



RAW MATERIAL IDENTIFICATION DATA

CHEMICAL INGREDIENTS

AQUAXYL™
C/2559/GB/06/October 2011

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.

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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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GENERAL INFORMATION

1. Commercial name

AQUAXYL™ (CODE: 35260B)

2. INCI name

Xylitylglucoside and Anhydroxylitol and Xylitol

3. Supplier

Head office

75, quai d'Orsay - 75321 Paris Cedex 07 - France

Tel.: +33 (0)1 40 62 55 55 Fax: +33 (0)1 40 62 52 53

Headquarter

22 Terrasse Bellini – Paris La Défense – 92800 Puteaux - France

Tel.: +33 (0)1 42 91 40 00 - Fax: +33 (0)1 42 91 41 41

www.seppic.com

Quality status of SEPPIC:

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

- Is SEPPIC plant OHSAS 18001 certified (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 SA8000 certified (Social Accountability Norm)?

☐ Yes

☒ No

SEPPIC is respecting, in the Group SEPPIC, 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.

4. Patent

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

☒ Yes

☐ No

SEPPIC owns full industrial property on this product. According to the continuous enlargement of this industrial property and the regular evolution of associated deliveries procedures, SEPPIC will provide patents requests numbers and/or patent numbers upon request.

5. Harmonized Customs Number

340213

FDA code: 53 PD 99

6. Raw material category and function

Skin conditioning agents-humectants-moisturizing and restructuring agent

7. Fields of application and use level

(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)

- Recommended use concentration: 1 – 5%
- Fields of application : Cosmetic

COMPOSITION

1. Chemical composition

See composition's statement attached

2. Chemical structure of each component

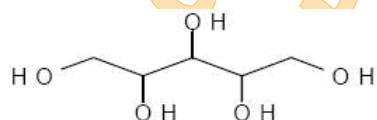
	N°CAS	CAS name	Synonym name
1	101469-75-4	D-Glucose, polymer with xylitol (9CI)	Xylitol, polymer with D-glucose (9CI)
2	53448-53-6	D-Xylitol, 1.4-anhydro-(9CI)	1.4-Anhydro-D-xylitol
3	87-99-0	Xylitol (6CI, 8CI, 9CI)	Wood sugar alcohol

Chemical structure:

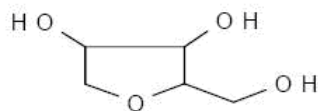
1: $(C_6H_{12}O_6 \cdot C_5H_{12}O_5)_x$

2: $C_5H_{10}O_4$

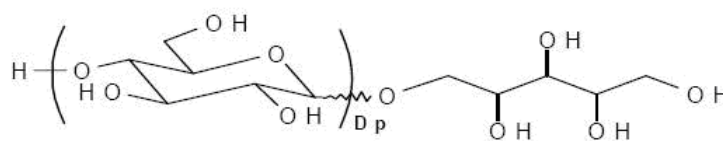
3: $C_5H_{12}O_5$



Xylitol



Xylitan



Xylityl-D-glucoside

3. Impurities

Information below results from the best of our knowledge and/or according to our suppliers' statements.

Type (chemical name)	Expected (Yes/No)	Concentration (if Yes)
Dioxin, PCB	Not applicable	
Ethylene oxide	Not applicable	
Other oxide (OP, OB, ...)	Not applicable	
1,4-dioxane	Not applicable	
Mono ethylene glycol	Not applicable	
Diethylene glycol	Not applicable	
Ethanol	Not expected	
Methanol	Not expected	
Isopropyl alcohol	Not expected	
Acetone	Not applicable	
Volatile Organic Compounds	Not applicable	
Other residual Solvents or VOC	Not expected	
<u>Aldehydes:</u>		
Formol	Not expected	
Acetaldehyde	Not expected	
Other aldehydes	Not expected	
Glycol ethers	Not applicable	
Phthalates	Not applicable	
3-dimethylaminopropylamine (DMAPA)	Not applicable	
Cocamidopropyl dimethylamine	Not applicable	
Monochloroacetic acid	Not applicable	
Dichloroacetic acid	Not applicable	
Free amines	Not applicable	
Nitrosamines	Not applicable	



Type (chemical name)	Expected (Yes/No)	Concentration (if Yes)
Nitrates	Not expected	
Nitrites	Not expected	
Proposition 65 and bill 484 (USA – CALIFORNIA) listed substances	Not expected	
Monomers	Not applicable	
Heavy metals:	Yes	< 10 ppm according to PH.EU.2.4.8.C*
Plomb**	Yes	<0.5 ppm
Cadmium**	Yes	<0.5 ppm
Mercury**	Yes	<0.5 ppm
Arsenic**	Yes	<0.5 ppm
Other	Yes	Not determined at the moment
Residual metal catalysts	Not expected	
Pesticides	Not expected	
Nanoparticles	Not expected	
Polycyclic Aromatic Hydrocarbons (PAH)	Not applicable	
Silicone and Latex	Not applicable	
Sewage sludge	Not applicable	
Endocrine perturbators	Not applicable	
Cytotoxic agents	Not applicable	
Mycotoxins	Not applicable	
Ochratoxins	Not applicable	
Mycoplasma	Not applicable	
Antineoplastic agent	Not applicable	
Asbestos	Not applicable	

** Tested on batches T94721, T02921, T13521 by ICP-MS (see report ANTELLIS VP11-079-CAAT1136A
Confidentiel f.pdf)



Type (chemical name)	Expected (Yes/No)	Concentration (if Yes)
fungi	Not applicable	
Camphre	Not applicable	
Menthol	Not applicable	
Eucalyptol	Not applicable	
Iodine and derivatives	Not applicable	
Melanin	Not applicable	
Psychotropic agents	Not applicable	
Narcotics	Not applicable	
Antibiotics	Not applicable	
Steroids, hormones, growth promoter	Not applicable	
Other :		
Water	Yes	15-17%
Glucose	Yes	0-5 %

Worrying Substance	Specific regulation	Compliance (Y/N)
Allergen	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	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



4. Microbiological data

- Microbiological Specifications:

Microorganism	Result (CFU/g)	Method	Monitoring
Total bacterial Aerobies	< 100 CFU	PH.EU. 2-6-12 and 2-6-13	<input checked="" type="checkbox"/> Each batch <input type="checkbox"/> Statistical analysis <input type="checkbox"/> Qualified batch only <input type="checkbox"/> Not applicable*
Total Yeasts and moulds	< 100 CFU	PH.EU. 2-6-12 and 2-6-13	<input checked="" type="checkbox"/> Each batch <input type="checkbox"/> Statistical analysis <input type="checkbox"/> Qualified batch only <input type="checkbox"/> Not applicable*
Specific pathogens E. Coli Salmonella	Abs/1g Abs/10g	PH.EU. 2-6-12 and 2-6-13	<input checked="" type="checkbox"/> Each batch <input type="checkbox"/> Statistical analysis <input type="checkbox"/> Qualified batch only <input type="checkbox"/> Not applicable*

*Not applicable: Not done because microbiological contamination of the product is not expected according to its structure.

- Other microbiological data:

[Vitro challenge test MIDAC 03 085 289-2 LCA0310 LCA0312 LCA0313 LCA0314 Aquaxyl confidential.gb.pdf](#)

[Vitro challenge test MIDAC 03 085 289 1 LCA0312 Aquaxyl compo confidential.pdf](#)

[Vitro challenge test MIDAC 03 085 289 1 LCA0313 Aquaxyl compo confidential.pdf](#)

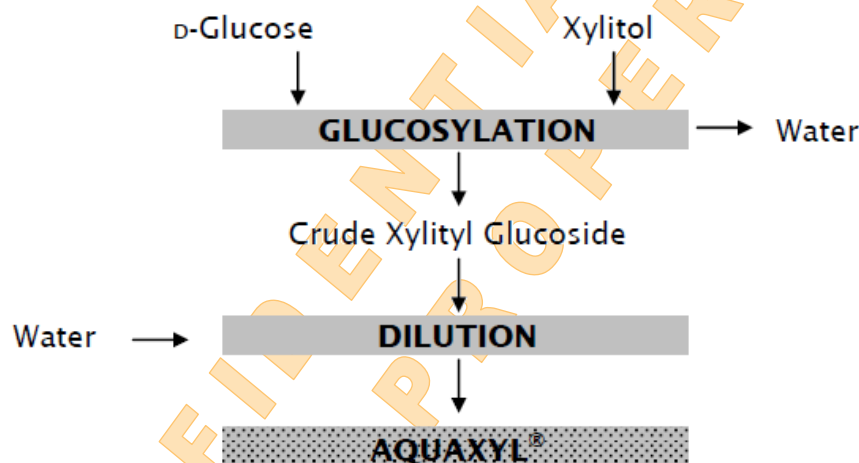
INFORMATION ON MANUFACTURING

1. Description of the manufacturing process

Process:

Etherification of glucose with xylitol.

Flowchart:



Country of Manufacturing: FRANCE

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

In the market since: 2004

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 guidelines
- ☐ ISO 22000
- ☐ Hazard Analysis & Critical Control Point (HACCP) defined by Codex Alimentarius



Microbiological (stage of decontamination):

Is the ingredient decontaminated or sterilized? ☐ Yes ☒ No

2. Origin of starting materials involved in the process

The following information come from data obtained until today of our current suppliers.

Are the starting materials of vegetable origin?

☒ Yes ☐ No

- Name of the plant: Glucose from wheat from Europe, and Xylitol from wood from Europe (preferentially) or from corn or wheat from Europe.
- Part of the plant:
fruit ☐, bark ☒, flower ☐, root ☐, kernel ☐, other (precise): seed
- Starting materials listed on CITES, Annexes I, II or III?
☐ 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

See SEPPIC GMO certificate

Are the starting materials of marine origin?

☐ Yes ☒ No

Are the starting materials of animal origin?

☐ Yes ☒ No

Are the starting materials of Human origin?

☐ Yes ☒ No

Are the starting materials of synthetic origin?

☐ Yes ☒ No



Are the starting materials of mineral origin?

☐ Yes ☒ No

Are the starting materials of biotechnology, fermentation, culturing cells.... origin?

☐ Yes ☒ No

Biotechnology can be defined as follows. Any technological application that uses biological systems or organisms to make or modify products or processes for specific use.

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

☐ Yes ☒ No

Definitions:

- 1. Nano-particle - highly dispersed particles less than 100 nm in size in at least one measurement, with an assigned structure and properties.*
- 2. Nano-material - materials and production, where an essential component, which determines their properties and designation, is the addition of nano-particles to their composition.*
- 3. Nano-technology - totality of the methods of intentionally obtaining and using nano-particles.*

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SUSTAINABLE DEVELOPMENT

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 points. For the existing processes, improvements are made to make them cleaner.

• Bio-based content: 100% (on dry product)

• During the manufacturing of your chemically transformed ingredient, are there intermediary reactions? ☐ Yes ☒ No

Organic and natural labels

Does the ingredient comply with an organic or natural label? ☒ Yes ☐ No

ECOCERT* (100% natural origin) and NATRUE (85% derived natural)

* Raw material approved by ECOCERT GREENLIFE, in conformity with Ecocert standards on natural and organic cosmetics.

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 concerned**

**REGULATION INFORMATION****1. Chemical inventories and Registration status per country****EUROPE:**

Component (usual name)	N°CAS (CAS name)	N°EINECS/ELINCS/NLP		REACH number (when available)
		EINECS	EILINCS	
D-Glucose, polymer with xylitol	101469-75-4	-	446-990-1 (for AQUAXYL)	REACH (AQUAXYL as a multi-constituent substance) : 01-0000018874-59-0000
1,4-Anhydro-D- xylitol	53448-53-6	258-560-9		
Xylitol	87-99-0	201-788-0		

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



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OTHER COUNTRIES:

	USA	JAPAN	AUSTRALIA	CANADA	CHINA	KOREA	NEW-ZEALAND	PHILIPPINES	TAIWAN
	TSCA	ENCS/ISHL	AICS	DSL, NDSL, PL=ICL market list	IECSC	KECI	NZIoC	PICCS	NECI
D-Glucose, polymer with xylitol	Not listed	Not listed	Listed	Listed	registered	Not listed	Not listed	Not listed	ECN process done
CAS nb 101469-75-4					See nota below*				
1,4-Anhydro-D- xylitol	Not listed	Not listed	Listed	Listed	registered	Not listed	Not listed	Not listed	ECN process done
CAS nb 53448-53-6					See nota below*				
Xylitol	Listed	Listed	Listed	Listed	Listed under	Listed	Listed	Listed	ECN process done
CAS nb 87-99-0		ENCS Number : (9)-315 ISHL Number : (9)-315			木糖醇 See nota below*	KE-35438			

AQUAXYL™ C/2559/GB/06/October 2011

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*Nota :Because SEPPIC registered Aquaxyl in CRC-MEP as mixture chemical substance, the chemical name is not the same as the components chemical name on Chemical regulatory documents like REACH file or TSCA certificate. (because the Chinese chemical name is different from the US chemical name).

Aquaxyl: China-chemical name:

“Reactant of glucose and xylitol,
葡萄糖与木糖醇的反应物 “will be listed
on IECSC after April 2014 (5 years since
registered)

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

KOREA:

KECI => Korean Existing Chemicals Inventory

NEW-ZEALAND:

NZIoC => New Zealand Inventory of Chemicals

PHILIPPINES:

PICCS => Philippine Inventory of Chemicals
and Chemical Substances

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)

AQUAXYL™ C/2559/GB/06/October 2011

This document is based on C 4580 GB 12 May 2010 RMID model.doc



2. Regulation status per country according to the final applications

Cosmetic applications: All the intentional components of the ingredient as mentioned in statement 11 235 have been audited.

Country or region	Identifier	Compliance with specific regulation?	
Europe	European INCI name: a) Xylitylglucoside b) Anhydroxylitol c) Xylitol	Regulation EC N° 1223/2009	Y
	PCPC INCI name (ID Monograph): a) Xylitylglucoside (ID: 17974) b) Anhydroxylitol (ID: 17975) c) Xylitol (ID: 3368)	Classical cosmetic: Federal Food, Drug and Cosmetic (FD&C) Act. 21 CFR 700 to 740	Y
USA	UNII: a) O0IEZ166FB b) 8XWR7NN42F c) VCQ006KQ1E	OTC : 21 CFR Part 3xx - OVER-THE-COUNTER DRUG PRODUCTS	Y (as excipient)
	J-INCI name (PCPC Japanese translation): a) キシリチルグルコシド b) 無水キシリトール c) キシリトール	Classical cosmetic: Japanese Standards of Cosmetics (Notification No.331 of 2000)	Y
Japan	No information available on QD monographs	Quasi Drug: Pharmaceutical Affairs Law of Japan (PAL)	N
	See chemical status above	Classical cosmetic: Industrial Chemicals (notification and Assessment) Act 1989	Y
Australia	AAN : a) Not listed b) Not listed c) Xylitol	Therapeutic Good: Therapeutic Goods Act 1989	N
	See chemical status above	Classical cosmetic*: The Food and Drug Act, Cosmetic Regulations (C.R.C., c. 869)	Y
Canada	NHP ingredient Database: a) Xylitylglucoside listed as non medicinal ingredient for topical use b) Anhydroxylitol listed as non medicinal ingredient for topical use c) Xylitol listed as non medicinal ingredient	Natural Health Product & Non-prescription Drugs: Category IV Monographs & Natural Health Products regulation (SOR/2003-196)	Y (as excipient)



Country or region	Identifier	Compliance with specific regulation?	
China	Chinese INCI names: a) 木糖醇基葡萄糖苷 for INCI name PCPC Xylitylglucoside - Is listed IECIC 2014 final version* (June 2014) b) 脱水木糖醇 for INCI name PCPC Anhydroxylitol - Is listed SFDA 2007 - Is listed IECIC 2014 final version* (June 2014) c) 木糖醇 for INCI name PCPC Xylitol - Is listed MoH 2003 - Is listed SFDA 2007 - Is listed IECIC 2014 final version* (June 2014)	Cosmetics (functional and non-functional): Hygienic Standard for cosmetics of 2007(GB7616-199)	Y
	* The IECIC 2014 list published by CFDA on June 30th, 2014 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



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Country or region	Identifier	Compliance with specific regulation?
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 tecnico 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

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-Birmanian ; 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



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Food applications: Not concerned

Pharmaceutical applications: Not concerned

Industrial applications (food contact, detergence ...): Not concerned



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PHYSICO-CHEMICAL DATA

- Physical form : Liquid
- Colour: Light yellow, clear
- Odour: Typical odor of sugar derivative
- Molecular weight of each component: 277 g/mole
- Relative density : 1.435 ± 0.002
- Melting point / Melting range : $< -5,0\text{ }^{\circ}\text{C}$
- Boiling point / Boiling range : $315\text{ }^{\circ}\text{C} \pm 2.6^{\circ}\text{C}$ (DSC method)
- Flash point : $244 \pm 1.5\text{ }^{\circ}\text{C}$ (closed cup)
- Ignition temperature : $> 423,00\text{ }^{\circ}\text{C}$
- Vapour pressure : $3,6 * 10^{-6}\text{ hPa}$ (at 25°C)
- pH (5% in water): 5,5 – 7,5 (at $20,00\text{ }^{\circ}\text{C}$)
- Partition coefficient: $\log \text{Pow} = -2$ (at 20°C)
- Viscosity Dynamic : at $20,00\text{ }^{\circ}\text{C}$ 2.000,00 cP
- Surface tension : 73 mN/m (1,01 g/l, $22\text{ }^{\circ}\text{C}$)
- Solubility (water or other solvents): Solubility in water: 674,00 g/l at 20°C
- UV spectrum: available on request
- Stability data: see attached certificate of analysis
- Analytical data: see attached certificate of analysis

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

- NFPA & HMIS rates: See SDS

NFPA ratings (scale 0-4): Health=0; Flammability=1; Instability=0

HMIS ratings (scale 0-4): Health=1; Flammability =1; Reactivity=0



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TOXICOLOGICAL DATA

In vitro tests

Toxicity	Method	Reference	Result
Mutagenicity	AMES	AMES LEMI 2001-DIB503-2 LCA01006 AQUAXYL f confidential	Non mutagenic
Mutagenicity	Chromosome Aberration	Tox Abb Chromo OCDE 473 SAFEPHARM 1190-112 AQUAXYL CONFIDENTIAL GB.pdf	Non clastogenic to human lymphocytes in vitro.
Eyes irritation	HETCAM	SEPPICtoxHETCAM2291_2571_25 72a confidential	Non irritant until 10%
	RBCA	SEPPICtoxRBCA986a confidential	
Tolerance on vaginal epithelium	Reconstructed human vaginal epithelia from SkinEthic (HVE): application on epithelial tissue cultures for 10min, 1h, 3h and 24h, cytotoxicity assessed (MTT)	Tox_In vitro vaginal tolerance non GLP_IDEA_6-09-24808-ID14- 08206_Aquaxyl 3%_LCA14089_a_confidential.pdf	Non irritant at 3% Aquaxyl according to the adopted scale (pH 6.9)

Human tests

Toxicity	Method	Reference	Result
Skin Irritation	Patch Test (20 volunteers)	Tox Patch 48h DERMSCAN R1010646-2 LCA 01006 AQUAXYL 3% a confidential	Non irritating at 3 %
Skin sensitization	M&M (51 volunteers)	Tox M&M ASTER PC3034 AQUAXYL 10% LCA03008 a confidential	The tests substance diluted at 10% in water did not induce sensitization reaction and was very well tolerated.

For other information: see SDS

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”

AQUAXYL™ C/2559/GB/06/October 2011

This document is based on C 4580 GB 12 May 2010 RMID model.doc



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ECOTOXICOLOGICAL DATA

Ecotoxicological data	Method	Reference	Result
Biodegradability	OECD 301D	Ecotox_Biodegradability (301D)_Ineris_DRC-12-131720_AQUAXYL	37.4% ThOD within a 28 day-period
Algae acute toxicity	OECD 201	Ecotox Algue C3 ou OCDE 201 SPL 1190-122 AQUAXYL notif 7a	EC50 values >100mg/L, NOEC=100mg/L Based on the geometric mean: ErC50-72h >77mg/L, NOEC=77mg/L
Daphnia acute toxicity	OECD 202	Ecotox Daphnie C2 ou OCDE 202 SPL 1190-121 AQUAXYL notif 7a	EC50-48h >100 mg/L, NOEC=100 mg/L
Fish acute toxicity	OECD 203	ECOTOX POISSON OCDE 203 SAES S-035-2008 AQUAXYL CHINE GB CONFIDENTIAL	LC50-96h >100mg/L, NOEC = 100mg/
Activated sludge	OECD 209	Ecotox - Boue Act Inh Resp (OCDE 209) CIT 32709EAS AQUAXYL CONFIDENTIAL GB.pdf	3-hour EC50 > 1000 mg/L

- Bioaccumulation: see Partition coefficient in section Physico-chemical data
- Adsorption/desorption coefficient : $K_{oc} \leq 10$
- Water hazard class (WGK): 1 See SDS Germany

HAZARD CLASSIFICATION

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 labeling of dangerous substances and preparations) or to the Regulation CLP 1272/2008?

☐

Yes

☒

No

See SDS



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PACKAGING LABELLING & STORAGE

Packaging: Plastic drum or plastic jerry can.

Selling unit size: 5 kg or 30 kg.

Nature/Type of Packaging

	Primary packaging	Pallet*
Size (cm)	Ø 31,5 ; h=51,7	114 x 114
Type of Material	Plastic drum	Wood
Specifications (weight, ...)	30 kg	794 kg (Gross weight) 24 drums / pallet

Or

	Primary packaging	Pallet*
Size (cm)	18 x 12,5 x 28	114 x 114
Type of Material	Plastic jerry can	Wood
Specifications (weight, ...)	5 kg	783 kg (Gross weight) 144 jerry can / pallet

Or

	Primary packaging	Pallet*
Size (cm)	19 x 19 x 25,5	114 x 114
Type of Material	Plastic drum	Wood
Specifications (weight, ...)	5 kg	422 kg (Gross weight) 72 drums / pallet

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

Labels

Final material labels are: ☒ printed as needed ☐ purchased pre-printed

Storage

Does the ingredient request special conditions before manipulation? ☐ Yes ☒ No

Does the ingredient request special conditions for storage?

Recommended storage temperature: (5 – 25) °C See SDS



APPENDICES

Please find attached the following documentation:

- SDS : Safety Data Sheet
- Composition Statement
- COA : Certificate of Analysis (Specifications: batch 1)
- Technical Data Sheet : C3316 GB



REACH

Europe

- REACH Statement
- 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 01



QHSE

- Seppic Management Commitment - S 4193 GB
- Seppic Assessment for Health and Beauty Ingredients – S 4404 GB
- Engagement on Social Responsibility on 22 Sept 2006
- Roundtable on Sustainable Palm Oil SEPPIC Statement – S 4392 GB
- RSPO Letter of Intent-Palm Oil – S 4397 GB
- RSPO acceptance letter
- Carbon footprint S 4489 GB
- QSE Manual (including ISO 9001 ; ISO 14001 ; OHSAS ; ISO 18001
certificates) of manufacturing plant
- GMP certificates (Castres and Lyon) Casher certificates (Lyon)





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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 Phtalates 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
- ECOCERT approval



Document approved at Castres, on October 21, 2010

Updated on October 10, 2011 Chinese Chemical regulatory part

Update on October 21, 2011 Heavy metals part-Version 06

Modified on May 23, 2012 manufacturing site

Modified tox and ecotox data on December 3, 2012 by M.BERGAL.

Updated by Carla Perez, on November 28, 2012 China cosmetic regulation and Australian chemical regulation.

Update function part in accordance with doc 6086GB on January 14, 2013

Update on July 23, 2013 glucose content

Update on October 17, 2013 regulatory status

Update on March 31, 2014 origin of raw materials.

Update on July 22, 2014 Cosmetic regulatory status in China and preamble

Update on February 5, 2015 Flowchart, GMP status

Update bio-based content on January 19, 2016

Adding tolerance data on vaginal epithelium on February 9, 2016

By Leslie LEVAS

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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Nota

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

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