

### 1. DEFINITION

#### DEFINITION

Hydroglycolic (Propanediol/Water) extract of Acemella oleracea aerial parts

#### DENOMINATION

##### INCI NAME

(PCPC - International Nomenclature of Cosmetic Ingredients)

Propanediol  
(and) Water  
(and) Acemella Oleracea Extract

##### EUROPEAN INVENTORY OF COSMETIC INGREDIENTS – COSING

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

Propanediol  
(and) Aqua  
(and) Acemella Oleracea Extract

##### ADDITIONAL INFORMATION ON THE DENOMINATION

Acemella oleracea, also known under its alternative names Spilanthes oleracea and Spilanthes Acemella, is commonly referred to as Spilanthes 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

Yes

Pediatric cosmetic applications  
(children under 3 years old)

No data available

Use during pregnancy and lactation (breastfeeding)

No data available

Other specific applications (eye products, intimate care...)

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

## GATULINE EXPRESSION AF (Code: 5891)

Last update: 10 January 2023

### 3. MANUFACTURING PROCESS AND COMPOSITION

| MANUFACTURING PROCESS  |                            |
|--|----------------------------|
| Hydroglycolic extraction   |                            |
| COMPOSITION  |                            |
| FULL LABELING (KEY LETTERS SYSTEM)   |                            |
| $75.0 \leq A_1$ ; $50.0 \leq A_2 < 75.0$ ; $25.0 \leq B < 50.0$ ; $10.0 \leq C < 25.0$ ; $5.0 \leq D < 10.0$ ; $1.0 \leq E < 5.0$ ; $0.1 \leq F < 1.0$ ; $G < 0.1$ |                            |
| Propanediol  | $50.0\% \leq A_2 < 75.0\%$ |
| Water  | $25.0\% \leq B < 50.0\%$   |
| Acemella Oleracea Extract  | $5.0\% \leq D < 10.0\%$    |
| MEDIAN VALUES  |                            |
| Median values are determined by taking the average of each key letter and adapting each result so that the total equals 100%.                                      |                            |
| Propanediol  | 61%                        |
| Water  | 32%                        |
| Acemella Oleracea Extract  | 7%                         |
| OTHER CONSTITUENTS (INCIDENTAL INGREDIENTS)  |                            |
| None   |                            |

### 4. 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>EUROPEAN UNION</b><br>(European Cosmetic Regulation 1223/2009 and its amendments)   | Approved  |
| <b>U.S.A.</b><br>(FD&C Act— 21 CFR 700 to 740)   | Approved  |
| <b>CANADA</b><br>(Food and Drugs Act and Cosmetic Regulations)   | Approved<br>(Import volume limited)*<br>Our product can be imported in Canada in quantities not exceeding per 12-month period and per importer (kg): 1667 |
| <b>MERCOSUR:</b> Argentina, Brazil, Paraguay and Uruguay; with association agreements with Chile and Bolivia<br>(Regulation for Personal Hygiene Products, Cosmetics & Perfumes) | Approved  |
| <b>AUSTRALIA</b><br>(Poisons Standard – SUSMP)   | Approved  |
| <b>NEW ZEALAND</b><br>(Cosmetic Products Group Standard)   | Approved  |
| <b>JAPAN</b><br>(Pharmaceutical Affairs Law - regulations for cosmetics)   | Approved  |

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|   |          |
|---|----------|
| <b>SOUTH KOREA</b><br>(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<br>(ASEAN Cosmetic Directive)  | Approved |
| <b>INDIA</b><br>(provisions of Indian Drug and Cosmetic Act)  | Approved |
| <b>Commonwealth of Independent States (CIS)</b><br>Official members: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Uzbekistan<br>Unofficial associate members: Turkmenistan, Ukraine | Approved |

### CHINA – NMPA STATUS

|   |                        |
|---|------------------------|
| <b>Overall status of the ingredient for cosmetic use in China</b> | Approved               |
| <b>NMPA notified trade name</b>                                   | GATULINE EXPRESSION AF |
| <b>NMPA ingredient notification code</b>                          | 121121-00312-7462      |
| <b>Company responsible for NMPA notification</b>                  | GATTEFOSSE SAS         |

### CHINA - INVENTORY OF EXISTING INGREDIENTS (IECIC) - 2021

| IECIC English name (NMPA notified) | IECIC Chinese name (NMPA notified) | Composition for NMPA notification |                |
|------------------------------------|------------------------------------|-----------------------------------|----------------|
|                                    |                                    | Composition range                 | Typical values |
| PROPANEDIOL                        | 1,3-丙二醇                            | 50-75%                            | 61.0%          |
| WATER                              | 水                                  | 25-50%                            | 32.0%          |
| ACMELLA OLERACEA EXTRACT           | 千日菊 (ACMELLA OLERACEA) 提取物         | 5-10%                             | 7.0%           |

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### 5. BORDER-LINE REGULATIONS

#### AUSTRALIA - USE IN THERAPEUTIC GOODS

| Status   | TGA name            | TGA reference number | Use  | Restrictions   |
|----------|---------------------|----------------------|--|--|
| Approved | Water potable       | 57905                | Available for use as an Active Ingredient in: Biologicals, Prescription Medicines<br>Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines<br>Not available as an Equivalent Ingredient in any application                            | /  |
| Approved | Propanediol         | 109912               | Not available as an Active Ingredient in any application<br>Available for use as an Excipient Ingredient in: Devices, Export Only, Listed Medicines<br>Not available as an Equivalent Ingredient in any application  | Applies to listed medicines :<br>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%.    |
| Approved | Blainvillea acmella | 107425               | Available for use as an Active Ingredient in: Listed Medicines, Prescription Medicines<br>Also available for use as a Homoeopathic Ingredient in Listed Medicines<br>Available for use as an Excipient Ingredient in: Listed Medicines, Prescription Medicines<br>Not available as an Equivalent Ingredient in any application | Applies to listed medicines :<br>When used as an excipient, permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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.

The Australian Register of Therapeutic Goods (ARTG) is available at: <https://www.ebs.tga.gov.au/>

#### JAPAN - USE IN QUASI DRUGS

| Status       | Adopted Japanese name    | MHW code         | Limitations  |
|--------------|--------------------------|------------------|--|
| Not approved | /<br>Purified water<br>/ | /<br>001370<br>/ | Not approved: Acemella Oleracea/Spilanthes Acemella<br>Not approved: Propanediol |

The Quasi-Drugs status is given for information only; it is based on the presence of the ingredient name in the List of Additives for Quasi-Drugs. It does not mean that the ingredient conforms with Quasi-Drugs requirements.

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## GATULINE EXPRESSION AF (Code: 5891)

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### CANADA - USE IN NATURAL HEALTH PRODUCTS

| Status                         | NHPID name                 | Route of administration/ Restrictions  |
|--------------------------------|----------------------------|--|
| Approved Chemical Name         | Trimethylene Glycol        | Role Non-medicinal<br>Purposes: Humectant , Solvent , Viscosity Decreasing Agent<br>Route Of Administration: Oral<br>Allowed Purposes: Humectant , Solvent<br><br>Route Of Administration: Topical<br>Allowed Purposes: Solvent , Viscosity Decreasing Agent |
| Approved Chemical Name         | Water                      | Role Medicinal:<br>Rationale: Classified as an NHP under Schedule 1, item 2 (an isolate) of the Natural Health Products Regulations.<br><br>Role Non-medicinal:<br>Purposes: Diluent , Solvent   |
| Approved Herbal Substance Name | Spilanthes Acmella Extract | Role non-medicinal:<br>Purposes: Skin-Conditioning Agent<br>Detail: Topical use only.  |

Under the Natural Health Products Regulations, which came into effect on January 1, 2004, natural health products (NHPs) are defined as: Probiotics; Herbal remedies; Vitamins and minerals; Homeopathic medicines; Traditional medicines such as traditional Chinese medicines; Other products like amino acids and essential fatty acids.

The Natural Health Products Ingredients Database (NHPID) lists acceptable medicinal and non-medicinal ingredients used in Natural Health Products. It is available at: <http://webprod.hc-sc.gc.ca/nhp-id-bdipn/search-rechercheReq.do>

## 6. NATURAL & ORGANIC COSMETICS

### STATUS OF THE INGREDIENT FOR ORGANIC/NATURAL COSMETIC FORMULATIONS

| Body              | Standard   | Status                | Evaluation conclusions                           |
|-------------------|--|-----------------------|--|
| <b>ECOCERT</b>    |  |                       |  |
| Ecocert Greenlife | Ecocert Standard for Natural and Organic Cosmetics | Approved raw material | Nat: 100%<br>Veg: 38%<br>Synth: 0%               |
| <b>COSMOS</b>     |  |                       |  |
| Ecocert Greenlife | COSMOS-standard                                    | Approved raw material | PPAI: 38 %<br>CPAI: 62 %<br>NNI: 0%<br>PeMo: 0 % |
| <b>NATRUE</b>     |  |                       |  |
| Bio-Inspecta      | NATRUE criteria                                    | Approved              | 62% derived natural, 5% natural, 33% water       |

ECOCERT: The following product has been evaluated by ECOCERT® Greenlife and complies with the ECOCERT standard for ingredients to be used in Ecological and Organic cosmetics. We would like to draw your attention to the fact that this product is not "Organic certified".

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Last update: 10 January 2023

### STATUS OF THE INGREDIENT FOR ORGANIC/NATURAL COSMETIC FORMULATIONS

| Body   | Standard | Status | Evaluation conclusions |
|--|----------|--------|------------------------|
| ECOCERT Definitions: Nat: Natural or from natural origin; Veg: Physically processed vegetal ingredients; Synth: Synthetic (petrochemical).   |          |        |                        |
| COSMOS: The following product has been evaluated by ECOCERT® Greenlife and complies with the COSMOS standard for ingredients to be used in COSMOS-Natural and COSMOS-Organic cosmetics. We would like to draw your attention to the fact that this product is not "Organic certified". |          |        |                        |
| COSMOS Definitions: PPAI = Physically Processed Agro-Ingredient; CPAI = Chemically Processed Agro-Ingredient; PeMo = Petrochemical Moieties; NNI: Non Natural Ingredients.   |          |        |                        |

### CALCULATIONS ACCORDING TO ISO 16128 STANDARD

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

- Natural content (CN): 39%
- Natural origin content (Cno): 100%
  - Organic content (CO): 0%
  - Organic origin content (COO): 0%

The indexes/ contents displayed above are based on Median Value Composition.

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).

## 7. RSPO CERTIFICATION

### ROUNDTABLE ON SUSTAINABLE PALM OIL

<http://www.rspo.org/certification>

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

## 8. CHEMICAL REGULATIONS

### CHEMICAL REGULATIONS

| INCI name                | CAS #                       | EC #                   | Chemical name                            |
|--------------------------|-----------------------------|------------------------|--|
| Propanediol              | 504-63-2<br>(or 26264-14-2) | 207-997-3<br>(or None) | 1,3-dihydroxypropane<br>(or Propanediol) |
| Water                    | 7732-18-5                   | 231-791-2              | Water                                    |
| Acmella Oleracea Extract | 90131-24-1                  | 290-335-0              | Spilanthes acmella, ext.                 |

EC numbers: There are three separate inventories. These are the European Inventory of Existing Commercial Chemical Substances (EINECS), the European List of Notified Chemical Substances (ELINCS) and the No-Longer Polymers (NLP) list.

EINECS numbers start with 2 or 3. ELINCS numbers start with 4. NLP numbers start with 5.

Substances without EC numbers were assigned "list numbers" in order to facilitate REACH submissions. They are solely of administrative, and not of regulatory relevance. The list numbers start with 6, 7, 8 or 9.

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### NATIONAL INVENTORIES

| INCI name                 | U.S.A. (TSCA) | Canada (DSL/NDSL) | Australia (AIIC) | China (IECSC) | Inventory names  |
|---------------------------|---------------|-------------------|------------------|---------------|--|
| Propanediol               | Listed        | DSL listed        | Listed           | Listed        | 1,3-Propanediol: AIIC, AREC, DSL, ECL, ENCS, IECSC, INSQ, NZIoC, PICCS, TCSI, TSCA / Propane-1,3-diol: DSL, EINECS, PICCS, REACH, TDCA, VNECI (or) Propanediol: DSL, ENCS, IECSC, NZIoC, TCSI, VNECI |
| Water                     | Listed        | DSL listed        | Listed           | Listed        | Water: AIIC, AREC, DSL, ECL, EINECS, ENCS, IECSC, INSQ, NZIoC, PICCS, REACH, TCSI, TDCA, TSCA, VNECI   |
| Acemella Oleracea Extract | Not listed    | Not listed        | Listed           | Listed        | Spilanthes acmella, ext.: EINECS, IECSC, REACH, TCSI, VNECI, AIIC  |

U.S.A.: Substances used in the following product categories are excluded from TSCA authority: foods, food additives, drugs, cosmetics.

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 to 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. Naturally occurring chemicals are exempted from AIIC listing. Chemicals not listed on the AIIC must be assessed before importation.

Australia: AIIC - Canada: DLS/NDSL - China: IECSC - European Union: EINECS, REACH - Japan: ENCS - Mexico: INSQ - New Zealand: NZIoC - Philippines: PICCS - South Korea: ECL, AREC - Switzerland: SWISS - Taiwan: TCSI - Thailand: TDCA - USA: TSCA - Vietnam: VNECI

### REACH REGULATION

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

**Overall status of the product**

Please refer to Safety Data Sheet

#### 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.