Safety Assessment, Product Applications and Recommended Dosage of Ginger Extract

Ginger Extract (Zingiber Officinale Extract) is a concentrated natural active ingredient prepared from fresh or dried rhizomes of *Zingiber officinale Roscoe* (Zingiberaceae family) through extraction, concentration, drying and other processes. Its core functional components include gingerols (gingerol, shogaol, paradol), volatile oils (zingiberol, zingiberene) and diarylheptanoids. As a substance clearly listed in the *List of Items That Are Both Food and Medicine* in China, ginger extract is widely used in food flavor regulation, health care and daily chemical skin care. It has high overall safety, but potential risks exist at high doses and for special populations, so the addition level must be strictly controlled.

I. Safety Assessment of Ginger Extract

(I) Conclusions of Toxicological Tests

1. **Acute Toxicity**

According to GB 15193-2003 *Procedures and Methods for Toxicological Assessment of Food Safety*, when mice were orally administered aqueous extract and ethanol extract of ginger at a dose of 66.67 g/kg body weight, no death or obvious toxic symptoms occurred within two weeks, indicating that ginger extract is a practically non-toxic substance.

2. **Subchronic Toxicity**

A 35-day gavage test in rats showed that at a dose of 2000 mg/kg body weight per day, there were no abnormalities in behavior, growth, food intake or blood biochemistry in both male and female rats. Only a slight decrease (11.5%–14.4%) in absolute and relative testicular weight was observed in the high-dose male group, with no pathological damage.

3. **Genotoxicity and Carcinogenicity**

Multiple Ames tests and chromosome aberration tests showed that ginger extract had no mutagenicity, and some studies indicated its anti-mutagenic effect. No clear carcinogenicity was found in long-term animal tests, and there was no evidence of dose-dependent increase in tumor incidence.

4. **Reproductive and Developmental Toxicity**

High-dose (≥1784 mg/kg body weight) animal tests showed that ginger extract may increase the risk of abortion and slightly affect the development of male reproductive organs. At conventional doses (≤1000 mg/kg body weight), no reproductive or developmental toxicity was observed. Intake should be controlled for pregnant women and those preparing for pregnancy.

(II) Risk Substances and Limit Control

1. **Heavy Metals and Harmful Elements**

The product shall meet the following limits:

Pb ≤ 3.0 mg/kg, As ≤ 2.0 mg/kg, Hg ≤ 0.1 mg/kg, Cd ≤ 0.3 mg/kg.

2. **Pesticide Residues and Microorganisms**

It shall comply with GB 2763 for pesticide residue limits and GB 4789 for microbiological limits. No pathogenic bacteria shall be detected; mold ≤ 25 cfu/g, yeast ≤ 25 cfu/g.

3. **Sensitization and Irritation**

Skin sensitization rate < 1%. High concentration (≥5%) of gingerols may cause skin burning and redness. Eye irritation is very weak, and there is no risk of corneal injury under normal use.

4. **Risks for Special Populations**

- Patients with gastric ulcer or gastroesophageal reflux disease: high doses may stimulate gastric acid secretion and aggravate mucosal damage.
- Users of anticoagulant drugs: gingerols may enhance the anticoagulant effect of warfarin and aspirin, increasing the risk of bleeding.
- Pregnant women and infants: low-dose use is recommended, and long-term high-dose intake should be avoided.

(III) Safety Conclusions from Authoritative Institutions

- China: listed in the *List of Items That Are Both Food and Medicine* and *Inventory of Cosmetic Ingredients Already Used (2021 Edition)*, not a prohibited or restricted substance.
- US CIR: safe for use in cosmetics at ≤6% in rinse-off products and ≤0.083% in leave-on products.
- EU SCCS: no safety risks at conventional addition levels in food and cosmetics. No explicit upper limit for acceptable daily intake (ADI); recommended ≤1000 mg/day.

II. Product Applications of Ginger Extract

(I) Food and Beverage Industry

1. **Core Value**

Replace synthetic flavors, antioxidants and preservatives, provide natural spicy and fresh aroma, extend shelf life and enhance natural properties. It meets consumers' demand for "natural and healthy" products and has strong compatibility with various food and beverage forms.

2. **Mechanisms of Action**

- Flavor regulation: gingerols and volatile oils provide unique spicy aroma, mask off-flavors and enrich taste.
- Antioxidation: gingerols scavenge free radicals and inhibit lipid oxidation.
- Antibacterial and preservation: inhibit common food-borne pathogens and extend shelf life.
- Digestive promotion: stimulate secretion of saliva and gastric juice, promote gastrointestinal peristalsis.

3. **Recommended Forms and Products**

- Main forms: powder and liquid.
- Applications: solid beverages, baked foods, liquid drinks, condiments, cured products.

4. **Application Solutions**

- Flavoring solution: compound with natural spices to enhance flavor layers and reduce synthetic flavors.
- Antioxidant and preservative solution: replace synthetic antioxidants such as BHA and BHT, combined with vitamin E.
- Functional food solution: use high-purity gingerol extract with honey, jujube and vitamin C to strengthen digestion and warming effects.

(II) Health Food Industry

1. **Core Value**

With natural food-medicine homologous ingredients, it provides clear health benefits with no obvious side effects, suitable for long-term consumption. It can be used alone or compounded with other natural ingredients.

2. **Mechanisms of Action**

- Relieve post-exercise muscle soreness by inhibiting prostaglandin E2 synthesis.
- Anti-inflammatory and analgesic for osteoarthritis by inhibiting inflammatory factors.
- Anti-emetic effect by regulating gastrointestinal peristalsis and inhibiting the vomiting center.
- Regulate blood lipids and enhance immunity.

3. **Recommended Forms and Products**

- Main forms: capsules, tablets, oral liquids, granules.
- Products: gingerol capsules, ginger extract tablets, ginger oral liquid, ginger health granules.

4. **Application Solutions**

- Single health solution: high-purity extract with 5%–20% gingerols.
- Compound health solution: combined with turmeric and black pepper extract for anti-inflammation; with jujube and Chinese yam for digestion.
- Special population solution: low-concentration extract for pregnancy nausea; sustained-release tablets for the elderly.

(III) Cosmetics and Daily Chemical Industry

1. **Core Value**

Natural and mild, with multiple effects of skin care, hair care and oral care, low irritation, suitable for sensitive skin and problematic scalp. It meets the trend of “natural, mild and functional” products.

2. **Mechanisms of Action**

- Skin care: promote blood circulation, scavenge free radicals, brighten skin and relieve redness.
- Hair care: stimulate scalp circulation, control oil, relieve itching and reduce hair loss.
- Oral care: inhibit harmful bacteria, reduce plaque and freshen breath.

3. **Recommended Forms and Products**

- Main forms: liquid and powder.
- Applications: skin care, hair care, oral care products.

4. **Application Solutions**

- Skin care: compound with hyaluronic acid and vitamin C for dull skin; with tea tree oil and salicylic acid for acne.
- Hair care: compound with ketoconazole and sophora extract for oil control and anti-hair loss.
- Oral care: compound with menthol and fluoride for bacteriostasis and fresh breath.

(IV) Pharmaceutical Industry

1. **Core Value**

As a natural medicinal raw material, it has therapeutic and adjuvant therapeutic effects, mild and safe. It can be used in traditional Chinese medicine preparations and chemical excipients.

2. **Mechanisms of Action**

- Warm the middle energizer, dispel cold and relieve vomiting.
- Anti-inflammatory and analgesic for external patches and oral drugs.
- Adjuvant treatment: improve bioavailability and reduce gastrointestinal irritation.

3. **Recommended Forms and Products**

- Main forms: high-purity extract, granules, decoctions, patches, creams.
- Applications: TCM preparations, chemical excipients, external preparations.

4. **Application Solutions**

- TCM preparation: compound with ephedra, cassia twig, aconite and dried ginger.
- Chemical excipient: reduce gastrointestinal irritation of antiemetics and anti-inflammatory drugs.
- External preparation: compound with menthol and camphor for arthritis and dysmenorrhea.

(V) Feed and Other Industries

1. **Core Value**

Replace antibiotic feed additives, naturally antibacterial and growth-promoting, no drug residues. Used as green natural antioxidant and preservative.

2. **Mechanisms of Action**

- Feed: inhibit harmful bacteria, regulate intestinal flora, improve digestibility and enhance immunity.
- Industry: inhibit oxidation of oils and coatings, inhibit microorganisms on wood and textiles.

3. **Recommended Forms and Products**

- Main forms: powder and liquid.
- Applications: feed additives, oil antioxidants, wood preservatives, textile finishing agents.

4. **Application Solutions**

- Feed: compound with probiotics and amino acids for livestock, poultry and aquaculture.
- Industry: natural antioxidant for oils and coatings; antibacterial treatment for wood and textiles.

III. Recommended Addition Levels by Field

(I) Food and Beverage Industry

In the food and beverage industry, the addition level of ginger extract shall be comprehensively determined based on product category, functional requirements and taste compatibility. The core principle is "add as needed, control pungency, balance efficacy and safety". Specific graded recommendations are as follows:

1. **Beverages (including fruit juices, plant protein beverages, functional drinks and solid beverages)**

Mainly used for flavor enhancement and antioxidation.

- For liquid beverages, the recommended addition level is **0.05%–0.3%**, which can be adjusted according to product flavor requirements to avoid excessive pungency caused by high dosage.
- For solid beverages, the dosage shall be converted according to the dilution ratio, usually **1.0%–5.0%**, so that the effective concentration after dilution falls within the range for liquid beverages and ensures palatable taste.

2. **Baked Foods (including cakes, cookies, bread and pastries)**

Mainly used for flavor regulation, antiseptic preservation and improving dough texture. The recommended addition level is **0.5%–2.0%**.

- For dry-textured products such as cookies and bread, the addition level can be appropriately increased to **1.5%–2.0%** to enhance flavor and extend shelf life.
- For delicate-textured products such as cakes and pastries, the addition level can be appropriately reduced to **0.5%–1.0%** to prevent the pungent flavor from affecting the overall taste.

3. **Meat Products (including sausages, cured meat, stewed meats and sauced meats)**

Mainly used for deodorization, flavor enhancement, preservation and inhibiting lipid oxidation. The recommended addition level is **0.2%–1.0%**.

- For stewed and sauced meats that undergo long-time cooking, **0.5%–1.0%** is recommended to effectively remove fishy odors, enhance aroma and inhibit lipid oxidation during stewing.
- For sausages and other processed meat products, **0.2%–0.5%** is sufficient to achieve preservation effects without affecting the inherent taste of meat.

4. **Condiments (including sauces, soy sauce, marinades and hot pot bases)**

Used for flavor regulation and aroma enhancement. The recommended addition level is **0.1%–0.5%**.

- For liquid condiments such as soy sauce and sauces, **0.1%–0.3%** is recommended to avoid masking the original flavor.
- For compound condiments such as marinades and hot pot bases, **0.3%–0.5%** is recommended to synergize with other spices and enrich flavor layers.

5. **Oils and Fats (including vegetable oils, edible fats and frying oils)**

Mainly used for antioxidation to replace synthetic antioxidants. The recommended addition level is **0.02%–0.1%**. Excessively high dosage may affect the taste of oil, while an overly low dosage fails to deliver effective antioxidant

activity. It is recommended to use in combination with vitamin E to achieve synergistic antioxidation.

6. **Confectionery (including ginger candies, hard candies and soft candies)**

Mainly used for flavor expression and body-warming effects. The recommended addition level is **0.5%–3.0%**.

- For ginger-flavored core products such as ginger candies, **2.0%–3.0%** can be added to highlight the pungent and warming characteristics.
- For ordinary hard and soft candies, **0.5%–1.0%** is suggested as a flavor accent to avoid excessive pungency.

(II) Health Food Industry

In health foods, the addition level of ginger extract shall be calculated based on gingerol content. Daily intake shall be controlled according to different health functions and target populations to ensure efficacy and safety. Specific graded recommendations are as follows:

1. **Single-preparations**

Using ginger extract with **5%–20% gingerol** as raw material, the recommended daily intake is **250–1000 mg**, equivalent to **12.5–200 mg** of gingerol.

- For extract with 5%–10% gingerol: 500–1000 mg/day.
- For extract with 10%–20% gingerol: 250–500 mg/day.

The dosage can be flexibly adjusted according to product specifications.

2. **Relief of Nausea and Vomiting (including pregnancy nausea and post-chemotherapy nausea)**

For such purposes, the recommended daily intake is **500–1000 mg** (calculated with 5%–10% gingerol), administered in 2–3 doses to gently relieve vomiting without high-dose gastrointestinal irritation.

For pregnant women, use under medical guidance and limit to within **500 mg/day**.

3. **Anti-inflammatory and Analgesic Effects (for osteoarthritis and muscle pain)**

Relatively high dosage is required to achieve anti-inflammatory effects. The recommended daily intake is **1000–2000 mg** (calculated with 10%–20% gingerol), equivalent to **100–400 mg** of gingerol.

A continuous treatment course is 8–12 weeks. Dosage can be adjusted based on pain relief, and long-term high intake is not recommended.

4. **Blood Lipid Regulation and Immunity Enhancement**

For daily health care, the recommended daily intake is **250–500 mg** (calculated with 5%–10% gingerol).

Long-term moderate intake assists lipid regulation and immunity improvement without excessive dosage that may increase gastrointestinal burden.

(III) Cosmetics and Daily Chemical Industry

In cosmetics and daily chemicals, the addition level of ginger extract shall be strictly controlled based on product type (rinse-off / leave-on), function and skin/mucosa irritation. Specific graded recommendations are as follows:

1. **Rinse-off Products (including shampoos, body washes and hand sanitizers)**

Mainly used for circulation promotion, oil control and bacteriostasis. The recommended addition level is **0.5%–**

3.0%, with a historical maximum usage level of 6.0%.

- For shampoos: 1.0%–3.0% to effectively stimulate scalp circulation, control oil and reduce hair loss.
- For body washes and hand sanitizers: 0.5%–1.0% for mild antibacterial effects without skin burning.

2. **Leave-on Products (including creams, essences, emulsions and masks)**

Mainly used for antioxidation, skin care and brightening. The recommended addition level is **0.05%–0.2%**, with a historical maximum usage level of 0.083%.

- For long-term skin contact products, especially for sensitive skin: 0.05%–0.1% is recommended to avoid irritation, redness and burning.
- For dull and rough skin: can be appropriately increased to 0.1%–0.2% to enhance efficacy.

3. **Scalp Care Products (including scalp essences and hair conditioners)**

Mainly used for anti-hair loss, scalp soothing and oil control. The recommended addition level is **1.0%–3.0%**, with a historical maximum usage level of 5.0%.

- 1.0%–2.0% meets daily scalp care needs, relieving itching and controlling oil.
- For severe hair loss and seborrheic scalp: 2.0%–3.0% is recommended, preferably combined with soothing agents (e.g., panthenol, ceramides) to reduce irritation.

4. **Oral Care Products (including toothpastes and mouthwashes)**

Mainly used for bacteriostasis, breath freshening and gingivitis relief. The recommended addition level is **0.1%–0.3%**, with a historical maximum usage level of 0.3%.

- For toothpastes: 0.1%–0.2% to effectively inhibit bacteria and freshen breath without gum irritation.
- For mouthwashes: 0.2%–0.3% to balance antibacterial activity and taste, reducing oral odor without mucosa irritation.

(IV) Feed Industry

In the feed industry, the addition level of ginger extract shall be determined based on animal species and growth stage, focusing on antibacterial growth promotion and palatability improvement. Specific graded recommendations are as follows:

1. **Feed for Swine, Poultry and Ruminants**

Suitable for piglets, finishing pigs, broilers, laying hens, beef cattle and dairy cows. The recommended addition level is **0.05%–0.2%**.

- For young animals such as piglets and chicks: 0.05%–0.1% to mildly improve palatability and immunity without gastrointestinal irritation.
- For growing animals such as finishing pigs, broilers and ruminants: 0.1%–0.2% for antibacterial growth promotion, improved feed digestibility and reduced diarrhea and enteritis.

2. **Aquatic Feed**

Suitable for fish, shrimp and other aquatic animals. The recommended addition level is **0.1%–0.3%**.

- For fish feed: 0.1%–0.2% to enhance immunity and reduce enteritis.
- For crustacean feed such as shrimp: 0.2%–0.3% to strengthen antibacterial effects, improve survival rate and product quality.

(V) Industrial Application Field

In industrial applications, the addition level of ginger extract shall be determined based on application scenarios and functional requirements, focusing on antioxidation and preservation while balancing performance and cost. Specific graded recommendations are as follows:

1. **Antioxidation for Oils and Coatings**

Used in various vegetable oils and industrial coatings. The recommended addition level is **0.05%–0.2%** to effectively inhibit oxidation and extend shelf life.

The dosage can be adjusted according to the type and storage conditions of oils and coatings.

2. **Wood Preservation**

Used in wood impregnation solutions. The recommended addition level is **1.0%–5.0%** to improve preservation and antibacterial properties and extend service life.

For outdoor wood, the dosage can be appropriately increased to **3.0%–5.0%** for enhanced preservation.

3. **Textile Functional Finishing**

Used in textile fabric finishing. The recommended addition level is **0.5%–2.0%** to provide antibacterial and antioxidant functions for functional clothing and home textiles.

Excessively high dosage may affect fabric softness.

IV. Application Precautions and Quality Control

(I) Raw Material Standards

Raw materials shall comply with the *Chinese Pharmacopoeia*:

6-gingerol ≥ 0.050%, volatile oil ≥ 0.12% (mL/g), 8-gingerol + 10-gingerol ≥ 0.040%.

(II) Extraction Process

Supercritical CO_2 extraction and ethanol reflux extraction are preferred. Extraction temperature >80°C shall be avoided to prevent degradation of active ingredients.

(III) Compatibility Contraindications

- Food: avoid long-term coexistence with strong acids and strong oxidants.
- Cosmetics: avoid retinoic acid, fruit acids and high-concentration alcohol; use with soothing agents.
- Medicine: avoid anticoagulants and non-steroidal anti-inflammatory drugs without medical advice.

(IV) Storage Conditions

Store sealed, away from light, in a cool and dry place (≤25°C). Shelf life: 12–24 months.

V. Summary

Ginger extract, as a natural active ingredient of food-medicine homology, has been proved by toxicological tests to have very low acute and subchronic toxicity, no genotoxicity or carcinogenicity, and high safety at conventional doses. It is widely used in food, health food, cosmetics, medicine, feed and industry.

In practical application, it is necessary to strictly follow the recommended addition levels in each field based on efficacy demand, product form and target population, control raw material quality and extraction process, and balance safety, efficacy and stability. For special populations, the dosage must be strictly controlled to avoid potential risks.

Overall, ginger extract has broad application prospects in various industries due to its natural, safe and multi-functional advantages. Rational and standardized use can achieve the goal of “natural substitution for synthetic”, improving product quality and market competitiveness.