Centella Asiatica Extract: Safety Assessment · Application Fields · Recommended Dosage

Centella Asiatica Extract is a natural mixture prepared from *Centella asiatica (L.) Urban*, a plant of the genus *Centella* in the Apiaceae family, through modern processes such as solvent extraction, ultrasonic-assisted extraction and membrane separation. Its core active components are pentacyclic triterpenoids including asiaticoside, madecassoside, asiatic acid and madecassic acid, with a CAS number of 84696-21-9 and an EC number of 283-640-5. It has been widely used in cosmetics, medicine, food, industry and other fields[1][2][3]. From the three core dimensions of safety assessment, application fields and recommended dosage, this paper conducts a systematic and hierarchical professional analysis combined with authoritative data and practical application scenarios, taking into account both scientificity and practicability, so as to provide a comprehensive reference for relevant practitioners.

Ⅰ. Safety Assessment of Centella Asiatica Extract

The safety assessment of Centella Asiatica Extract follows a three-dimensional system of "toxicological tests + authoritative institution certification + regulatory compliance", with reference to the *Cosmetic Safety Technical Specification (2015 Edition)*, *Technical Guidelines for Cosmetic Safety Assessment* and the evaluation standards of international authoritative institutions (CIR, SCCS). It covers all-dimensional toxicological endpoints such as acute toxicity, irritation and sensitization, confirming its safety to the human body and the environment within the scope of rational use. The specific assessment contents are as follows.

1.Basic Information and Compliance Premises

1.1 Raw material compliance: Centella Asiatica Extract has been included in the *Catalogue of Used Cosmetic Raw Materials (2021 Edition)* with the serial number 03171. It is not a prohibited substance in China, the European Union, the United States and other mainstream markets, and can be legally used in cosmetics, food, medicine and other compliant fields.

1.2 Hazardous substance control: The main hazardous substances that may be contained in this raw material are pesticide residues (from the raw material planting link). During the production process, it is necessary to ensure that the indicators such as pesticide residues, heavy

metals, microorganisms and aflatoxins meet the regulatory requirements of the corresponding fields through GAP planting base management, raw material pretreatment and finished product testing. Among them, the limits for heavy metals are lead ≤10mg/kg, arsenic ≤2mg/kg, mercury ≤1mg/kg; for microorganisms, the total bacterial count of cosmetic grade is ≤1000CFU/g, and food grade complies with the requirements of GB 2760.

1.3. **Authoritative certification support**: It has passed international quality system certifications such as GMP, ISO22716, ECOCERT and COSMOS, and complies with the US FDA OTC registration and South Korean KFDA certification standards. Its safety assessment data is included in the *International Cosmetic Safety Assessment Data Index*.

2 Core Toxicological Assessment Data (Precise Quantification)

Toxicological assessment covers key endpoints such as oral/dermal acute toxicity, skin/eye irritation, sensitization and genotoxicity. The data are all from standardized toxicological tests and evaluation reports of international authoritative institutions (CIR, SCCS), as follows:

2.1. **Acute toxicity**: The oral LD_{50} (mice) > 5000mg/kg and dermal LD_{50} (rats) > 2000mg/kg. According to the acute toxicity classification standard, it is rated as "practically non-toxic", and a single exposure will not cause acute damage to the human body.

2.2. **Skin irritation and corrosion**: Rabbit dermal irritation tests show that the skin irritation reaction scores at 24h, 48h and 72h are all 0, with no irritation symptoms such as erythema and edema, which is rated as "non-irritating to skin". The slight irritation reaction to damaged skin can subside within 24h without corrosiveness.

2.3. **Eye irritation**: Rabbit eye irritation tests show no congestion or edema of the ocular mucosa, no corneal damage, and the irritation reaction score < 3, which is rated as "non-irritating to eyes". In case of accidental eye contact, rinsing with clean water can relieve the discomfort without special treatment.

2.4. **Sensitization**: Human skin patch tests (n=300) show that the sensitization rate is < 0.3%, and only a very small number of people may have mild contact erythema (incidence rate < 0.1%), and the symptoms are reversible. The US CIR assessment clearly states that there is no sensitization risk when the raw material contains no sensitizing impurities and the added concentration complies with the specifications.

2.5. Genotoxicity and chronic toxicity: The AMES test, chromosome aberration test and mouse micronucleus test all show "negative" results with no mutagenicity. The subchronic oral toxicity test (rats, 90 days) shows that the NOAEL (No Observed Adverse Effect Level) is 1000mg/kg·d. Long-term exposure (in accordance with the recommended dosage) will not cause chronic damage to the liver, kidney, reproductive system, etc., and has no carcinogenicity or reproductive and developmental toxicity.

3. Restrictions and Precautions for Safe Use

3.1. Concentration limit: There are clear limits on the safe added concentration for different application fields and product types. Exceeding the limit may increase the risk of irritation (see the chapter of "Recommended Dosage" for specific limits). In the cosmetics field, the US CIR clearly states that the safety is fully guaranteed when the concentration is ≤0.082% for rinse-off products and ≤0.5% for leave-on products.

3.2. Applicable population limit: It is suitable for the vast majority of people (including those with sensitive skin, pregnant women and lactating women). However, when pregnant/lactating women use compound formula products containing this ingredient, they need to avoid irritating ingredients such as high-concentration acids and retinol; it is forbidden for people allergic to Centella Asiatica Extract, and it is recommended that people with allergic constitution conduct a local test first (behind the ear/inner side of the arm, use after 24h without abnormality).

3.3. Compatibility limit: Avoid direct mixing with high-concentration acids (pH < 3.0) and strong oxidants, which may lead to the degradation of active ingredients and increase the risk of skin irritation at the same time; there is no safety conflict when compounded with hyaluronic acid, ceramide, panthenol and other ingredients, and the synergistic effect can be achieved.

3.4. Storage and stability: Seal, protect from light and store in a cool and dry place (temperature 15-25℃, relative humidity < 60%) with a shelf life of 24 months; improper storage (high temperature, humidity, exposure to the sun) may lead to ingredient oxidation. Although no toxic and harmful substances are produced, the efficacy will be reduced and the irritation may be slightly increased.

4 Conclusion of Safety Assessment

Based on the comprehensive analysis of toxicological data, authoritative institution certification and regulatory compliance, under the premise of "complying with the recommended dosage, controlling hazardous substances and following compatibility specifications", Centella Asiatica Extract will not cause harm to human health under normal, reasonable and foreseeable use conditions. It has a high safety level and is suitable for application in multiple fields and for multiple populations. Its risks mainly come from "excessive concentration addition, excessive raw material impurities and improper compatibility", which can be completely avoided through strict production control and use specifications.

Ⅱ. Application Fields of Centella Asiatica Extract

Relying on its mild active effects (anti-inflammatory and soothing, barrier repair, wound healing and anti-aging, antioxidant, etc.) and high safety, Centella Asiatica Extract has penetrated into four core fields: cosmetics, medicine, food and industry. The application scenarios, product forms and core function focus of different fields are significantly different. Combined with practical application cases and technical parameters, the detailed classification is as follows.

1 Cosmetics Field (Core Application Field, Proportion ＞70%)

The cosmetics field is the main application scenario of Centella Asiatica Extract, whose core function is a skin protectant. It is suitable for various skin types such as sensitive skin, acne-prone skin and premature aging skin, and the applied products cover all categories such as skin care, color cosmetics and body care. Relying on its anti-inflammatory, repair and anti-aging effects, it has become a core raw material in the "mild repair" track.

1.1. Core Application Scenarios and Product Forms

(1) **Barrier repair and sensitive soothing products**: Targeting barrier damage, redness and stinging caused by over-cleaning, acid peels, seasonal changes and post-medical aesthetic surgery, the core function is to strengthen the stratum corneum barrier, inhibit inflammatory reactions and quickly soothe discomfort; product forms include repair serums, soothing masks, barrier creams, ampoules and medical cold compresses. Representative products include Anua 70% Centella Asiatica Serum, Dr.Jart+ CICAPAIR Repair Series and La Roche-Posay B5 Repair

Mask.

(2) **Acne-prone skin and acne mark care products**: Relying on anti-inflammatory and antibacterial properties, it inhibits *Cutibacterium acnes* and *Staphylococcus aureus*, relieves inflamed acne, reduces inflammatory residues, and at the same time assists in repairing red acne marks and mild acne pits; product forms include anti-acne gels, acne mark serums and oil-control toners, which are often compounded with salicylic acid, azelaic acid and other ingredients (control the concentration to avoid excessive irritation).

(3) **Anti-premature aging and anti-aging products**: By promoting the proliferation of fibroblasts and increasing the synthesis of type I collagen, it improves dry lines, fine lines and skin sagging, and at the same time scavenges free radicals (DPPH scavenging rate up to 85%) to resist external damage; product forms include anti-aging creams, firming serums and eye creams, which are often synergized with ceramide, retinol, peptides and other ingredients to enhance the anti-aging effect.

(4) **Body care products**: Used for the prevention of stretch marks (enhancing skin elasticity and reducing fiber breakage), body scar repair and soothing dry skin; product forms include body lotions, stretch mark oils and scar repair creams. Some products combine microcapsule technology to achieve long-term release of active ingredients.

1.2. Application Advantages and Technical Adaptability

It is suitable for common cosmetic dosage forms (water-based, oil-based, gel, emulsion, cream). Innovative preparations such as water-soluble asiaticoside, nanoemulsion and liposome can improve the transdermal absorption efficiency by 3-5 times; the "repair trident" formula composed of "ceramide + panthenol" has become an industry consensus, realizing a closed-loop repair of "soothing - filling - moisturizing"[3][4]; it complies with the ISO 16128 natural index requirements and can be used in natural and organic cosmetic formulations.

2 Pharmaceutical Field (Clinical-Grade Application, Precise Repair)

The pharmaceutical field mainly adopts high-purity Centella Asiatica Extract (the content of asiaticoside + madecassoside ⩾40%), whose core functions are to promote wound healing, anti-inflammation and anti-scar hyperplasia. It is clinically applied to the repair of skin damage and the treatment of inflammation. All products must comply with the Good Manufacturing Practice (GMP) for pharmaceuticals, with definite curative effect and high safety.

2.1. Core Application Scenarios and Product Forms

(1) **Wound repair preparations**: Used for the repair of burns, scalds, traumas and post-operative wounds, accelerating wound healing, shortening the healing time by 30-50% and reducing the risk of scar hyperplasia; product forms include topical ointments, gels and medical dressings (hydrocolloid dressings, biofilms), which are commonly used in dermatology, surgery and burn departments in clinical practice.

(2) **Scar repair products**: Targeting hypertrophic scars, atrophic scars and surgical scars, by inhibiting the over-proliferation of collagen fibers, it improves the appearance of scars by 40-60% and softens scar tissue; product forms include scar patches and scar repair gels, which can be used alone or in combination with medical aesthetic methods such as laser and microneedle for auxiliary repair.

(3) **Adjuvant treatment of inflammatory skin diseases**: Used for the adjuvant treatment of chronic inflammatory skin diseases (such as psoriasis and eczema), relieving skin itching, erythema, desquamation and other symptoms and reducing inflammatory reactions; product forms include topical creams, oral tablets/capsules (for large-area wounds or scenarios where local medication is not possible).

(4) **Ulcer treatment products**: Used for the repair of chronic ulcers such as lower extremity ulcers and oral ulcers, promoting ulcer healing and reducing the risk of infection. Clinical application can significantly shorten the ulcer repair cycle.

2.2 Food Field (Natural Empowerment, Functional Extension)

In the food field, Centella Asiatica Extract is used as a natural flavor and antioxidant, with the core advantages of being natural and non-toxic and having a unique flavor. At the same time, it can enhance the antioxidant property of food and extend the shelf life. Its application complies with China's *National Food Safety Standard for the Use of Food Additives* (GB 2760).

2.3 Core Application Scenarios and Product Forms

(1) **Functional food**: Focusing on the effects of improving microcirculation, regulating mood and protecting venous health, product forms include functional beverages, solid beverages, capsules and tablets. Among them, venous health products are the core application scenario, relying on its active ingredients to improve venous return, suitable for people who sit or stand for a long time.

(2) **Ordinary food**: Used as a natural flavor in seasonings, pastries, biscuits, meat products, etc., endowing products with a unique herbal aroma. At the same time, its triterpenoid saponins and flavonoids can enhance the antioxidant property of food and extend the shelf life; product forms include herbal seasonings, Centella Asiatica-flavored pastries and functional beverages.

2.4. Application Specifications

It must comply with food safety standards, and the raw material purity must reach food grade (the content of asiaticoside + madecassoside ⩾10%) without pesticide residues, excessive heavy metals and other problems.

2.5 Industrial and Other Fields (Natural and Environmental Protection, Diversified Empowerment)

As a natural raw material, Centella Asiatica Extract has been applied in various industrial fields such as textile, chemical industry and feed by virtue of its antioxidant, coloring and antibacterial properties. Its core advantage is environmental protection and non-toxicity, which meets the "green development" demand of modern industry.

2.5.1 Textile industry: Used as a natural dye to provide yellow to brownish yellow color for cotton, linen, silk and other textiles, and also used for fabric finishing to improve the hand feel and appearance quality of fabrics; some products combine microcapsule technology to keep the Centella Asiatica fragrance for a long time and release it evenly; the application must comply with the Oeko-Tex Standard 100 certification requirements.

2.5.2. Chemical industry: Used as an antioxidant and stabilizer to improve the performance of plastic, rubber and other chemical materials and extend their service life; participate in organic synthesis reactions as a catalyst or auxiliary agent, and the application must comply with the REACH regulation registration requirements.

2.5.3. Other fields: Used as a feed flavoring agent to improve feed palatability; used for flavoring tobacco products to enhance product flavor; used as a natural antibacterial agent in daily necessities (such as hand sanitizer, laundry detergent) to enhance the antibacterial effect.

III. Recommended Dosage of Centella Asiatica Extract

The recommended dosage of Centella Asiatica Extract mainly depends on three factors: "application field, product type and purity of active ingredients (content of asiaticoside + madecassoside)". The dosage varies significantly in different scenarios. Combined with authoritative standards, clinical data and practical application experience, the precise quantitative range, core suggestions and precautions are given by field classification to ensure "maximizing efficacy + safety without risk".

Note: The following dosages are all based on "Centella Asiatica Extract (conventional purity: asiaticoside + madecassoside 10-30%)". The dosage

of high-purity products (40% and above) can be reduced proportionally (e.g., for 70% high-purity products, the dosage is 1/2-1/3 of that of conventional purity products); the dosage of low-purity products (< 10%) needs to be appropriately increased, but not exceeding the upper limit of the corresponding field.

1 Cosmetics Field (Core Scenario, Recommended by Product Type)

The dosage in the cosmetics field must strictly follow the requirements of the US CIR and China's *Catalogue of Used Cosmetic Raw Materials*, and be adjusted according to the product efficacy positioning. The core principle is: "mainly for soothing and repair with moderate concentration; supplemented by anti-aging and scar repair with appropriately increased concentration but not exceeding the upper limit".

Product Type	Recommended Dosage (Conventional Purity)	Dosage of High-Purity (≥40%)	Core Precautions
Soothing masks, toners, sprays (rinse-off/light leave-on)	0.1%-0.5%	0.05%-0.25%	Do not exceed 0.5% to avoid high-concentration irritation; suitable for sensitive skin and can directly contact damaged skin
Repair serums, barrier creams, eye creams (leave-on)	0.5%-2.0%	0.25%-1.0%	0.5%-1.0% is recommended for sensitive skin, and 1.0%-2.0% for healthy skin; avoid compounding with high-concentration acids
Anti-acne gels, acne mark serums	1.0%-3.0%	0.5%-1.5%	Can be compounded with 0.5%-1.0% salicylic acid to enhance the anti-acne effect; avoid using on severely damaged acne
Medical cold compresses, post-medical aesthetic repair products	2.0%-5.0%	1.0%-2.5%	Must comply with medical-grade standards with no sensitizing impurities in raw materials; use 72h after surgery to reduce the risk of irritation
Body lotions, stretch mark oils, scar repair creams	1.0%-3.0%	0.5%-1.5%	Stretch mark products are recommended to be used from the second trimester of pregnancy with the concentration controlled at 1.0%-2.0%

Supplementary note: Reference for the maximum historical dosage in the cosmetics field — 54.791% for rinse-off products, 24.722% for leave-on products (facial), 0.95% (trunk), 0.2% (ocular). However, it is not recommended to approach this upper limit in practical application to avoid irritation risk.

2 Pharmaceutical Field (Clinical-Grade Application, Strictly Recommended by Dosage Form)

The dosage in the pharmaceutical field must comply with pharmaceutical production specifications and be set based on clinical efficacy data. The core requirements are: raw material purity ⩾40%, and the dosage is accurately controllable to ensure clinical efficacy and safety:

2.1. **Topical ointments and gels (wound repair, scar repair)**: The recommended dosage is 5.0%-10.0% for high-purity raw materials, and the dosage of conventional purity raw materials needs to be adjusted to 10.0%-20.0%; clinical verification shows that this concentration can shorten the wound healing time by 30-50% and improve the scar by 40-60%.

2.2. **Medical dressings (hydrocolloid, biofilm)**: The recommended dosage is 3.0%-8.0% for high-purity raw materials. Sustained-release technology is adopted to ensure the continuous action of active ingredients on the wound and reduce the risk of infection.

2.3. **Oral tablets and capsules**: The recommended dosage (based on daily intake) is 100-200mg per person per day for high-purity raw materials, which needs to be adjusted according to pharmaceutical specifications. The daily intake shall not exceed 500mg per person per day to avoid long-term excessive consumption.

2.4. **Ulcer treatment products**: The recommended dosage of topical preparations is 8.0%-12.0% for high-purity raw materials, and the oral preparations follow the same standards as the above-mentioned oral products.

3 Food Field (Recommended by Food Type, Complying with GB 2760 Standards)

The dosage in the food field follows the principle of "safety and non-toxicity, flavor adaptability and effective antioxidant", and strictly complies with China's GB 2760 standards. The specific recommendations are as follows:

3.1. **Functional beverages and solid beverages**: The recommended dosage is 0.01%-0.5% (w/w). Example: add 10-50g to 1000L of functional beverages, and 1-5g to 1000g of solid beverages.

3.2. **Pastries, biscuits and meat products**: The recommended dosage is 0.01%-0.3% (w/w). Used as an antioxidant and flavoring agent, it can extend the food shelf life and endow a light herbal flavor at the same time.

3.3. **Food additives (natural antioxidants)**: The recommended dosage is 0.05%-0.5% (w/w), suitable for various processed foods to replace artificial antioxidants and improve food safety.

4 Industrial Field (Recommended by Industry Demand, Complying with Relevant Standards)

The dosage in the industrial field is adjusted according to product characteristics and process requirements, complying with ISO 9001, REACH, Oeko-Tex Standard 100 and other relevant standards. The specific recommendations are as follows:

4.1. **Textile industry**: Used as a dye, the dosage is 0.5%-5% of the fabric weight (o.w.f.); used as a finishing agent, the dosage is 0.1%-2% of the fabric weight (o.w.f.). Example: add 0.5-5kg for dyeing 100kg of cotton fabric.

4.2. **Chemical industry**: Used as an antioxidant/stabilizer to improve the performance of plastic, rubber and other chemical raw materials and extend their service life; participate in organic synthesis reactions as a catalyst or auxiliary agent, and the application must comply with the REACH regulation registration requirements.

4.3. **Feed and tobacco fields**: The dosage in feed is 0.05%-0.2% (w/w), and the dosage in tobacco is 0.01%-0.05% (w/w), adapting to flavor and functional requirements.

5 Core Practical Suggestions for Dosage

5.1. **Purity adaptation**: The higher the purity of active ingredients, the lower the dosage can be. It is recommended to prioritize the selection of high-purity raw materials (≥40%), which can not only ensure the efficacy, but also reduce the irritation risk and reduce the raw material consumption to control costs.

5.2. **Efficacy matching**: For the core of "soothing and repair", control the dosage at 0.1%-2.0%; for the core of "promoting healing, anti-scar and strong anti-aging", it can be increased to 2.0%-10.0% (subject to the upper limit of the corresponding field).

5.3. **Compatibility test**: Conduct formula compatibility test before addition, especially when compounding with high-concentration acids and oxidants, to confirm no ingredient degradation and no increased irritation.

5.4. **Batch consistency**: The content of active ingredients in different batches of Centella Asiatica Extract may have slight differences (allowable deviation ±5%). The dosage needs to be fine-tuned according to the actual test results to ensure the consistency of product efficacy and safety.

IV. Summary

As a natural extract with "high safety, multiple efficacies and multiple scenarios", Centella Asiatica Extract has a safety assessment covering all-dimensional toxicological endpoints. Verified by authoritative institution certification and regulatory compliance, it has extremely high safety under rational use. Its application fields have realized diversified coverage of cosmetics, medicine, food and industry, among which the cosmetics field is the core scenario, the pharmaceutical field highlights clinical value, and the food and industrial fields reflect the advantages of natural environmental protection. The recommended dosage must be accurately set in combination with the "application field, product type and raw material purity", taking into account both efficacy and safety.

With the upgrading of technologies such as supercritical CO_2 extraction and targeted delivery, the purity and utilization rate of active ingredients of Centella Asiatica Extract will be further improved, and its application scenarios will continue to expand. In the future, it is expected to achieve more precise and efficient applications in the fields of medical aesthetics, high-end medicine and natural food, and become one of the core categories in the field of natural raw materials.