienic Standard for cosmetics of 2007(GB7616-199)	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	Y
New Zealand	/	Hazardous Substances and New Organisms Act 1996 & Cosmetic Product Group Standard	Y
HONG KONG	/		Y
Korea	/	Classical cosmetic: Korean Cosmetic Products Act	Y
	No data available on cosmeceutical or QD Monographs	Cosmeceutical/ Quasi Drug according definition of functional cosmetics in Cosmetics Act Korea	N
Asean	/	ASEAN Harmonized Cosmetic Regulatory Scheme	Y

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

See Reference 19

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PHYSICO-CHEMICAL DATA

- Molecular weight of each component: Polyacrylate-13: MW > 1Million Daltons
- 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.

TOXICOLOGICAL DATA

Acute and repeated toxicity

In vitro tests:

Toxicity endpoint	Method	Reference	Result
Mutagenicity	Ames test (OECD 471)	LEMI R2004-DTT662-2 FINAL LCE04003 a confidential.pdf	Non (pro)mutagenic
Eye irritation	HET CAM	SEPPICtoxHETCAM2652a.pdf	Non irritant in a 3% dilution
	RBCA	SEPPICtoxRBCA993a.pdf	Non irritant in a 5% dilution

Human tests:

Toxicity endpoint	Method	Reference	Result
Skin Irritation	Patch Test 48h, occlusive (20 volunteers)	DERMSCAN 1040031 LCE04002-58735 a confidential.pdf	Non irritating at 4.60% in water
Skin sensitization	HRIPT, occlusive (50 volunteers)	M&M ASTER PC3504 LCE04014a confidential	Non irritating and non sensitizing at 5% 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"

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ECOTOXICOLOGICAL DATA

No ecotoxicity data performed on Sepiplus 400.
By analogy and based on literature data, Sepiplus 400 is expected to be:

- Non readily biodegradable
- Non bioaccumulative

Non toxic to aquatic organisms (based on acute aquatic toxicity tests)

HAZARD CLASSIFICATION

EUROPE

According to the physico-chemical, toxicological and ecological data, does this ingredient classify as dangerous according to the Directives 67/548/CEE and 1999/45/CE (classification and labelling of dangerous substances and preparations) or to the Regulation CLP 1272/2008?

See SDS for Europe

GERMANY

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

See Reference 20

USA (national standards)

NFPA & HMIS rates: *See SDS for USA*

See Reference 21

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APPENDICES

Please find attached the following documentation:

- SDS : Safety Data Sheet ☒
- Composition File : Statement 11 041 Composition ☒
- COA : Certificate of Analysis (Specifications: batch 1) ☒
- SCD : Safety Complementary Data template xxxx & Statement xxxx safety data expertise report ☐
- Technical Data Sheet ☐

Chemical regulation

Europe - REACH

- REACH Statement ☒
- 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 01 ☒
- 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 ☐
- ISO 9001certificate by AFAQ
  - Certificate N° 1992/745 (AFAQ) ☒
- ISO 14001certificate by AFAQ
  - Certificate N° 2000/14894 for Castres (AFAQ) ☒
  - Certificate N°2009/36161 for Qing Pu (AFAQ) ☐
- OHSAS 18001certificate 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 exAFFaPS). ☒
- GMP certificates for cosmetic ingredients

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- 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 ☒
- Seppic Assessment for food ingredients S 4644 GB ☒
- Social Accountability Norm SA8000 – 060922

- SEPPIC commitment on Social Responsibility:

SA 8000 social responsibility ☒

- SEPPIC code of conduct (GB version after FR one)-S4382 FR/GB ☒
- RSPO Commitment 6726 ☒

General Certificates only for cosmetic uses:

- 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 091GMO 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 10 039 no DEG cosm gb ☒
- Statement 10 033 nanomaterials Cosm gb ☒
- Statement 11 257 WHEAT free Cosm gb ☒
- Statement 12 029 Production annuelle psychotrope fr ☒
- Statement 06 038 Formol free Cosm ingredients gb ☒
- Statement 08 001 Paraben free Cosm ingredients gb ☒
- Statement 08 032 Pesticides 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 ☒
- COSMOS/ECOCERT & NaTrue approvals ☐

Document approved at Paris La Défense on July 20, 2015

By Leslie Levas
Cosmetic regulatory affairs Manager

This information constitutes the knowledge of Seppic at this date.

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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
November 25, 2019	Chinese Cosmetic regulation update, Microplastics regulation update	Matthieu BOUFFARTIGUE

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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.
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).
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
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

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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 Recommandation 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): http://chemexcil-reachhelp.com/index.php?option=com_content&task=view&id=31&Itemid=44 REACH amendments regarding restrictions: http://ec.europa.eu/enterprise/sectors/chemicals/reach/restrictions/index_en.htm
Reference 18	USA: TSCA => Toxic Substances Control Act JAPAN: ENCS => Existing and New Chemical Substances ISHL => Industrial Safety and Health Law AUSTRALIA: AICS => Australian Inventory of Chemical Substances CANADA: DSL => Domestic Substance List NDSL => Non-Domestic Substance List

	CHINA: IECSC => Inventory of Existing Chemical Substance Control http://cciss.cirs-group.com/ KOREA: KECI => Korean Existing Chemicals Inventory NEW-ZEALAND: NZIoC => New Zealand Inventory of Chemicals PHILIPPINES: PICCS => Philippine Inventory of Chemicals and Chemical Substances. The PICCS inventory has been made available through the EMB website: www.gov.ph and http://202.57.47.222/internal/CasREgistry.aspx MEXICO: INSQ => Mexican National Chemicals Inventory published first on November 2012 by National Institute of Ecology and Climate Change (INECC) http://www.ine.gob.mx/insq 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: http://csnn.cla.gov.tw/content/Substance_Query_Q.aspx The updated Existing chemical substances inventory (ECSI) is now available on CSNN website: http://csnn.cla.gov.tw/content/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) see Mexico. 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

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Nota:
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