SEPPIC PARIS
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RAW MATERIAL IDENTIFICATION DATA

CHEMICAL INGREDIENTS

MONTANOV™ 202
C/1048/GB/12/June 2021

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..

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

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A. PRODUCT IDENTITY AND GENERAL INFORMATION

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GENERAL INFORMATION

1. Commercial name

MONTANOV™ 202 (Code: 36196T)

2. INCI name

Arachidyl Alcohol and Behenyl Alcohol and Arachidyl Glucoside

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

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

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- 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: Non ionic emulsifier
- Recommended use concentration: 0.5 - 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

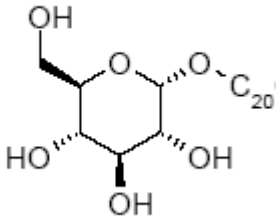
	CAS number	CAS name	Synonym
1	90604-34-5	Alcohols, C20-22	Adol 67, Adol 71, C20-22 Alcohols, Alfol 2022
2	100231-68-3	D-Glucoside, eicosyl	Eicosyl D-glucoside

CAS number 90604-34-5 can be covered by two separate CAS numbers:
CAS 626-96-9 and CAS 661-19-8

Chemical structure of main components:

Component 1: $C_{20}H_{42}O$ = $CH_3(CH_2)_{18}CH_2OH$ & $C_{22}H_{46}O$ = $CH_3(CH_2)_{20}CH_2OH$

Component 2: $C_{26}H_{52}O_6$ = $(C_6H_{11}O_5)$-O-$(CH_2)_{19}$-Me



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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
Water	0-1 %
Glucose	0-1 %
Impurities	**Comments**
Methanol	Not expected
Ethanol	Not expected
Isopropyl alcohol	Not expected
1,4-butanediol	Not expected
Acetone	Not expected
Monoethylene glycol	Not expected
Diethylene glycol	Not expected
Phenol	Not expected
Alkyl phenols	Not expected
Ethylene oxide	Not expected
Other oxide (OP, OB, …)	Not expected
1,4-dioxane *(see Reference 3)*	Not expected
Volatile Organic Compounds *(see Reference 4)*	No VOC higher than the pertinent level (0.1%)
Other residual Solvents *(see Reference 5)* according to ICH Q3C Guidelines, USP <467> & EP 5.4	No residual solvents higher than the applicable level

Technically unavoidable traces are permitted according to provisions of Chap IV-Art 17 of European Cosmetic Product Regulation 1223/2009/EC.

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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 Cooper* : < 5 ppm
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)*	Not expected
Glycol ethers	Not expected
Phthalates	Not expected
Terpenes	Not expected
3-dimethylaminopropylamine (DMAPA)	Not expected
Cocamidoppropyldimethylamine	Not expected
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

* Tested on batch T53015
** 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

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Impurities	Comments
Preservatives Parabens (salts and esters of 4-hydroxybenzoic acid) Other antimicrobiological agents (fungicides, biocides…)	Not expected
Polycyclic Aromatic Hydrocarbons (PAH): benzopyrenes & DMSO…	Not expected
Hydroquinone; Methyletherhydroquinone (MEHQ) Other hydroquinone dérivatives	Not expected
Nitrates	Not expected
Nitrites	Not expected
Sulfites	Not expected
Antioxidants (Reduction agents)	Not expected
Oxydants: H2O2…	Not expected
Proteins	Not expected (arachidyl alcohol is not derived from peanut oil - see page 14)
Soy & soybeans, nuts (peanuts, Tree nuts), cereals, yeast, corn, milk, eggs, seeds, fish, shellfish.	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

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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	Compliant See Allergenic Substances Statement

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4. Microbiological data

Microorganism	Result	Method	Monitoring
Total bacterial Aerobies	<100 CFU/g	PE 2.6.12	☐ Each batch ☐ Statistical analysis ☐ Qualified batch only ☒ Not applicable*
Total Yeasts and moulds	<100 CFU/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*

*Not applicable: the risk of microbiological contamination of the product is not expected according to its structure (nearly anhydrous).

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B. MANUFACTURING, ORIGIN AND SUSTAINABLE DEVELOPMENT

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INFORMATION ON MANUFACTURING

Country of Manufacturing: FRANCE

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

In the market since: 1997

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

In case of vegetable origin:

Starting materials	Name of the plant	Part of the plant	Origin of the plant
Arachidyl Alcohol Behenyl Alcohol	Rapeseed/Mustard	Seeds	Europe (Germany, UK and France)/ India
Glucose	Wheat/Corn	Seeds	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

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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.

Bio-based content of the product:

- Renewable content measured according to the “Association Chimie du Végétal” (ACDV) standard : 100%
- Natural origin index according to ISO 16128 standard: 100% natural origin content

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2. Labels

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

☒ Yes ☐ No

ECOCERT: 100% Natural origin
COSMOS: 100% CPAI
NATRUE: 100% Derived natural

For the Nordic Swan Ecolabel, please contact us for more information

See Reference 16

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PACKAGING, LABELING & STORAGE

1. Packaging

Nature/type of packaging: Cardboard box

CAM70L

	Primary packaging*	Secondary packaging	Pallet**
Type of Material	Single-layer film of polyethylene LDPE	Cardboard	Wood
Size (cm)	39x29x57 (Thickness 150µm)	38.5 x 28.5 x 56	100 x 120 x 128
Specifications (weight, …)	-	Net weight: 25 kg	546 kg 20 cardboard/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

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.

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C. REGULATORY AND INTRINSIC DATA

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REGULATORY INFORMATION

1. Chemical inventories and regulatory status

EUROPE

Chemical name	Synonym	N°EC (assigned by ECHA)	Status in the supply chain	REACH status
Acetalization products between glucose and C20/22 alcohol	Arachidyl glucoside and arachidyl alcohol and behenyl alcohol	ECHA number: 923-835-0	Manufacturer	01-2119385312-42-0000

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

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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
		TSCA	ENCS/ISHL	AICS	DSL/NDSL
Alcohol C 20 - 22	CAS: 629-96-9	Listed under 1-Eicosanol	Listed under 1-Eicosanol ENCS/ISHL: (2)-217	Listed under 1-Eicosanol	Listed DSL under 1-Eicosanol
	CAS: 661-19-8	Listed under 1-Docosanol	Listed under 1-Docosanol ENCS/ISHL: (2)-217	Listed under 1-Docosanol	Listed DSL under 1-Docosanol
D-glucoside, eicosyl CAS: 100231-68-3		Not listed	Listed under D-glucoside, eicosyl ENCS/ISHL: (5)-3641	Listed under D-glucoside, eicosyl	Not listed

		CHINA	NEW-ZEALAND	PHILIPPINES	TAIWAN
		IECSC	NZIoC	PICCS	TCSI
Alcohol C 20 - 22	CAS: 629-96-9	Listed under 1-二十醇	Listed under 1-Eicosanol	Listed under 1-Eicosanol	Listed
	CAS: 661-19-8	Listed under 二十二烷-1-醇	Listed under 1-Docosanol	Listed under 1-Docosanol	Listed
D-glucoside, eicosyl CAS: 100231-68-3		Listed under 二十烷基-D-配糖物	Listed under D-glucoside, eicosyl	Not listed	Listed

See Reference 18

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2. Regulatory status according to the final applications

Cosmetic applications

All the intentional components of the ingredient as mentioned in statement 10 130 have been audited.

Country or region	Identifier (if available)	Compliance with specific regulation?	
Europe	European INCI name: a) Arachidyl alcohol b) Behenyl Alcohol c) Arachidyl Glucoside	Regulation EC N° 1223/2009	Y
USA	PCPC INCI name (ID Monograph): a) Arachidyl alcohol (ID: 6198) b) Behenyl Alcohol (ID: 262) c) Arachidyl Glucoside (ID: 11228)	**Classical cosmetic:** Federal Food, Drug and Cosmetic (FD&C) Act. 21 CFR 700 to 740	Y
	UNII: a) 1QR1QRA9BU b) 9G1OE216XY c) 6JVW35JOOJ	**OTC :** 21 CFR Part 3xx - OVER-THE-COUNTER DRUG PRODUCTS	Y (as excipient)
Japan	J-INCI name (PCPC Japanese translation): a) アラキルアルコール b) ベヘニルアルコール c) アラキルグルコシド	**Classical cosmetic:** Japanese Standards of Cosmetics (Notification No.331 of 2000)	Y
	Listed on Japan quasi drug list	**Quasi Drug**: Pharmaceutical Affairs Law of Japan (PAL)	Y
Australia	See chemical status above	**Classical cosmetic:** Industrial Chemicals (notification and Assessment) Act 1989	Y
	AAN : a) Arachidyl alcohol (dermal use only, limit: 1%, not to be included in topical products intended for use in eye vicinity) b) Behenyl Alcohol (dermal use only) c) Arachidyl Glucoside (dermal use only, limit: 1%, not to be included in topical products intended for use in eye vicinity)	**Therapeutic Good:** Therapeutic Goods Act 1989	Y as excipient (dermal use only, limit: 1.6%, not to be included in topical products intended for use in eye vicinity)

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Canada	See chemical status above	**Classical cosmetic:** The Food and Drug Act, Cosmetic Regulations (C.R.C., c. 869)	Y*
	* For uses covered under the Canadian Food and Drugs Act only		
	NHP ingredient Database: a) Arachidyl alcohol listed as non medicinal ingredient b) Behenyl Alcohol listed as non medicinal ingredient c) Arachidyl Glucoside 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) 花生醇 Arachidyl Alcohol for INCI name PCPC is listed IECIC 2015 Final version* b) 山嵛醇 Behenyl Alcohol for INCI name PCPC is listed IECIC 2015 Final version* c) 花生醇葡糖苷 Arachidyl Glucoside for INCI name PCPC 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
Saudi Arabia	/	Guidance for products classification & the Gulf Standard GSO 1943/2009	Yes

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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

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PHYSICO-CHEMICAL DATA

- Molecular weight :
  - C20-22 Alcohols: 304g/mol
  - Arachidyl Glucoside : 467g/mol to 793g/mol according to polymerization degree (DP = 1 to 3; for example DP=1.38: PM= 529g/mol)
- UV spectrum: no absorption
- IR spectrum: Average spectrum performed by attenuated total reflectance (ATR-monoreflexion GE) from three batches-qualitative data available upon request
- Stability data: *see attached CoA*
- Analytical data: *see attached CoA*
- Other physico-chemical data: *see SDS and CoA of the product*

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

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TOXICOLOGICAL DATA

Acute and repeated toxicity

In vitro tests:

Toxicity endpoint	Method	Reference	Result
Mutagenicity	Bacterial Reverse Mutation Test (Ames - OECD 471)	Tox Mutagenicity AMES SAFEPHARM 1190 005 - MONTANOV 202 a confidential	Non (pro)mutagenic (tested up to 5000 µg/plate)
	In vitro Mammalian Chromosome Aberration Test (OECD 473)	Tox CHROMOSOME ABERRATION OCDE 473 IIBAT 08013 LCE07104 MONTANOV 202 GB CONFIDENTIAL	Non (pro)genotoxic (tested up to 500 µg/mL)
	In vitro Mammalian Cell Gene Mutation Test (OECD 476)	Tox MOUSE LYMPHOMA ASSAY OCDE 476 IIBAT 08014 LCE07104 MONTANOV 202 GB CONFIDENTIAL	Non (pro)mutagenic (tested up to 250 µg/mL)
Eye irritation	HETCAM test based on the Official Journal of the Republic of France (N° 300), December 26th, 1996.	Tox HET CAM SEPPIC 1105 - MONTANOV 202 1% f confidential.PDF	Non irritant at 1% in water (score = 0)
	RBCA test adapted from INVITTOX protocol N°37	Tox RBCA SEPPIC 856 - MONTANOV 202 1% a confidential.PDF	Non irritant at 1% in aqueous matrix
Tolerance on Immature Skin	Human Immature Reconstructed Epidermis (SkinEthic model, cultured 10 days instead of 17 days for a mature epidermis): test item application for 16h; evaluation of cell viability (MTT), IL1-alpha cytokine release, histological analysis	Tox_Tolerance immature epidermis_IDEA_6-47-28602-ID-15-05475_Montanov 202 2%_LCE15030_a_confidential.pdf	Montanov 202 at 2% showed no significant cytotoxic effect and no inflammatory response. At the structural level, the test item showed no significant alterations.
Tolerance on Injured Skin	Reconstructed Human Epidermis (Skinethic RHE™) physically impaired. Exposure time: 24h Parameters evaluation: cellular viability (MTT), barrier function/integrity (TEER measurement and	Tox_In vitro impaired skin tolerance_vitroscreen_VS 27-17_MONTANOV 202 2%_LCE17029_a_confidential.pdf	Montanov 202 at 2% showed no significant cellular mortality (95% viability), no significant effect on barrier function/integrity (low biotin passage),and slight modifications at structural level but not

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	biotin permeability), Histo-morphological analysis (H&E, scoring 0 to 4).		significant based on injured control group (Score 1: stratum corneum: thicker and swollen). The results are consistent to conclude as non-irritant classification
Tolerance on vaginal epithelium	Reconstructed human vaginal epithelium (SkinEthic HVE™). Exposure times: 10min, 1h, 3h and 24h, cytotoxicity assessed (MTT)	Tox_Vaginal tolerance_non GLP_IDEA_6.09_6.09-32864-ID-1603570_Montanov 202 2%_LCE16019_a_confidential .pdf	Non irritant at 2% according to the adopted scale.
Tolerance on gingival epithelium	Reconstructed human gingival epithelium from SkinEthic (HGE). Exposure times: 10min, 1h, 3h and 24h, cytotoxicity assessed (MTT)	Tox_In vitro Gingival tolerance non GLP_IDEA_6.09_G-44071_MONTANOV 202 2%_TOX18004_a_confidential	Non irritant at 2% according to the adopted scale (pH = 6.5).
Tolerance on upper airway epithelium	Reconstructed human upper airway epithelium (MucilAir™). Exposure time: 3h followed by 24h recovery.. Parameters evaluation: Cellular viability (Resazurin assay), Barrier function/integrity (TEER measurement), Cell membrane integrity (LDH release), Histo-morphological analysis (Alcian Blue - staining scoring 0 to 3), Inflammation (IL-8 release)	Tox_Upper airway tolerance_Vitroscreen_VS 85-19_MONTANOV 202 2%_TOX19095_a_confidential	Montanov 202™ at 2% showed no cellular mortality (100% viability), no increase of IL-8 release. The Slight effects observed on barrier function (TEER 66,1% of negative control NC), and cell membrane integrity (LDH 3,7 mU/mL at 3h versus < LOD for NC) were considered not significant. No histo-morphologicall change was observed. Conclusion: Good tolerance according to the adopted scale.

Human tests:

Toxicity endpoint	Method	Reference	Result
Skin Irritation	Patch test 48H (12 volunteers-occlusive patches)	Tox HICV IEC R61073D MONTANOV 202 5% paraffin oil GB CONFIDENTIAL	Non irritant at 5% (in paraffin oil)
Skin sensitization	Marzulli & Maibach (50 volunteers-occlusive patches)	Tox Sensitizing M&M IEC 70168RD3-MONTANOV 202 5% a confidential	Non irritant nor sensitization reaction at 5% (in water)

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For other information: see SDS 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

Ecotoxicological data	Method	Reference	Result
Biodegradability	OECD 301F	Biodegradability OCDE 301F MONTANOV 202 Ibacon GmbH	67% biodegradation at 28 days – Montanov 202 is readily biodegradable
Algae acute toxicity	OECD 201	Ecotox OCDE 201 LAUS AB06103104G301L3 MONTANOV	ErL50 (72h) >100 mg/l NOEL (72h) =100 mg/l
Daphnia acute toxicity	OECD 202	Ecotox OCDE 202 LAUS AB06103104G201L3 MONTANOV 202	EL50 (48h) = >100 mg/l NOEL (48h) = 100 mg/l
Daphnia chronic toxicity	OECD 211	Ecotox_Daphnia Chronic OECD211_Envigo_41502364_Montanov 202_a_confidential	LL50 immobilization (21d) > 100 mg/L LL50 reproduction (21d) > 100 mg/L NOEL (21d) = 100 mg/L
Toxicity to soil macroorganisms	OECD 222	Ecotox_Earthworm chronic OECD222_Harlan_D 86315_Montanov 202_a_confidential	LOEC > 1000 mg/kg dry soil NOEC = 1000 mg/kg dry soil

Adsorption/desorption coefficient : Log Koc > = 4.49 - <= 5.05 (OECD 106)

Bioaccumulation potential:

No accumulation of the substance is expected based on the various metabolic pathways and excretion routes which can be expected for Montanov™ 202.

Montanov™ 202 is not classified for the environment according to (EU) n°1272/2008 (CLP) based on ecotoxicological data (see above) and is not PBT/vPvB.

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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

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APPENDICES

Please find attached the following documentation:

- SDS : Safety Data Sheet ☒
- Composition File : Statement 10 130 MONTANOV 202 Composition ☒
- COA : Certificate of Analysis (Specifications: batch 1) ☒
- SCD : Safety Complementary Data ☒
- Process : Flow chart 18 042 MONTANOV 202 ☒
- 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 - ☒

Other countries

- Chemical regulation ECN in Taiwan S 4625 GB ☒

QHSE

- Quality Manual of manufacturing plants (including ISO 9001 ; ISO 14001 ; OHSAS 18001 certificates) ☒
  - Castres (S3563/GB) ☒
- ISO 9001 certificate by SGS
  - Certificate N° 1992/745
  - GMP certificates for cosmetic ingredients of SEPPIC CASTRES ☒
- ISO 14001 certificate by SGS
  - Certificate N° 2000/14894 for Castres ☒
- OHSAS 18001 certificate by SGS
  - Certificate N° 2009/36114 for Castres ☒
- Seppic Management Commitment - S 4193 GB ☒
- Seppic Assessment for Health and Beauty Ingredients – S 4404 GB ☒

General Certificates only for cosmetic uses:

- Statement 01 020 no BSE Cosm gb ☒
- Statement 01 024 GMO free Cosm 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 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 protein free Cosm gb ☒

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- 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 minérals Cosm Ingredients 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 ☒
- COSMOS/ECOCERT & NaTrue approvals ☒

Document approved at Castres on 08/04/2020

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.

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UPDATES

Version (date)	Type of update	Responsible person
March, 99	1048V1/GB/MARCH 99	C. PITZ
December, 9	1048V2/GB/DECEMBER 9	C. PITZ
July, 2000	1048V3/GB/JULY 2000	C. PITZ
May, 2001	1048V4/GB/may 2001	C. PITZ
August, 2003	1047/GB/05/August 2003	C. PITZ
December, 2004	1047/GB/06/December 2004	C. PITZ
May, 2006	1047/GB/7/may 2006	C. PITZ
July, 2008	1048/GB/01/July 2008	C. PITZ
December, 2004	1048/GB/06/ December 2004	C. PITZ
May, 2005	1048/GB/07/ March 2005	C. PITZ
May, 2006	1048/GB/08/may 2006	C. PITZ
August, 2003	1048/GB/09/ August 2003	C. PITZ
November, 2009	1048/GB/09/ Novembre 2009	C. PITZ
September, 2010	1048/GB/09/ September 2010	J.WOZNIAK
April, 2020	1048/GB/10/April 2020 (complete new template)	M. BOUFFARTIGUE
June 2, 2021	Addition of tolerance test on upper airway epithelium	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. 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

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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/

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	CANADA: 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;

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	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

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