

### 1. DEFINITION

#### DEFINITION

Extract (Betaine/Water/Propanediol) of *Murraya koenigii* leafy stems.

#### DENOMINATION

##### INCI NAME

(PCPC - International Nomenclature of Cosmetic Ingredients)

Betaine  
(and) Water  
(and) Propanediol  
(and) *Murraya Koenigii* Stem Extract

##### EUROPEAN INVENTORY OF COSMETIC INGREDIENTS - COSING

(European Commission database - [COSING](#))

Betaine  
(and) Aqua  
(and) Propanediol  
(and) *Murraya Koenigii* Stem Extract

### 2. FIELD OF USE

#### FIELD OF USE

This product is a cosmetic ingredient.  
It is recommended for use in cosmetic formulations.

This ingredient must be used according to appropriate regulations. Use of the ingredient outside the fields of use recommended by Gattefossé is under the responsibility of the ingredient user.

#### Special applications

Oral cosmetic applications	No data available
Pediatric cosmetic applications (children under 3 years old)	No data available
Use during pregnancy and lactation (breastfeeding)	No data available

This information is based on our current knowledge. The status for our ingredient given in this section represents Gattefossé Regulatory Affairs department personal views on the subject matters. These views have not been adopted or in any way approved legally and should not be relied upon as a statement.

Please consult the document "Tox and safety overview" for additional information.

# Regulatory data sheet (RDS) - Cosmetic and personal care applications

## ELEVASTIN (Code: 5959)

Last update: 16 February 2021

### 4. MANUFACTURING PROCESS AND COMPOSITION

#### MANUFACTURING PROCESS

Extraction of *Murraya koenigii* in a solvent composed of betaine, propanediol and water.

#### COMPOSITION

##### FULL LABELING (KEY LETTERS SYSTEM)

$75.0 \leq A_1$  ;  $50.0 \leq A_2 < 75.0$  ;  $25.0 \leq B < 50.0$  ;  $10.0 \leq C < 25.0$  ;  $5.0 \leq D < 10.0$  ;  $1.0 \leq E < 5.0$  ;  $0.1 \leq F < 1.0$  ;  $G < 0.1$

Betaine	$25.0\% \leq B < 50.0\%$
Water	$25.0\% \leq B < 50.0\%$
Propanediol	$25.0\% \leq B < 50.0\%$
Murraya Koenigii Stem Extract	$5.0\% \leq D < 10.0\%$

##### OTHER CONSTITUENTS (INCIDENTAL INGREDIENTS)

None

### 5. COSMETIC REGULATIONS

#### REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS (Non-exhaustive list of countries, please contact us for additional information)

<b>EUROPE</b> (European Cosmetic Regulation 1223/2009 and its amendments)	Approved
<b>U.S.A.</b> (FD&C Act— 21 CFR 700 to 740)	Approved
<b>CANADA</b> (Food and Drugs Act and Cosmetic Regulations)	Approved* - our product can be imported in Canada in quantities not exceeding per 12-month period and per importer (kg): 1000
<b>MERCOSUR:</b> Argentina, Brazil, Paraguay and Uruguay; with association agreements with Chile and Bolivia (Regulation for Personal Hygiene Products, Cosmetics & Perfumes)	Approved
<b>AUSTRALIA</b> (Notification & Assessment Act 1989, as amended—TGA)	Approved (Some requirements may apply, please contact us for additional information)
<b>NEW ZEALAND</b> (Cosmetic Products Group Standard)	Approved
<b>JAPAN</b> (Pharmaceutical Affairs Law - regulations for cosmetics)	Approved
<b>KOREA</b> (Cosmetics Law - Korea Food & Drug Administration KFDA)	Approved
<b>TAIWAN</b>	Approved
<b>ASEAN:</b> Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, VietNam (ASEAN Cosmetic Directive)	Approved

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### REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS (Non-exhaustive list of countries, please contact us for additional information)

<b>INDIA</b> (provisions of Indian Drug and Cosmetic Act)	Approved
<b>Commonwealth of Independent States (CIS)</b> Official members: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Uzbekistan Unofficial associate members: Turkmenistan, Ukraine	Approved
<b>Gulf Cooperation Council (GCC)</b> Official members: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE (United Arab Emirates)	Approved

\* Import volume limited: Please contact us for additional information.

### REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS CHINA (Hygienic Standard for Cosmetics) Normal and Special cosmetics

<b>Overall status of the product</b>	Approved	
<b>IECIC Status of Components</b>		
<b>INCI Name</b>	<b>Status</b>	<b>Chinese Name</b>
Betaine	Listed IECIC 2015	甜菜碱
Water	Listed IECIC 2015	水
Propanediol	Listed IECIC 2015	1,3-丙二醇
Murraya Koenigii Stem Extract	Listed IECIC 2015	调料九里香 (MURRAYA KOENIGII) 茎提取物

IECIC 2015 list: Inventory of existing cosmetic ingredients in China (IECIC) issued by CFDA on December 23<sup>rd</sup>, 2015

### REGULATORY STATUS OF THE INGREDIENT FOR BORDER-LINE APPLICATIONS

	Status	Denomination	Identifier	Additional information
<b>AUSTRALIA</b> <b>Therapeutic goods</b> <b>(TGA)</b>	Approved	Betaine Propanediol Potable water Murraya koenigii	67679 109912 57905 83255	<p><b>Use:</b>                      BETAINE: Available for use as an Active Ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines. Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines. Available for use as an Equivalent Ingredient in: Export Only.                      PROPANEDIOL: Not available as an Active Ingredient in any application. Available for use as an Excipient Ingredient in: Export Only, Listed Medicines. Not available as an Equivalent Ingredient in any application.                      WATER: Available for use as an Active Ingredient in: Biologicals, Prescription Medicines. Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines. Not available as an Equivalent Ingredient in any application.                      MURRAYA KOENIGII: Available for use as an Active Ingredient in: Export Only, Listed Medicines, Over the Counter, Prescription Medicines. Also available for use as a Homoeopathic Ingredient in Listed Medicines. Available for use as an Excipient Ingredient in: Prescription Medicines. Not available as an Equivalent Ingredient in any application.</p> <p><b>Restrictions:</b>                      BETAINE: In Listed Medicines: Only for use in topical medicines for dermal application.</p>



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### REGULATORY STATUS OF THE INGREDIENT FOR BORDER-LINE APPLICATIONS

	Status	Denomination	Identifier	Additional information
				PROPANEDIOL: In Listed Medicines: Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
<b>JAPAN QUASI-DRUGS</b>	Not approved	Trimethylglycine Purified water / Murraya koenigii extract	523156 001370 / 532243	Propanediol not approved
<p><b>AUSTRALIA:</b> Australia has a two-tiered system for the regulation of medicines, including complementary medicines:                      Registered Medicines: higher risk medicines must be registered on the Australian Register of Therapeutic Goods (ARTG), which involves individually evaluating the quality, safety and effectiveness of the product.                      Listed Medicines: lower risk medicines containing pre-approved, low-risk ingredients. Ingredients must be evaluated and included in the Therapeutic Goods (Permissible Ingredients) Determination before they can be used listed medicines.</p> <p><b>JAPAN:</b> Quasi-drugs include Mouth wash products (for disinfection of the mouth); Deodorants; Talc powder (with active ingredient); Hair-growth products; Depilatories; Hair dyes (oxidative); Bath preparations (with active ingredients); Permanent wave products; Medicated cosmetics (including anti-dandruff shampoos and rinses, Leave-on acne products for prevention of acne, anti-chapping and anti-frostbite lotions, whitening products and anti-bacterial products); Medicated toothpastes ...)</p>				

## 6. ORGANIC COSMETICS

### STATUS OF THE INGREDIENT FOR ORGANIC COSMETIC FORMULATIONS

Body	Standard	Status	Evaluation conclusions
<b>COSMOS</b>			
Ecocert Greenlife	COSMOS-standard	Approved raw material	PPAI: 60.21 % CPAI: 26 % NNI: 0% PeMo: 0 %
<p>COSMOS: The following product has been evaluated by ECOCERT® Greenlife and complies with the COSMOS® standard for ingredients to be used in Natural and Organic cosmetics. We would like to draw your attention to the fact that this product is not "Organic certified".</p> <p>COSMOS Definitions: PPAI = Physically Processed Agro-Ingredient ; CPAI = Chemically Processed Agro-Ingredient ; PeMo = Petrochemical Moieties ; NNI : Non Natural Ingredients.</p>			

## 7. NATURALITY

### CALCULATIONS ACCORDING TO ISO 16128 STANDARD

#### Guidelines on Technical Definitions and Criteria for Natural & Organic Cosmetic Ingredients

- Natural index (In): 0,25 to 0,50
- Natural origin index (Ion): 1
  - Organic index (IO): 0
- Organic origin index (IOO): 0

This has been determined based on the origin of the raw materials (including intentionally added additives, if any) and our manufacturing processes.

This is based on our current knowledge and understanding of the available texts (ISO 16128-1 and ISO 16128-2).

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### 8. RSPO CERTIFICATION

ROUNDTABLE ON SUSTAINABLE PALM OIL <a href="http://www.rspo.org/certification">http://www.rspo.org/certification</a>	
Product status	Gattefossé RSPO certification number
Product certified RSPO Mass Balance. More information on: <a href="http://www.RSPO.org">www.RSPO.org</a>	Supply Chain Certificate (SCC) number: BVC-RSPO-1-1106949778.

### 9. CHEMICAL REGULATIONS

CHEMICAL REGULATION			
INCI Name	CAS #	EC #	Chemical name
Betaine	107-43-7	203-490-6	Betaine
Water	7732-18-5	231-791-2	Water
Propanediol	504-63-2	207-997-3	Propane-1,3-diol
Murraya Koenigii Stem Extract	None	924-428-0	Murraya koenigii

NATIONAL INVENTORIES					
	U.S.A. (TSCA)	Canada (DSL/NDSL)	Australia (AIC)	China (IECSC)	Other inventories
Betaine	Listed	DSL listed	Listed	Listed	D-Glucitol (English, French, German, Spanish) (TSCA, DSL, EINECS, AICS, SWISS, PICCS, ASIA-PAC, NZIoC)
Water	Listed	DSL listed	Listed	Listed	Water (TSCA, DSL, EINECS, ENCS, AICS, ECL, PICCS, ASIA-PAC, NZIoC)
Propanediol	Listed	DSL listed	Listed	Listed	1,3-Propanediol (TSCA, DSL, ENCS, AICS, ECL, PICCS, ASIA-PAC, NZIoC)
Murraya Koenigii Stem Extract	Not listed	Not listed our product can be imported in Canada in quantities not exceeding per 12-month period and per importer (kg): 1000	Not listed	Notified*	Murraya koenigii (EINECS)

U.S.A.: Substances that are regulated under other federal regulations, including food additives, drug, cosmetics... are not subject to TSCA regulation. "Naturally occurring substances" are not subject to Premanufacture Notice reporting.

Canada: Substances not listed on DSL or NDSL can be imported in Canada in quantities not exceeding 100 kg per 12-month period and per importer. Substances listed on NDSL only can be imported in Canada in quantities not exceeding 1000 kg per 12-month period and per importer. Please contact us if you go beyond these volumes. In addition, substances not listed in DSL or NDSL, but listed in the "in-commerce list" can be freely used in Products Regulated Under the Food and Drugs Act (F&DA). In addition, substances considered as "Natural" according Health Canada's definition are exempted from New Substances regulation.

Australia: The Australian Inventory of Chemical Substances (AICS) has been replaced by the Australian Inventory of Industrial Chemicals (AIIC) since July 2020. Chemicals listed on the AIIC are available for industrial use in Australia; however, importers must register with Australian authorities before importing the chemical in Australia. Some chemicals require specific information to be provided to Australian authorities.



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### NATIONAL INVENTORIES

	U.S.A. (TSCA)	Canada (DSL/NDL)	Australia (AIC)	China (IECSC)	Other inventories
Naturally occurring chemicals are exempted from AIC listing. Chemicals not listed on the AIC must be assessed before importation.					
*China: if your company intends to import our ingredient as chemical entities in China, please consult us.					

### REACH REGULATION

#### (REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS)

Overall status of the product	Please refer to Safety Data Sheet
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#### Liability clause

The information contained in this document is based on our knowledge of the related product(s) at the date indicated herein, and is provided in good faith. Notwithstanding the foregoing, no guarantee is made in respect of the product's(s') properties or efficacy, or the continued exactitude and completeness of the information herein. No contractual tie is formed by the provision of this information. This document does not relieve the user from conducting all tests and verifications to ensure the product's(s') suitability for each intended use. Nothing herein shall be construed as a recommendation or licence to use any information that does or may conflict with any intellectual property. We make no representation or warranty, express or implied, that use of this information will not infringe any intellectual property of Gattefossé or any third party. The user assumes all risks and liability incurred if a product is used other than for the purpose designated by Gattefossé. This statement does not relieve the user from verifying its conformity with all current applicable laws and regulations, and the user shall remain solely liable for ensuring its continued conformity therewith.

