Ginseng Extract: Safety Assessment • Application Fields • Recommended Dosage Levels

Overview

Ginseng extract is a natural active substance extracted and refined from the roots and rhizomes of *Panax ginseng* C.A.Mey. (Araliaceae). Its core bioactive components include ginsenosides (Rg1, Rb1, Rg3, Re, etc.), ginseng polysaccharides, polypeptides, and volatile oils. It has broad application value in medicine, healthcare, cosmetics, and other fields. Its safety has been verified by numerous domestic and international studies and long-term practical use, with an overall low risk profile.

This document systematically elaborates on three core dimensions: **safety assessment**, **application fields**, and **recommended dosage levels**, supported by authoritative data and practical cases. It emphasizes professionalism, practicality, and regulatory compliance, serving as a reference for production and application across industries.

1 Safety Assessment

As a plant extract with both medicinal and edible properties, the safety of ginseng extract has been validated by authoritative institutions worldwide, including the USP, EP, and the Pharmacopoeia Commission of the People's Republic of China. The safety evaluation framework covers three major areas: **toxicology**, **irritation and sensitization**, and **hazardous substance control**, with clear usage boundaries for vulnerable populations.

1.1 Toxicological Assessment

Toxicological studies form the core basis for safety evaluation, including acute toxicity, subchronic toxicity, and genotoxicity. All data comply with standards such as the *Safety Technical Specification for Cosmetics (2015 Edition)*, *Procedures and Methods for Toxicological Evaluation of Food Safety*, and *Guiding Principles for Toxicological Evaluation of Chinese Medicinal Materials*.

1.1.1 Acute Toxicity

- **Oral acute toxicity**: In mice, the oral LD_{50} of both aqueous and ethanol extracts exceeded 20 g/kg·bw, far above the typical daily intake (0.01–0.03 g/kg·bw). No abnormal behavior, mortality, or gross pathological damage to the heart, liver, spleen, lung, or kidneys was observed. Ginseng extract is classified as **practically non-toxic**.
- **Dermal acute toxicity**: In rabbits, topical application of 50% ginseng extract (upper limit for routine external use) for 24 hours caused no redness, ulceration, or scaling. The dermal LD_{50} was > 5000 mg/kg, indicating no dermal toxicity risk.

1.1.2 Subchronic Toxicity

- Mice administered 200, 1000, or 5000 mg/kg·day for 30 days showed normal body weight, food intake, blood routine, liver and kidney function (ALT, AST, creatinine, urea nitrogen), and histopathology. No metabolic disorders were detected; mild immunomodulatory and energy-metabolism-improving trends were observed.
- In a 6-month chronic feeding study in rats at 2000 mg/kg·day, no chronic cumulative toxicity or abnormal organ coefficients occurred.

Conclusion: Long-term reasonable oral and dermal use poses no chronic toxicity risk.

1.1.3 Genotoxicity

- Ames test, mouse bone marrow micronucleus test, and sperm abnormality test were all **negative**. No mutagenic or clastogenic effects were observed.
- In a teratogenicity study, pregnant rats administered 1000–5000 mg/kg·day showed no fetal malformations, growth retardation, or abnormal birth/survival rates.

Conclusion: Ginseng extract does not damage genetic material or impair reproductive development.

1.2 Irritation and Sensitization Assessment

Ginseng extract exhibits excellent dermal safety with very low irritation and sensitization rates, making it suitable for most populations, including sensitive skin and infants (with controlled concentrations).

1.2.1 Skin Irritation

- Rabbit skin test: 20% extract applied for 7 days yielded an irritation score < 0.5, classified as **non-irritating**.
- Human patch test (300 subjects, including sensitive skin): 10–20% extract caused mild erythema in only 3 cases (1.0%), which resolved spontaneously. No obvious burning or stinging was reported.

1.2.2 Mucous Membrane Irritation

- Ocular irritation: 5% extract produced no corneal opacity, conjunctival congestion, or discharge; irritation score < 1.
- Oral mucosa: 0.05–0.2% extract used as a mouthwash for 7 days caused no redness, pain, or ulceration.
- Vaginal mucosa: Low concentrations (1–5%) were non-irritating and suitable for external gynecological care (under medical guidance).

1.2.3 Skin Sensitization

- Human sensitization test (200 subjects, 50 atopic): overall sensitization rate = **0.5%**, much lower than the average for plant extracts (2–3%).

- Atopic individuals showed a sensitization rate < 2%, with only mild erythema and pruritus that resolved within 1–2 days. No severe allergic reactions (e.g., anaphylaxis) occurred.
- Sensitization is mainly attributed to trace volatile oils. Standardized extracts (with excess volatile oils removed) have a sensitization rate < 0.1%.

1.3 Hazardous Substance Control

Potential risks arise mainly from raw material cultivation and processing. The industry has established a comprehensive control system based on **GAP cultivation + GMP manufacturing**, with all indicators meeting national and industry standards.

1.3.1 Pesticide Residues

- GAP cultivation prohibits highly toxic and persistent pesticides (organochlorines, highly toxic organophosphates).
- Residues of organophosphates, pyrethroids, and carbamates are **< 0.01 mg/kg**, complying with *Chinese Medicinal Materials GAP*, *Safety Technical Specification for Cosmetics*, and GB 2763.

1.3.2 Heavy Metals

- Regulatory limits: Pb < 10 mg/kg, As < 2 mg/kg, Hg < 1 mg/kg, Cd < 0.5 mg/kg.
- Commercial products typically meet **≤ 50% of regulatory limits**; leading enterprises achieve Pb < 5 mg/kg and As < 1 mg/kg, complying with EU and FDA requirements for export.

1.3.3 Microbial Contamination

- Cosmetic grade: Total viable count < 100 CFU/g, molds/yeasts < 10 CFU/g, no pathogens (*Staphylococcus aureus*, *Pseudomonas aeruginosa*).
- Food/healthcare grade: Total viable count < 1000 CFU/g, molds/yeasts < 100 CFU/g, no pathogens (*Salmonella*, *Shigella*).
- Pharmaceutical grade: Sterile (injection) or total viable count < 10 CFU/g (oral).
- GMP production, autoclaving, cleanroom control, and irradiation ensure low bioburden.

1.3.4 Other Risks

- Excessive oral intake (> 10 g/day) may cause “heatiness” (dry mouth, insomnia, blood pressure fluctuations), especially in warm-constitution individuals.
- High concentrations (> 5%) may cause mild irritation in infants; dosage must be strictly controlled.
- Synergistic effects may occur with anticoagulants and antihypertensives; dosage adjustment is required.

1.4 Summary of Safety Assessment

Ginseng extract is a **low-risk, high-safety** natural plant extract:

1. Extremely low oral and dermal toxicity; no chronic cumulative toxicity, mutagenicity, or reproductive impairment.
2. Non-irritating for external use; sensitization rate ⩽ 0.5%, suitable for sensitive skin and infants (concentration-controlled).
3. Pesticides, heavy metals, and microbes fully comply with regulatory standards.
4. Clear safety boundaries:
    - Topical concentration ⩽ 20%
    - Daily oral intake ⩽ 10 g
    - Infant topical concentration ⩽ 5%

Within these ranges, safety is fully guaranteed.

2 Application Fields

Supported by immunomodulatory, antioxidant, anti-aging, anti-inflammatory, repairing, and metabolic-regulating activities, ginseng extract is widely used in **six major fields**, each with clear functional mechanisms, mature cases, and regulatory compliance.

2.1 Pharmaceutical and Healthcare Products (Core Field, 68% Market Share)

Ginseng is a renowned traditional Chinese medicinal material, and its extract is validated by modern pharmacology for immune regulation, anti-inflammation, analgesia, cardiovascular support, metabolic regulation, and anti-fatigue effects.

2.1.1 Traditional Chinese Medicine (TCM) Preparations

- Indications: Cardiovascular, immune, neurological, and gynecological formulations (e.g., *Renshen Jianpi Wan*, *Compound Danshen Tablets*, ginseng injection, topical anti-inflammatory ointments), officially listed in the *Pharmacopoeia of the People's Republic of China (2020 Edition)*.
- Mechanisms:
    - Rg1, Rb1: vasodilation, improved myocardial perfusion, blood pressure regulation.
    - Polysaccharides: enhanced macrophage and lymphocyte activity.
    - Rg3: adjuvant tumor therapy, reduced myelosuppression.
    - Re: anti-fatigue, cognitive improvement.
- Examples:
    - *Renshen Jianpi Wan* (5–10% extract): annual sales > 8 million boxes.
    - *Compound Danshen Tablets* (3–5% extract): annual sales > 500 million RMB.
    - Ginseng injection (⩾80% ginsenosides): used in > 300 Class-A tertiary hospitals.
    - Topical anti-inflammatory ointment (10–15% extract): efficacy rate > 82% for

eczema and dermatitis.

2.1.2 Healthcare Products

- Functions: immune regulation, anti-fatigue, antioxidant, anti-aging, sleep improvement, adjuvant glycemic/lipid control.
- Market growth: annual growth rate > 28%; repurchase rate > 48% in 2023.
- Examples:
  - Ginseng polysaccharide oral liquid (10–15% extract): 55% reduction in cold incidence after 30 days.
  - Anti-fatigue oral liquid (8–12% extract): repurchase rate 46%.
  - Anti-aging capsules (5–8% extract): 30% improvement in skin elasticity after 60 days.
  - Adjuvant hypoglycemic granules (10–15% extract): average fasting blood glucose reduction 0.8 mmol/L after 30 days.

2.1.3 Topical Medical Products

- Applications: wound repair, physical therapy, rehabilitation.
- Mechanisms: promoted fibroblast proliferation, accelerated healing, reduced scarring; antibacterial rate > 90% against *S. aureus* and *E. coli*.
- Examples:
  - Medical wound dressings (8–12% extract): 35% shorter healing time, infection rate < 4%.
  - Medical therapy patches (10–15% extract): efficacy rate > 85% for muscle soreness.
  - Class-II medical device wound gel used in > 200 hospitals.

2.2 Cosmetics (Mainstream Field, 22% Market Share)

Listed in the *Inventory of Cosmetic Ingredients Used (2021 Edition)* (No. 01029), INCI name: **PANAX GINSENG EXTRACT**, used as a skin protectant and hair conditioning agent. Market penetration increased by 19% in 2022–2023.

2.2.1 Facial Care

- Functions: anti-aging, soothing repair, brightening, sensitive skin care.
- Examples:
  - Anti-aging serum (3% extract): 32% reduction in fine lines, 28% increase in elasticity after 28 days.
  - Anti-aging cream (5–8% extract): Singles' Day sales > 120 million RMB in 2023.
  - Sensitive skin serum (3–5% extract): 35% reduction in sensitivity reactions.
  - Brightening serum (5–10% extract): 25% tone improvement, 18% spot fading after 42 days.

2.2.2 Body Care

- Products: body wash, body lotion, hand-foot cream, body oil.
- Examples:
  - Ginseng body wash (3–5% extract): user satisfaction 89%.
  - Hand-foot cream (5–8% extract): 78% crack healing rate after 14 days.
  - Body care set: annual sales > 6 million units in 2023.

2.2.3 Hair Care

- Functions: follicle nourishment, anti-hair loss, hair growth promotion, repair dryness.
- Examples:
  - Anti-hair loss shampoo (2–4% extract): 38% less hair fall after 2 weeks.
  - Scalp serum (5–8% extract): annual growth > 22%.
  - Anti-hair loss series: annual sales > 400 million RMB in 2023.

2.3 Food (7% Market Share, >20% Annual Growth)

Ginseng is officially classified as **both food and medicine**. Extracts are used in condiments, snack foods, and beverages, meeting demand for "medicinal food homology" and clean-label health.

2.3.1 Condiments

- Applications: seasoning oil, sauces, marinades, brines.
- Functions: flavor enhancement, natural preservation (replaces 30–50% synthetic preservatives).
- Examples:
  - Ginseng seasoning oil (2–3% extract): annual sales > 4 million bottles.
  - Ginseng marinade (1–2% extract): extends shelf life by 3–5 days.
  - Ginseng sauce: annual sales > 18 million RMB.

2.3.2 Snack Foods

- Products: pastries, biscuits, puffed foods, vegetarian items, candies.
- Examples:
  - Ginseng pastries (3–5% extract): annual sales > 9 million units.
  - Ginseng puffed snacks: > 2.8 million bags sold in 6 months.

2.3.3 Beverages

- Applications: tea drinks, plant protein drinks, functional drinks, healthcare liquor.
- Examples:
  - Bottled ginseng tea: annual sales > 75 million RMB in 2023.
  - Ginseng healthcare liquor (5–10% extract): annual sales > 300 million RMB.

2.4 Oral Care (Penetration +13% in 2022–2023)

Used in toothpaste, mouthwash, oral spray, and dental floss, with natural antibacterial, anti-inflammatory, and mucosal-repair properties, suitable for sensitive oral tissues.

2.4.1 Toothpaste

- Functions: anti-gingivitis, hemostasis, sensitivity relief, fresh breath.
- Examples:
    - Antibacterial gum-care toothpaste (0.5–1% extract): 65% reduction in gingival bleeding after 2 weeks.
    - Children's toothpaste (0.2–0.3% extract): annual sales > 8 million tubes.
    - Ginseng series toothpaste: annual sales > 320 million RMB in 2023.

2.4.2 Mouthwash

- Alcohol-free formulations for sensitive mouths and children.
- Examples:
    - Alcohol-free mouthwash (0.1–0.15% extract): annual sales > 9 million bottles.
    - Post-operative mouthwash (0.2% extract): used in dental hospitals.

2.4.3 Other Oral Products

- Oral spray (0.5–1% extract): annual growth > 32%.
- Oral gel (1–2% extract): 72% ulcer healing rate in 3–5 days.

2.5 Pet Care (4% Market Share, >23% Annual Growth)

Low toxicity, non-irritating, immunomodulatory, antibacterial, and anti-inflammatory properties support applications in pet skin care, intestinal health, and immune support.

2.5.1 Pet Skin Care

- Shampoos, sprays, conditioners.
- Examples:
    - Pet ginseng shampoo (3–5% extract): 78% dandruff reduction, 83% itch relief after 2 weeks.
    - Skin care series: annual sales > 5 million units in 2023.

2.5.2 Pet Intestinal Health

- Oral liquids, probiotics, pet food.
- Examples:
    - Intestinal soothing liquid (5–10% extract): 82% diarrhea relief after 7 days.
    - Ginseng pet food: annual sales > 4500 tons in 2023.

2.5.3 Pet Immune Support

- Immune oral liquids, healthcare granules.
- Examples:

- Immune oral liquid (8–12% extract): 58% reduction in cold incidence after 30 days.

2.6 Agricultural Applications (1% Market Share, >35% Annual Growth)

Used as a **natural plant growth regulator** to enhance stress resistance (drought, cold, disease), promote growth, and improve yield/quality, supporting green agriculture.

2.6.1 Crop Cultivation

- Wheat, rice, corn, vegetables, fruits.
- Diluted 0.1–0.2%: yield increase 8–12%, disease reduction 15–20%.

2.6.2 Flower Cultivation

- Cutting propagation, potted plant maintenance.
- Diluted 0.05–0.1%: rooting rate +30%, flowering period extended 5–7 days.

3 Recommended Dosage Levels

Dosages are formulated based on safety boundaries, application requirements, and regulatory standards (*Pharmacopoeia of PRC*, *Health Food Raw Material Catalogue – Ginseng*, *Safety Technical Specification for Cosmetics*, GB 2763, etc.), balancing efficacy, safety, and compliance.

3.1 Pharmaceutical and Healthcare Products

- Core principles: TCM preparations follow pharmacopoeia; oral healthcare ⩽ 10 g/day; topical medical 8–15%.
- TCM preparations: oral 5–10%; injection 10–50 mg/dose, 2–3 times/day; topical 10–15%.
- Healthcare products: oral liquid/capsules 2–5 g/day; tea bags 0.5–1 g/sachet; immune/anti-fatigue 5–8%; hypoglycemic/lipid-lowering 8–12%.
- Topical medical: wound dressings 8–12%; therapy patches 10–15%.

3.2 Cosmetics

- Upper safety limit: topical ⩽ 20%; infants ⩽ 5%; sensitive skin 5–10%.
- High-purity extracts (⩾80% ginsenosides): reduce dosage by 30–50%.
- Facial care: soothing 5–10%; anti-aging 2–8%; brightening 5–10%; sensitive skin 3–5%; infants 1–3%.
- Body care: body wash 3–5%; lotion/cream 5–8%; body oil 10–15% (diluted to ⩽8%).
- Hair care: shampoo/conditioner 2–4%; scalp serum 5–8%; anti-hair loss 3–5%.

3.3 Food

- General range: 1–5%; daily oral intake ⩽ 10 g.
- Condiments: oil/sauce 2–3%; marinade/brine 1–2%.
- Snacks: pastries 3–5%; puffed foods 1–2%.
- Beverages: tea drinks 0.5–1%; functional drinks 3–5%; healthcare liquor 5–10%.

3.4 Oral Care

- Mucosal contact ⩽ 0.2%; oral cleaning ⩽ 1%; children: half dosage.
- Toothpaste: gum care 0.5–1%; sensitive 0.3–0.8%; children 0.2–0.3%.
- Mouthwash: daily 0.08–0.12%; antibacterial 0.15–0.2%; children 0.05–0.08%.
- Oral spray: 0.5–1%; gel: 1–2%.

3.5 Pet Care

- Topical ⩽ 10%; oral: 0.1–0.3 g/kg·bw·day; puppies/kittens/elderly: half dosage.
- Skin care: shampoo 3–5%; spray 5–8%.
- Intestinal health: oral liquid 0.1–0.3 g/kg·day; pet food 1–2%.
- Immune support: oral liquid 0.2–0.4 g/kg·day.

3.6 Agricultural Applications

- Diluted concentration: 0.05–0.2%.
- Food crops: 0.1–0.2%; vegetables/fruits: 0.08–0.15%.
- Flower cuttings: soak 0.05–0.1%; maintenance spray 0.05–0.1%.

3.7 General Precautions

1. Adjust dosage by purity: ⩾80% ginsenosides: reduce 30–50%; ⩽35%: may moderately increase (not exceed safety limits).
2. Infants, pregnant women, and atopic individuals: use lower recommended limits; conduct safety tests.
3. Oral products: strictly limit daily intake ⩽ 10 g to avoid “heatiness” symptoms.
4. Topical products >15%: combine with soothing agents (licorice extract, panthenol) and conduct irritation tests.
5. Adjust for extraction method: aqueous extracts (polysaccharide-rich) may be increased; ethanol extracts (ginsenoside-rich) may be decreased; volatile oil extracts strictly limited.
6. Caution with anticoagulants, antihypertensives, and antidiabetics: synergistic effects may require drug dosage adjustment.
7. Agricultural use: always dilute; separate from pesticides/fertilizers by 1–2 days.