

CosmEthically ACTIVE Certificate

Technical Document

Version 1.0

www.cosmethicallyactive.com



Modern CosmEthics

Modern CosmEthics is a certification body that awards the CosmEthically ACTIVE certification mark. The key operational unit at Modern CosmEthics is the Modern CosmEthics Expert Team comprised of experts professionally active in the fields of cosmetology, pharmacognosy, pharmacy and chemistry, with competencies and in-depth knowledge in the area of cosmetic formulation and cosmetic ingredients of natural origin.

Modern CosmEthics' mission is to build and promote natural, sustainable, ethical and cosmetically active products with a special emphasis on scientific evidence, physiological compatibility and the rational formulating of cosmetics.

Contact information

Address:

Modern CosmEthics
Širimo dobro besedo d. o. o.
Črnova 3a
SI-3320 Velenje
Slovenia, Europe

Contact:

E-mail: info@cosmethicallyactive.com
Website: <https://cosmethicallyactive.com>
Phone: +386 31 492 496 (CET +1), Ms. Katja Schoss

About the 'Technical Document'

This 'Technical Document' defines basic principles, criteria and work processes in the certification of products with the CosmEthically ACTIVE certification mark. Criteria are reviewed regularly according to the availability of new scientific and technical data, and the evolution of cosmetics and chemicals legislation. The principle of the CosmEthically ACTIVE criteria is legislation of the European Union.

Last valid version: Version 1.0, November 2020

Copyright

© Širimo dobro besedo d. o. o.

All rights reserved. This 'Technical Document' is the property of Modern CosmEthics, Širimo dobro besedo d. o. o. No part of this publication may be reproduced, distributed or processed, in any form or by any means, to any extent or by any process without the prior written permission of Modern CosmEthics.

Contents

Modern CosmEthics	2
Contact information.....	2
About the 'Technical Document'	2
Copyright.....	2
1 CosmEthically ACTIVE certificate - introduction.....	4
2 Objectives and general information	5
2.1 Basic principles and criteria – general overview	5
3 Flowchart of the CosmEthically ACTIVE certification.....	7
4 Categories of cosmetic ingredients.....	9
4.1 Permitted cosmetic ingredients.....	10
4.2 Examples.....	10
4.2.1 General examples	10
4.2.2 Permitted preservatives.....	11
4.2.3 Permitted fragrances and perfuming ingredients.....	12
4.2.4 Nanomaterials.....	12
4.2.5 Cosmetic ingredients of animal origin.....	12
4.2.6 Cosmetic ingredients of recombinant origin.....	12
4.2.7 Not permitted and restricted cosmetic ingredients.....	12
4.3 Recommendations	13
4.4 Change to an ingredient's status	13
5 Claims communication.....	14
6 Certification process – Assessment of a cosmetic product	15
6.1 Documentation and product sample	15
6.2 Cosmetic formulation.....	16
6.3 Packaging.....	16
6.4 Assessment report and corrections	16
6.5 Control and audit.....	17
6.6 Certificate renewal.....	17
Annex I – Examples of analytical specifications.....	18

1

CosmEthically ACTIVE certificate – introduction

Need for certification

Natural cosmetics have evolved into an increasingly growing industry that follows the needs and demands of aware consumers and emerging environmental issues. Due to the lack of an officially harmonised, regulatory definition of natural cosmetics at the global or national level, different certification approaches have emerged, mainly focused on the naturalness of cosmetic ingredients based on their origin and processing. This is of the utmost importance in terms of environmental impacts. However, additional aspects urgently need to be covered to facilitate the establishment of natural cosmetics as a branch of high-quality, skin-compatible, sustainable and rational cosmetics. That's where the CosmEthically ACTIVE certificate plays a key role.

New cosmetics era

CosmEthically ACTIVE is the first certificate that pursues an integral approach to the evaluation of cosmetic products. It reviews a cosmetic product by the 1) origin of the ingredients, 2) environmental impacts, 3) level of physiological compatibility, 4) concentration of the cosmetically active ingredients and the science-based evidence behind them, 5) principles of rational formulating with no redundancy, and 6) non-misleading, ethical claims.

Based on science

The main added value and uniqueness of the CosmEthically ACTIVE certificate is the scientific assessment of a cosmetic product during the certification process, made by independent cosmetology scientists. **Scientific evaluation is a guarantee that CosmEthically ACTIVE certified products are of the highest quality and truly natural, active, skin, animal and environmentally friendly.**

2

Objectives and general information

This 'Technical Document' defines basic principles, criteria and work processes in the certification of products with the CosmEthically ACTIVE certification mark. It applies to the regulatory category of products defined as cosmetic products.

2.1 Basic principles and criteria – general overview

Origin and impacts of the ingredients

Permitted are cosmetic ingredients of completely natural origin, semisynthetic origin and synthetic origin that are structurally identical to naturally present substances, or that have the ability to (bio)degrade into naturally present substances and express a high rate of physiological compatibility. The ultimate goal of ingredients' selection is to ensure the highest possible level of environmental protection and physiologically compatible cosmetic activity.

Physiological compatibility

The overall composition of a cosmetic product must follow the parameters of the skin's or hair's natural physiology, such as the beneficial value of pH.

Evidence-based cosmetics

The selection of individual cosmetic ingredients is evidence-based. Cosmetically active ingredients are incorporated at active concentrations that have been proven to express desired cosmetic effects after application, or desired action may be predictable based on the ingredient's chemistry when scientific evidence regarding cosmetic activity is not available.

Rational formulating

Rational cosmetic products are demanded: individual cosmetic ingredients are selected on a case-by-case basis, based on their functions and desired cosmetic activity, and technological and sensory aspects, without redundant ingredients. The total number of ingredients should be kept to a minimum.

Claims communication

The CosmEthically ACTIVE certification process evaluates claims used to communicate certified products. Misleading, false and legally prohibited claims are not permitted.

Animal testing ban

A cosmetic product must not be tested on animals because the concept of the CosmEthically ACTIVE certificate pursues the highest of values and ethical principles. An animal testing ban has already been enacted in EU cosmetics legislation.

Legislative

National regulatory authorities and this certification process require a cosmetic product to comply with the applicable cosmetic legislative, depending on the market where a product is registered. The main regulations covering cosmetic products in force in the EU are: [Regulation \(EU\) 1223/2009 on cosmetic products](#), [Commission Regulation \(EU\) 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products](#), [Regulation \(EC\) 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals](#), and [Regulation \(EC\) 834/2007 on organic production and labelling of organic products](#). For non-EU countries, other documents are relevant, including 1) USA: [Federal Food, Drug & Cosmetic Act \(FD&C Act\)](#), [Summary of color additives for use in the United States in Foods, Drugs, Cosmetics and Medical devices](#); 2) Australia: [Industrial Chemicals \(Consequential Amendments and Transitional Provisions\) Act 2019](#), [Consumer Goods \(Cosmetics\) Information Standard 2020](#); etc.

Note: *During the CosmEthically ACTIVE certification process, compliance with the applicable national regulations is not checked, and Modern CosmEthics shall not be held liable for deviations from those regulations. The CosmEthically ACTIVE certificate and 'Assessment report' prepared during scientific evaluation of a cosmetic product in the certification process shall by no means serve as a basis or substitute for the 'Cosmetic Product Safety Report' (in the EU), or any other legal documents applicable to the market where a cosmetic product is registered or sold.*

3

Flowchart of the CosmEthically ACTIVE certification

Certification process	Provided by Modern CosmEthics	Provided by the Applicant
<p>STEP 1 NON-DISCLOSURE AGREEMENT</p> <p>Modern CosmEthics signs a non-disclosure agreement (NDA).</p> <p>The Applicant pays the certification fee.</p>	<ul style="list-style-type: none">• NDA• Proforma invoice	<ul style="list-style-type: none">• Signed NDA
<p>STEP 2 PRE-REVIEW</p> <p>Pre-review of the cosmetic product's INCI list of ingredients for their compliance with the CosmEthically ACTIVE criteria on permitted and non-permitted cosmetic ingredients.</p> <p>A compliant cosmetic product enters the review phase, while a non-compliant cosmetic product is discussed for possible changes.</p>	<ul style="list-style-type: none">• Pre-review assessment report	<ul style="list-style-type: none">• Complete list of the cosmetic product's ingredients defined by their INCI names
<p>STEP 3 REVIEW</p> <p>The Applicant completes the application form for the cosmetic product to be certified.</p> <p>An Assessor of the Modern CosmEthics Expert Team reviews a cosmetic product for its compliance with the CosmEthically ACTIVE criteria. The Assessor prepares and the Expert Board adopts the assessment report.</p>	<ul style="list-style-type: none">• Application form• Statement of conformity	<ul style="list-style-type: none">• Completed application form (upon agreement, other forms of documents are accepted, e.g. excel tables)• Technical documentation for individual ingredient (certificate of analysis, technical datasheet, SDS/MSDS, etc.)• A sample of the product, including the original packaging as sold: 1 unit for samples >30 g, 2 units for samples <30 g• A written statement that the cosmetic product was not tested on animals

STEP 4
ASSESSMENT REPORT

The Applicant receives the product's assessment report within 30 working days after receipt of the sample, unless agreed otherwise.

- Assessment report
- Notification regarding the awarding of the CosmEthically ACTIVE certificate

–

STEP 5
LOGO INFORMATION

The Applicant receives detailed information about the use of the CosmEthically ACTIVE certification mark for the approved cosmetic product(s). The Applicant receives the certification mark logo.

- Rules on the use of the CosmEthically ACTIVE certification mark
- Logo

–

STEP 6
LICENCING AGREEMENT AND CERTIFICATE

A licencing agreement is signed, and the certificate is granted to the Applicant.

- Licensing agreement
- Certificate
- Invoice
- Signed licensing agreement

4

Categories of cosmetic ingredients

This section is the first defining element of the CosmEthically ACTIVE concept. It is characterised by a significant shift from the criteria of conventional certifications for natural and/or organic cosmetics where, in general, cosmetic ingredients are classified into natural ingredients, chemically and physically processed natural ingredients, and nature-identical ingredients, which are further classified by the minimum and/or maximum content permitted in a cosmetic product.

Categories of cosmetic ingredients according to CosmEthically ACTIVE criteria are based on the origin of ingredients and the ability of degradation after application to the human body or release into the environment. There are no artificially defined percentages referring to individual categories of ingredients, and CosmEthically ACTIVE certification does not distinguish between different natural and/or organic categories.

The concept of CosmEthically ACTIVE is focused on the intersection of cosmetic activity/performance, the environmental impacts of ingredients and physiological compatibility. A cosmetic product is scientifically evaluated as a whole. This concept is based on a rational understanding of modern cosmetology and makes the CosmEthically ACTIVE certificate an advanced certification system strongly oriented towards the healthy and ethical future of our planet.

Origin of cosmetic ingredients

Permitted are cosmetic ingredients that fulfil one of the following conditions:

- **Condition 1:** Substances of natural, semisynthetic or synthetic origin that are structurally identical to substances naturally present in the human body and in our environment (e.g. in the plant, fungi and animal worlds, and of mineral origin, except petrochemical-derived cosmetic ingredients);
- **Condition 2:** Substances of semisynthetic or synthetic origin that are composed from the body's or environment's own building blocks into which they are subsequently broken down; and
- **Condition 3:** Substances of semisynthetic or synthetic origin with a high rate of (bio)degradability into substances structurally identical to the body's or environment's own substances. However, those ingredients are only permitted when, due to specific chemical or technological characteristics, there is not a suitable replacement with substances complying with condition 1 or 2.

Note: *Substances of natural origin are those isolated directly from natural sources. Substances of semisynthetic origin are those that are produced from substances isolated from natural sources and subsequently modified chemically. Substances of synthetic origin are those that are produced through chemical synthesis.*

4.1 Permitted cosmetic ingredients

Cosmetic ingredients that fulfil condition 1

Permitted are the following substances and chemical groups of substances considered as naturally present in the environment:*

- Herbal drugs and powdered herbal drugs
- Plant extracts and juices
- Vegetable butters and oils, and unsaponifiable compounds
- Essential oils, absolutes, CO₂ extracts and hydrolates
- Monosaccharides, oligosaccharides and polysaccharides
- Amino acids, peptides and proteins
- Vitamins and provitamins
- Vegetable waxes
- Other secondary plant metabolites: phenolic, carboxylic and terpenic compounds, etc.
- Mineral (anorganic) cosmetic ingredients

Cosmetic ingredients that fulfil conditions 2 and 3

Permitted are substances that are obtained from the body's or environment's own building blocks into which they are subsequently broken down, and substances with a high rate of (bio)degradability into the body's or environment's own building blocks. Please see the main document 'List of permitted cosmetic ingredients'. The list is continuously updated and amended based on new scientific evidence, particularly in the areas of cosmetology and toxicology.

Certain cosmetic ingredients are allowed only if produced by a specific synthetic process, as not all processes are equally environmentally friendly or they may produce impurities with different dermal impacts. Cosmetic ingredients produced by chemical reactions of specific health and environmental hazards, such as alkoxylation (ethoxylation, propoxylation, etc.), are only allowed in a highly limited range, as they are irreplaceable due to their specific functions.

4.2 Examples

4.2.1 General examples

Sorbic acid (INCI: *Sorbic Acid*) is a naturally present substance found in, for example, fruits of *Sorbus aucuparia*. As a cosmetic ingredient, it is used as a preservative, and is typically of synthetic origin. Sorbic acid fulfils condition 1.

Allantoin (INCI: *Allantoin*) is a naturally present substance found in, for example, roots of *Symphytum officinale*. As a cosmetic ingredient, it is used as a skin conditioning, skin protecting and soothing ingredient, and is typically of synthetic origin. Allantoin fulfils condition 1.

* The list is to be considered general and indicative only, as naturally occurring substances comprise a large group of structures. Please check with the certification body for details or in case of doubt.

Decyl glucoside (INCI: *Decyl Glucoside*) is a synthetic compound produced from decyl alcohol (1-decanol) and glucose, linked with a biodegradable ester (glycosidic) bond. Decyl alcohol is obtained through the reduction of decanoic acid, which results from the hydrolysis of vegetable triglycerides such as coconut or palm oil. Glucose is obtained through the hydrolysis of starch, e.g. corn, potato or wheat starch. Decyl glucoside as a cosmetic ingredient is used as a surfactant for skin and hair cleansing, and an emulsion stabiliser. Decyl glucoside fulfils condition 2.

Panthenol (INCI: *Panthenol*) is a synthetic compound typically produced from α -hydroxy- β , β -dimethyl- γ -butyrolactone and 3-aminopropanol. In the skin, it is converted to pantothenic acid or vitamin B₅. Panthenol as a cosmetic ingredient is used as an antistatic, hair conditioning and skin conditioning ingredient. Panthenol fulfils condition 2.

Propylene glycol or 1,2-propanediol (INCI: *Propylene Glycol*) is a synthetic compound typically produced from 1) propylene oxide or 2) glycerol. Only the latter substance is permitted. Propylene glycol as a cosmetic ingredient is used as a humectant, skin conditioning ingredient, solvent and viscosity controlling ingredient. Propylene glycol produced from glycerol fulfils the condition of avoiding the use of propoxylation, i.e. a chemical reaction of specific health and environmental hazard, and thus condition 3.

Cationic guar (INCI: *Guar Hydroxypropyltrimonium Chloride*) is a semisynthetic compound typically produced from naturally present guar gum and synthetic (3-chloro-2-hydroxypropyl)trimethylammonium chloride. It has anti-static, film forming, skin conditioning and viscosity controlling properties, but is permitted for use according to CosmEthically ACTIVE criteria as a hair antistatic only. It fulfils condition 3.

4.2.2 Permitted preservatives

Preservation in natural cosmetics is among the most demanding formulation aspects, for both conventional products with typically long shelf lives and niche products of small, hand-made production series. In terms of rational preservation, the approach of selecting an evidence-based preservative concentration is strongly supported, which is the minimum possible concentration to avoid significant unwanted reactions (e.g. irritation or allergenic response, inhibition of microbiota) and concurrently the maximum concentration needed to achieve sufficient antimicrobial protection.

Permitted are the following substances officially defined as preservatives according to the Regulation (EC) 1223/2009 (please consider the defined restrictions in the aforementioned regulation):

- Benzoic acid, potassium benzoate, sodium benzoate
- Benzyl alcohol
- Citric acid (and) silver citrate
- Dehydroacetic acid, sodium dehydroacetate
- Phenoxyethanol
- Propionic acid, potassium propionate, sodium propionate
- Salicylic acid, potassium salicylate, sodium salicylate
- Silver chloride (deposited on titanium dioxide)
- Sorbic acid, potassium sorbate, sodium sorbate
- Undecylenic acid, potassium undecylenate, sodium undecylenate

Please note that, within the concept of self-preserving cosmetics, the addition of cosmetic ingredients with an antimicrobial action that are primarily used as 1) functional technological constituents of a cosmetic product and/ or 2) for their positive effects on the skin or hair contributes significantly to the total preservative function. The following are some typical examples marketed commercially as preservation boosters: *p*-anisic acid and sodium anisate, glyceryl caprylate, *Lactobacillus* ferment, levulinic acid and sodium levulinate, 1,2-pentanediol (pentylene glycol, sugar derived), phenethyl alcohol, etc.

4.2.3 Permitted fragrances and perfuming ingredients

Permitted are naturally occurring aromatic substances such as essential oils, absolutes and CO₂ extracts, and isolates. Aromatic substances of semisynthetic origin and synthetic origin are permitted if conditions specified in the section on 'Origin of cosmetic ingredients' are fulfilled.

Cosmetic ingredients used as fragrances and perfuming ingredients recognised as skin sensitising by the European Chemicals Agency (ECHA) and/or restricted by the International Fragrance Association (IFRA) must be used according to applicable restrictions.

4.2.4 Nanomaterials

Nanomaterials are not permitted, as there is currently inadequate information on the risks associated with their use, except for titanium dioxide and zinc oxide used as UV-filters. Both ingredients must be used in accordance with the opinions of the Scientific Committee on Consumer Safety (SCCS); the documents [SCCS/1489/12 Revision of 11 December 2012](#), [SCCS/1516/13 Revision of 22 April 2014](#), [SCCS/1617/20 Final Opinion](#).

4.2.5 Cosmetic ingredients of animal origin

Cosmetic ingredients of animal origin are not permitted, as the concept of the CosmEthically ACTIVE certificate pursues the highest of values and ethical principles.

4.2.6 Cosmetic ingredients of recombinant origin

The concepts of naturalness and natural cosmetics are intrinsically linked to sustainability, which, on the other hand, is the ultimate goal of modern technological innovation. Recombinant biotechnology as both a science and industrial sector has contributed beneficially to the availability of cosmetic ingredients in terms of, for example, biodegradability and renewability. It raises, however, important ethical and social questions.

Legislative in the European Union follows strict health and environmental conditions related to the application of biotechnological methods, including the use of genetically modified organisms, covered in the documents [Council Directive 90/219/EEC](#), [Council Directive 98/81/EC](#), [Commission Decision 2000/608/EC](#), [Council Directive 90/220/EEC](#), [Directive 2001/18/EC](#), [Council Decision 2002/811/EC](#), [Regulation \(EC\) 1830/2003](#), [Directive 2009/41/EC](#). Cosmetic ingredients of recombinant origin are permitted only if their manufacturing and/or processing is strictly in compliance with the aforementioned regulations.

4.2.7 Not permitted and restricted cosmetic ingredients

Not permitted are the following substances and chemical groups of substances:

- Denatured alcohol
- Halogenated substances
- Petrolatum, mineral oil, paraffin and other petrochemical-derived cosmetic ingredients
- Silicones
- Sodium lauryl sulphate, ammonium lauryl sulphate and sodium coco sulphate

- Nanomaterials*
- Cosmetic ingredients produced by ethoxylation or propoxylation*
- Antiperspirants
- Cosmetic ingredients of animal origin
- Cosmetic ingredients under assessment as endocrine disrupting by the European Chemicals Agency (ECHA)

Cosmetic ingredients recognised as skin sensitising by the ECHA and/or restricted by the International Fragrance Association (IFRA) must be used according to applicable restrictions.

4.3 Recommendations

Strongly supported are the use of: cosmetic ingredients of local origin, cosmetic ingredients of organic origin and palm oil from sustainable sources. These are, however, only recommendations, not necessary conditions.

4.4 Change to an ingredient's status

The list of permitted cosmetic ingredients is reviewed and modified regularly according to the availability of new scientific and technical data, and the evolution of cosmetics and EU legislation on the registration, evaluation, authorisation and restriction of chemicals (REACH). A certificate holder is informed about changes in the lists of permitted and not permitted cosmetic ingredients.

Compliance with the currently valid list of permitted cosmetic ingredients is re-verified during the certificate renewal process. The transition period for required reformulation activities is defined in agreement with the certificate holder.

* Exceptions are only allowed to a very limited degree, as they are irreplaceable due to their specific functions.

5

Claims communication

This section is the second defining element of the CosmEthically ACTIVE concept. **It strives for a fair, evidence-based communication of a product's claims, and protects cosmetics and users against misleading advertising.**

Claims about the cosmetic activity and properties of a cosmetic product are based on the product's composition, including the presence of cosmetically active ingredients that are mainly responsible for the desired, specific skin care effects (e.g. antioxidative effects). Without a suitable concentration, no significant activity can be expected. The Applicant's own clinical tests and/or studies are not required to demonstrate cosmetic activity. Cosmetic activity is evaluated based on scientific literature.

Note: A cosmetic product is not a medicine. Cosmetics are not intended to treat or prevent diseases, but rather to nurture and maintain the body in a good condition. Claims indicating possible therapeutic properties are not permitted.

During the CosmEthically ACTIVE certification process, an independent scientific assessment of a cosmetic product is made. Claims used for describing and marketing a product, including claims on the packaging, are evaluated. Misleading, false and legally prohibited claims are not permitted.

Example: Hyaluronic acid hydrating gel for mature skin with soothing effects

INCI	Content (%)	Function
<i>Aloe Barbadensis Leaf Juice</i>	20	skin conditioning
<i>Allantoin</i>	0.1	skin conditioning, skin protecting, soothing
<i>Gluconolactone (and) Sodium Benzoate</i>	q.s.	preservative
<i>Hyaluronic acid</i>	0.001	moisturising
<i>Xanthan Gum</i>	0.7	gel forming
<i>Aqua</i>	q.s.	solvent
<i>Citric acid</i>	q.s.	buffering

Not approved claim: Hyaluronic acid hydrates the skin, and reduces the appearance of fine lines and wrinkles.

Explanation: The content of hyaluronic acid in the formulation is too low to exert the claimed effect on the skin.

Suggested approved claim: Hydrating gel for mature skin with soothing effects.

Explanation: The contents of *Aloe barbadensis* leaf juice and allantoin are suitable to exert the claimed soothing effect.

6

Certification process – Assessment of a cosmetic product

The key element of the certification process is the scientific assessment of a cosmetic product, made by an appointed Assessor who is an independent cosmetology scientist. First, a cosmetic product is assigned an application reference number to ensure complete anonymity, under strict confidentiality. A sample of a cosmetic product (repacked, if necessary, to avoid the identification of the Applicant) and corresponding technical documentation provided by the Applicant is then sent to an Assessor from the Modern CosmEthics Expert team who is responsible for the assessment of a cosmetic product, and an assessment report is prepared. Assessors are professionals active in the fields of cosmetology, pharmacognosy, pharmacy and chemistry, with competencies in the area of cosmetic formulation and in-depth knowledge about ingredients of natural origin.

The presented evaluation approach aims to ensure a high level of quality of CosmEthically ACTIVE certified products, in terms of both the quality of raw materials and the product itself according to the principles of the CosmEthically ACTIVE criteria.

6.1 Documentation and product sample

The Applicant must provide **technical documentation** for individual cosmetic ingredients in the formulation, including certificates of analysis, technical datasheets and SDSs/MSDSs issued by the ingredients' supplier/manufacturer. It is strictly demanded that the certification body is informed immediately if the supplier/manufacturer is replaced, and new technical documentation must be provided.* Technical documentation serves as a basis for the evaluation of quality of raw materials.

The Applicant must provide **a sample of a product**, which is one unit for samples >30 g and two units for samples <30 g in the original packaging as sold. If the product is in the phase of development, packaging and packaging claims are reviewed separately. The sample serves as a basis for the evaluation of the quality of the cosmetic formulation.

** Please note that the quality of raw materials from different suppliers/manufacturers may vary significantly. Please consult with the certification body for compliance. The transition period for possible correction activities is defined in agreement with the certificate holder. In case of non-compliance, the certificate may be withdrawn.*

6.2 Cosmetic formulation

The assessment of a cosmetic formulation comprises three parts:

- 1. The evaluation of quantitative and qualitative composition.** The basic principles and criteria of the CosmEthically ACTIVE certificate must be complied with to ensure that the formulation as a whole is of evidence-based, balanced and rational composition, and highly compatible with the physiological needs of the skin/hair. For details, please see sections '2 Objectives and general information', '4 Categories of cosmetic ingredients' and '5 Claims communication'.
- 2. The evaluation of the quality of individual cosmetic ingredients as raw materials.** Technical documentation concerning raw materials is reviewed. Cosmetic ingredients with highly insufficient technical documentation are not acceptable and are deemed a major deficiency.* Cosmetic ingredients with technical documentation of poor quality are deemed a minor deficiency,* and discussed with the Applicant for possible changes. Examples of analytical specifications for cosmetic ingredients of suitable quality are presented in Annex I.
- 3. Basic analysis.** A cosmetic product is analysed to test, for example, organoleptic properties, pH value, physical stability, the content of ingredients, etc.

6.3 Packaging

Version 1.0 of the CosmEthically ACTIVE certificate does not evaluate materials of a cosmetic product's packaging. However, the use of recyclable and/or biodegradable packaging material is strongly supported.

CosmEthically ACTIVE certification evaluates claims written on the primary and/or secondary packaging. For details, please see the section '5 Claims communication'.

6.4 Assessment report and corrections

The above-defined topics are evaluated in the assessment report. The assessment report is issued within 30 working days after receipt of the sample, unless agreed otherwise.

Based on the professional opinion of an Assessor and the Expert Board, 1) the awarding of the CosmEthically ACTIVE certificate is approved directly if a cosmetic product meets the criteria, or 2) minor and major deficiencies are identified. Minor deficiencies are defined as insignificant deviations from the CosmEthically ACTIVE criteria, e.g. insufficient specifications of raw materials and ambiguous claims,* and are discussed with the Applicant for possible corrections. Major deficiencies are critical and conflict with the criteria of the CosmEthically ACTIVE certificate, e.g. insufficient content of a leading cosmetically active ingredient, non-physiological pH of a cosmetic product and, false claims,* and are discussed with the Applicant for necessary corrections.

* Please check with the certification body for details or in case of doubt.

6.5 Control and audit

Control over the truthfulness of information included in documents/materials provided by the Applicant (i.e. a cosmetic product's composition, technical documentation, packaging, etc.) is carried out regularly. An on-site audit is conducted by prior arrangement, if the certification body deems that necessary.

6.6 Certificate renewal

The CosmEthically ACTIVE certificate is valid for two years. Six months prior to the expiry certificate of the, the certificate holder is informed by the certificate body. In the certificate renewal process, the composition of a cosmetic product, including compliance with the currently valid list of permitted cosmetic ingredients, technical documentation of ingredients, packaging, claims, etc., are re-verified. In case of major changes that were not previously reported to the certification body and that lead to non-compliance with the CosmEthically ACTIVE criteria,* the certificate may be withdrawn. Minor changes* are discussed with the certification body and a transition period for correction activities is defined in agreement with the certificate holder.

* Please check with the certification body for details or in case of doubt.

Annex I – Examples of analytical specifications

CERTIFICATE OF ANALYSIS

Product: Almond Oil Cold Pressed, Organic
INCI Prunus Amygdalus Dulcis Oil
Lot-no.: 20-08
Date of analysis: 24.09.2020
Agriculture: Slovenia
Production country: UK
Production date: 08.2020

Characters: liquid, light-yellow colour, weak, sweetish-nutty odour

Test result:

Parameter	Unit	Specification	Result
Acid value			
Method: DIN EN ISO 660	mg KOH/g	<4.0	1.0
Peroxide value			
Method: DIN EN ISO 3960	meq O ₂ /kg	<10.0	4.0
Relative density (20 °C)			
Method: DIN EN ISO 15212-1	–	0.910–0,925	0.916
Refraction index (20 °C)			
Method: DIN 51423-2	–	1.4680–1.4730	1.4705
Unsaponifiable matter			
Method: Eur Ph 8.0	%	0.2–1.5	0.8

Fatty acids in fat (methyl ester) Method: ISO 12966 mod., GC/FID	Unit	Specification	Result
C14:0 Myristic acid	%	–	0.03
C16:0 Palmitic acid	%	4.0–9.0	6.6
C16:1 Palmitoleic acid	%	<0.8	0.6
C17:0 Margaric acid	%	–	0.06
C17:1 c-Heptadecenic acid	%	–	0.1
C18:0 Stearic acid	%	<4,0	2.2
C18:1 c-Vaccenic acid	%	–	1.2
C18:1 Oleic acid	%	62.0–86.0	67.7
C18:2 Linoleic acid	%	7.0–30.0	21.3
C20:0 Arachidic acid	%	<1.0	0.1
C20:1 Eicosenoic acid	%	<1.0	0.1
C22:1 Erucic acid	%	–	< 0.05

TECHNICAL DATASHEET – CHAMOMILLA RECUTITA EXTRACT

Product:	CHAMOMILLA RECUTITA EXTRACT (APIGENIN 0.5%)
Botanical name:	<i>Matricaria chamomilla</i> L. syn. <i>Chamomilla recutita</i> (L.) Rauschert
Botanical family:	Asteraceae
CAS number:	84082-60-0
Part of plant used:	Inflorescences
Solvent extraction:	Ethanol 60/Water 40
Excipients:	Maltodextrin (from corn) <= 50%

Raw material analysis	Specifications
ASSAY	Apigenin and apigenin-7-glucoside (HPLC, Ph. Eur.) >= 0.5% w/w
DER	1-3:1
APPEARANCE	Hygroscopic powder
COLOUR	Light brown
ODOUR	Characteristic
TASTE	Characteristic
DENSITY	400-600 g/l
SOLUBILITY	Sparingly soluble in water
pH	4.0-6.0 (1:10)
LOSS ON DRYING	<= 6.0% w/w
HEAVY METALS	< 20 ppm (C method Ph. Eur. current ed.) Pb <= 3 ppm Cd <= 1 ppm Hg <= 0.1 ppm
RESIDUAL SOLVENT	Complies with Ph. Eur. current ed. and Dir. 2009/32/EC
PESTICIDES	Complies with Ph. Eur. current ed. Complies with Regulation 2005/396/EC and later updates, reference to the ratio E/D
AFLATOXINS	Aflatoxin B1 < 2 ppb; Aflatoxin B1, B2, G1, G2 < 4 ppb
POLYCYCLIC AROMATIC HYDROCARBONS	PAH 4 (Sum of benzo (a) pyrene, benzo (a) anthracene, benzo (b) fluoranthene e chrysene) <= 50 ppb (Reg. 1933/2015/EU) Benzo (a) pirene <= 10 ppb (Reg. 1933/2015/EU)
TOTAL BACTERIA	<= 5x10000 cfu/g (TAMC, Ph. Eur. 5.1.8, cat. B, oral use)
YEASTS AND MOULDS	<= 5x100 cfu/g (TYMC, Ph. Eur. 5.1.8, cat. B, oral use)
PATHOGENS	<i>Salmonella</i> : absent/25 g; <i>E. coli</i> : absent/1 g (Ph. Eur. 5.1.8, cat. B, oral use)
BILE-TOLERANT GRAM-NEGATIVE BACTERIA	<= 100 ufc/g (Ph. Eur. 5.1.8, cat. B, oral use)

COMPLIANCE

PHARMACOPOEIA Analytical methods comply with Ph. Eur. current ed., except where otherwise specified

GENERAL NOTICES

INCI NAME	Chamomilla Recutita Flower Extract
EINECS/ELINCS NUMBER	282-006-5
DRYING METHOD	Spray-drying
ORIGIN OF THE PLANT	Cultivated plant, Europe
ORIGIN OF RAW MATERIAL	Europe
ANALYTICAL MARKER	Apigenin
ACTIVES OF THE PLANT	Essential oil (chamazulene, α -bisabolol, etc.); flavonoids (apigenin, luteolin, etc.), the latter are calculated as apigenin and apigenin-7-glucoside $\geq 0.5\%$ w/w
TYPE OF PRODUCT AND USE	Food and cosmetic grade
PRESERVATIVES	None
ANTIOXIDANTS	None
ALLERGENS	Free from food allergens (Reg. 1169/2011/EU, Annex II) It does not contain gluten
PARTICLE SIZE	$\geq 90.0\%$ through 300 micron
RADIOACTIVITY	< 600 Bq/Kg
HANDLING	Handle in well ventilated room, avoid the contact of powder with fire sources, such as flames and sparks, etc
STORAGE	Store in a cool, dry, and ventilated place away from light, in original containers, tightly closed, or in inert plastic containers
NUTRITIONAL VALUES	Carbohydrates: 90–95%; fats: 0–1%; proteins: 0–1%; minerals: 3–5%. Calories: 409 Kcal/100 g (1711 KJ/100 g)

NOTES

NOTES GMO free (Reg. 1829-1830/2003/EC); BSE/TSE free

CLP

P261 Avoid breathing dust/fume/gas/mist/ vapours/spray.

ESSENTIAL OIL CHROMATOGRAPHY

Gas chromatography, GC-MS

Date:	28/09/2020
Essential oil:	Neroli
Lot Number:	NER-04
Density to 20°C (g/cm ³):	0.8700
Refractive index:	1.4715
Optical rotation to 20°C:	NA
Culture mode:	Cultivated, organic
Country:	France
Production date:	06/2019
Shelf life:	06/2024
Extraction mode:	Steam distillation
Latin Name:	<i>Citrus × aurantium</i> subsp. <i>aurantium</i>
Used Parts:	Flowers

Molecule	%		
ALPHA-PINENE	0.78	ALPHA-TERPINEOL	4.37
SABINENE	0.83	NEROL	1.15
BETA-PINENE	12.10	GERANIOL*	3.13
BETA-MYRCENE	2.25	LINALYL ACETATE	1.62
ALPHA-TERPINENE	0.26	METHYL ANTHRANILATE	0.26
LIMONENE*	15.46	NERYL ACETATE	1.51
CIS-BETA-OCIMENE	0.91	GERANYL ACETATE	3.04
TRANS-BETA-OCIMENE	8.65	BETA-CARYOPHYLLENE	0.85
GAMMA-TERPINENE	0.30	GERMACRENE D	0.20
TERPINOLENE	0.59	ALPHA-FARNESENE	0.25
LINALOOL*	32.79	NEROLIDOL	2.64
TERPINENE-4-OL	0.41	FARNESOL*	2.78
		Total identified	97.13

* Allergens