Safety Assessment, Product Applications and Recommended Dosage of Garlic Extract

Garlic extract is a concentrated natural active ingredient prepared from fresh or dried bulbs of *Allium sativum L.* (Liliaceae, Allium) using processes such as steam distillation, solvent extraction and supercritical CO_2 extraction. Its main functional components include organosulfur compounds such as allicin, diallyl trisulfide and diallyl disulfide, supplemented by flavonoids, polysaccharides and other auxiliary active ingredients.

As a substance explicitly listed in China's *Catalog of Items That Are Both Food and Traditional Chinese Medicine*, garlic extract is widely used for food flavoring, health promotion, antibacterial and antiseptic functions, as well as daily chemical and skin care applications. It is generally safe at common dosages, yet potential risks exist at high doses or for special populations, requiring strict control of addition levels.

I. Safety Assessment of Garlic Extract

(I) Conclusions of Toxicological Studies

1. **Acute Toxicity**

In accordance with GB 15193-2003 *Procedures and Methods for Toxicological Assessment of Food Safety*, oral gavage tests in mice showed that the oral LD_{50} of allicin is 309–600 mg/kg bw, while that of garlic oil is up to 15.1 g/kg bw. No mortality or obvious toxic symptoms (e.g., abnormal behavior, weight loss, organ damage) were observed within two weeks. It is classified as a low-toxicity substance with no acute poisoning risk at normal usage levels.

2. **Subchronic Toxicity**

In a 28-day gavage study in rats, garlic essential oil administered at 15, 25 and 50 mg/kg bw/day caused no abnormalities in behavior, growth, food intake, blood biochemistry or histopathological lesions in major organs. The NOAEL (no-observed-adverse-effect level) was > 50 mg/kg bw/day.

In rats fed 0.15% allicin (3 mL/kg bw) for 10 consecutive weeks, no pathological abnormalities were found in the liver, spleen, kidneys or other key organs, indicating no chronic cumulative toxicity.

3. **Genotoxicity and Carcinogenicity**

Multiple Ames tests, mammalian erythrocyte micronucleus assays and CHO-K1 cell chromosome aberration tests showed that garlic extract/garlic acid is non-mutagenic and does not induce chromosome damage. Some studies suggest its organosulfur components inhibit carcinogen metabolism and exert antimutagenic and potential anticancer activities.

Long-term animal feeding studies found no tumor induction or dose-dependent increase in tumor incidence, confirming no carcinogenic risk.

4. **Reproductive and Developmental Toxicity**

Animal studies showed that garlic extract at normal doses (≤ 100 mg/kg bw/day) has no adverse effects on

reproductive organs, embryonic development or offspring growth.

High doses (> 200 mg/kg bw/day) may slightly affect reproductive performance (e.g., mild reduction in sperm motility), but no fetal malformations or developmental abnormalities were observed. Pregnant women and those preparing for pregnancy are advised to use low doses and avoid long-term high intake.

(II) Hazardous Substances and Limit Control

1. **Heavy Metals and Harmful Elements**

Must comply with relevant industry standards:

Pb ≤ 2.0 mg/kg, As ≤ 1.0 mg/kg, Hg ≤ 0.1 mg/kg, Cd ≤ 0.3 mg/kg, ensuring raw materials are free of heavy metal contamination.

2. **Pesticide Residues and Microorganisms**

Shall meet GB 2763 (pesticide residue limits) and GB 4789 (microbiological limits).

No detection of pathogenic bacteria (Salmonella, *Staphylococcus aureus*, etc.);

Mold ≤ 25 cfu/g, Yeast ≤ 25 cfu/g, Total aerobic plate count ≤ 10^4 CFU/g (food/feed grade).

3. **Sensitization and Irritation**

Skin sensitization rate < 1%; no reports of skin allergy or photosensitivity.

Low concentrations (< 1%) are non-irritating to intact skin; high concentrations (> 5%) may cause transient burning sensation without corrosion.

Ocular irritation is very weak: dilutions (< 0.5%) show no obvious irritation, while undiluted liquid may cause conjunctival congestion. Direct contact with eye mucosa should be avoided.

4. **Risks for Special Populations**

- Patients with gastric ulcer, gastritis or GERD: High-dose allicin may stimulate gastric acid secretion and aggravate mucosal injury; low-dose use or avoidance is recommended.
- Users of anticoagulants: Allicin may enhance the effects of warfarin, aspirin and other anticoagulants, increasing bleeding risk. Use under medical supervision is required.
- Pregnant women and infants: Low-dose use is recommended, avoiding long-term high intake; infants shall be administered under adult supervision.

(III) Safety Conclusions from Authoritative Institutions

- **China**: Listed in the *Catalog of Items That Are Both Food and Traditional Chinese Medicine* and *Inventory of Cosmetic Ingredients Already in Use (2021 Edition)*. Garlic oil/garlic extract is approved as a food flavor in GB 2760; allicin complies with GB 7300.1002-2022 as a feed additive. It is not a prohibited or restricted substance.
- **US FDA**: Classified as GRAS (Generally Recognized as Safe) (§184.1317) for use as a food additive.
- **US CIR**: Safe for cosmetics at ≤ 12.88% in rinse-off products and ≤ 1.2% in leave-on products.

- **EU SCCS**: No safety risks at conventional dosages in food and cosmetics. No formal ADI established; recommended safe daily intake of allicin is approximately 100 mg.

II. Product Applications of Garlic Extract

(I) Food and Beverage Industry

1. **Core Value**

Replaces synthetic flavors, antioxidants and preservatives, provides natural garlic aroma, inhibits bacteria, resists oxidation and extends shelf life. Aligns with consumer demand for natural, healthy products and is highly compatible across food and beverage forms.

2. **Mechanisms**

- **Flavor modulation**: Allicin and organosulfur compounds deliver natural garlic notes, mask off-flavors (meat odor, beany taste, pickling off-notes) and enhance flavor profile.
- **Antioxidation**: Scavenges free radicals, inhibits lipid oxidation, reduces malondialdehyde and delays quality deterioration, outperforming some synthetic antioxidants.
- **Antibacterial preservation**: Strongly inhibits *E. coli*, *S. aureus*, Salmonella, molds and other foodborne pathogens by disrupting cell membranes, with antibacterial activity ~15 times that of phenol.
- **Digestive promotion**: Stimulates saliva and gastric juice secretion, accelerates gastrointestinal motility and relieves discomfort.

3. **Recommended Forms & Products**

- Preferred forms: powder, liquid (garlic oil), microcapsules. Powder suits solid foods; liquid suits liquids and sauces; microcapsules mask garlic odor.
- Applications: solid beverages, baked goods, functional drinks, condiments, meat products, pickled foods, snack foods.

4. **Application Solutions**

- **Flavoring**: Compound with pepper, anise, cinnamon, ginger and other spices to enhance layers, reduce synthetic flavors and mask fishy notes in hot pot bases, sauces, sausages.
- **Antioxidant & preservative**: Replace BHA, BHT and combine with vitamin E, tea polyphenols for meat, oils and pickled products to meet natural food standards.
- **Functional food**: Use high-purity allicin with microencapsulation to mask odor, compound with probiotics and dietary fiber for immunity and gut health.

(II) Health Food Industry

1. **Core Value**

Natural food-medicine ingredient with clear health benefits and minimal side effects, suitable for long-term

consumption. Used alone or in blends for immunity support, auxiliary lipid-lowering, anti-radiation and anti-fatigue functions.

2. **Mechanisms**

- **Immunity enhancement**: Activates macrophages and lymphocytes, improves resistance and reduces infection risk.
- **Auxiliary lipid-lowering**: Inhibits cholesterol synthesis, reduces total cholesterol and triglycerides.
- **Anti-radiation**: Scavenges radiation-induced free radicals and alleviates fatigue and immune decline.
- **Anti-fatigue**: Polysaccharides and sulfur compounds support energy metabolism and relieve physical exhaustion.

3. **Recommended Forms & Products**

- Capsules, tablets, powder, oral liquid; microencapsulated forms reduce pungent odor.
- Products: allicin capsules, garlic extract tablets, garlic oral liquids, health granules. 33 related health foods approved in China.

4. **Application Solutions**

- **Single-ingredient**: 5%–20% allicin extract in capsules/tablets for daily immunity and mild fatigue relief.
- **Compound**: Blend with turmeric and black pepper extract (enhances absorption) for lipid-lowering and anti-inflammation; combine with jujube and Chinese yam for digestion.
- **Special populations**: Low-concentration (<10%) sustained-release tablets for the elderly; combine with vitamin C and wolfberry extract for radiation-exposed groups.

(III) Cosmetics and Daily Chemical Industry

1. **Core Value**

Mild and natural, with skin care, hair care and oral care benefits. Low irritation, suitable for sensitive skin and problematic scalps, supporting natural, gentle and efficacious positioning.

2. **Mechanisms**

- **Skin care**: Inhibits *Cutibacterium acnes*, reduces redness and inflammation, scavenges free radicals, resists aging and repairs the skin barrier.
- **Hair care**: Improves scalp circulation, controls sebum, inhibits Malassezia, relieves itching, dandruff and hair loss.
- **Oral care**: Inhibits oral pathogens, reduces plaque and gingivitis, and freshens breath.

3. **Recommended Forms & Products**

- Liquid for essences, shampoos, mouthwashes; powder for masks and toothpaste.
- Products: garlic serum, cream, mask, shampoo, scalp serum, toothpaste, mouthwash.

4. **Application Solutions**

- **Skin care**: Blend with tea tree oil, salicylic acid, panthenol for acne-prone skin; combine with hyaluronic

acid and vitamin C for brightening.

- **Hair care**: Compound with ketoconazole and sophora extract for oil control, anti-dandruff and hair loss prevention; add squalane and amino acids for dry hair.
- **Oral care**: Mix with menthol and fluoride for antibacterial, anti-gingivitis and breath-freshening effects without residual garlic odor.

(IV) Pharmaceutical Industry

1. **Core Value**

Natural medicinal material with therapeutic and adjuvant effects, mild and low-toxic. Used in TCM preparations and chemical excipients for respiratory, gastrointestinal and skin inflammations, suitable for patients sensitive to synthetic drugs.

2. **Mechanisms**

- **Antibacterial and anti-inflammatory**: Inhibits bacteria and fungi, assists in treating colds, bronchitis, enteritis, gastritis, acne and dermatitis.
- **Auxiliary lipid-lowering**: Supports lipid management and reduces cardiovascular risk.
- **Pharmaceutical excipient**: Improves bioavailability and reduces gastrointestinal irritation of antibiotics and anti-inflammatory drugs.

3. **Recommended Forms & Products**

- High-purity extract (allicin ≥20%), granules, decoctions, creams, gels.
- Products: TCM granules, anti-inflammatory decoctions, pharmaceutical excipients, topical antibacterial creams, anti-acne gels.

4. **Application Solutions**

- **TCM preparations**: Compound with honeysuckle, forsythia for respiratory and skin inflammations; combine with atractylodes and poria for gastrointestinal health.
- **Chemical excipients**: Reduce GI irritation and enhance antibacterial efficacy of antibiotics.
- **Topical formulations**: Blend with menthol and petrolatum for skin inflammation and acne, avoiding oral side effects.

(V) Feed and Other Industries

1. **Core Value**

Replaces antibiotic feed additives with natural antibacterial and growth-promoting effects, no drug residues. Used as a green antioxidant, preservative and bactericide in agriculture and industry.

2. **Mechanisms**

- **Feed**: Inhibits intestinal pathogens, balances gut flora, improves feed utilization, promotes growth, enhances immunity and reduces diarrhea.

- **Agriculture**: Acts as botanical fungicide and insecticide for organic farming, improves soil environment.
- **Industry**: Antioxidant for oils, coatings and leather; preservative for wood, paper and textiles.

3. **Recommended Forms & Products**

- Powder for feed and agricultural sprays; liquid for wood impregnation and water treatment.
- Products: compound feed, aquafeed, botanical fungicides, oil antioxidants, wood preservatives, water treatment odorants.

4. **Application Solutions**

- **Feed**: Blend with probiotics and amino acids for livestock, poultry and aquaculture; combine with ginger extract for fish and shrimp to reduce enteritis.
- **Agriculture**: Dilute 500–1000× for foliar spray in organic farming.
- **Industry**: Use as natural antioxidant for oils and coatings; impregnation for wood and textiles; odorant for heating pipe networks.

III. Recommended Dosage by Field

(I) Food and Beverage Industry

Dosed based on product type, function and sensory acceptability, prioritizing efficacy, safety and odor control.

1. **Beverages**

- Liquid drinks: 0.01%–0.1%
- Solid drinks: 0.5%–3.0% (converted after reconstitution)

Microencapsulated form recommended to mask odor.

2. **Baked goods**: 0.1%–0.5%

- Garlic-focused biscuits/bread: 0.3%–0.5%
- Cakes/pastries: 0.1%–0.2%

3. **Meat products**: 0.1%–0.3%

- Stewed/Marinated: 0.2%–0.3%
- Sausages: 0.1%–0.2%

4. **Condiments**: 0.2%–0.5%

- Soy sauce, sauces: 0.2%–0.3%
- Marinades, hot pot bases: 0.3%–0.5%

5. **Edible oils**: 0.02%–0.1%

Combine with vitamin E for synergistic effect.

6. **Pickled & snack foods**: 0.1%–0.4%

- Pickles: 0.1%–0.3%
- Garlic chips, nuts: 0.2%–0.4%

(II) Health Food Industry

Dosed based on allicin content and targeted health functions.

1. **Single-ingredient products**

Daily intake: 90–2000 mg (equivalent to 3.6–400 mg allicin)

- 5%–10% allicin: 72–800 mg/day
- 10%–20% allicin: 45–400 mg/day

2. **Immunity & anti-fatigue**: 90–500 mg/day (3.6–50 mg allicin)
3. **Auxiliary lipid-lowering**: 500–2000 mg/day (50–400 mg allicin), 8–12 weeks per cycle
4. **Anti-radiation**: 200–800 mg/day (10–80 mg allicin), divided into 2–3 doses

(III) Cosmetics and Daily Chemicals

Controlled to avoid irritation, based on rinse-off/leave-on classification.

1. **Rinse-off products**

- Shampoo: 1.0%–5.0%
- Body wash, hand sanitizer: 0.5%–1.0%

Max historical use: 12.88%

2. **Leave-on products**: 0.1%–1.0%

- Sensitive skin: 0.1%–0.5%
- Acne/dull skin: 0.5%–1.0%

Max historical use: 1.2%

3. **Scalp care**: 1.0%–3.0%

Blend with soothing agents to reduce irritation.

4. **Oral care**: 0.1%–0.3%

- Toothpaste: 0.1%–0.2%
- Mouthwash: 0.2%–0.3%

Max historical use: 0.5%

(IV) Feed Industry

Based on animal species and growth stage.

1. **Swine, poultry, ruminants**: 0.01%–0.02% (80–200 g/ton)

- Young animals: 0.01%–0.015%
- Finishing animals: 0.015%–0.02%

2. **Aquafeed**: 0.008%–0.015% (80–150 g/ton)

- Fish: 0.008%–0.012%
- Shrimp: 0.012%–0.015%

(V) Agricultural and Industrial Applications

1. **Agricultural spraying**: Dilute 500–1000×, stock solution 0.1%–0.2%
2. **Oils & coatings**: 0.02%–0.1%
3. **Wood, leather, paper preservation**: 1.0%–3.0%
4. **Water treatment (odorant)**: 0.003%–0.01% (30–100 g/ton water)

IV. Application Precautions and Quality Control

(I) Raw Material Standards

Use garlic conforming to *Chinese Pharmacopoeia*: allicin ≥0.15%, volatile oil ≥0.2% (mL/g). Free of mold, off-odor and impurities; heavy metals and pesticide residues within limits.

(II) Extraction Process

Prefer supercritical CO_2 extraction (<60°C) to retain active ingredients without solvent residues, or ethanol reflux extraction. Avoid temperatures >80°C to prevent allicin degradation. Purify to reduce pungent odor.

(III) Compatibility Contraindications

- **Food**: Avoid alkaline substances (baking soda) and strong oxidants, which degrade allicin.
- **Cosmetics**: Avoid retinoic acid, AHAs and high-concentration alcohol; combine with panthenol, ceramide to reduce irritation.
- **Pharmaceuticals**: Avoid concurrent use with anticoagulants and NSAIDs due to increased bleeding risk; use under medical supervision.

(IV) Storage Conditions

Store sealed, light-proof, in cool and dry conditions (≤25°C) to prevent moisture, oxidation and degradation.

- Powder: moisture-proof, anti-caking
- Liquid (garlic oil): sealed to prevent leakage and volatilization
- Microcapsules: avoid high temperature and humidity

Shelf life: 12–24 months. Discontinue use if caking, off-odor or discoloration occurs.

V. Summary

Garlic extract, a natural food-medicine ingredient, demonstrates very low acute and subchronic toxicity, no genotoxicity or carcinogenicity, and high safety at conventional dosages. Its key component allicin provides antibacterial, antioxidant and health-promoting effects across food, health food, cosmetics, pharmaceuticals, feed, agriculture and industry.

In practice, dosage should follow field-specific recommendations based on functional needs, product form and target population. Raw material quality and extraction stability must be strictly controlled. Special populations require dose limitation to avoid risks. Microencapsulation and compounding effectively mask garlic odor and improve stability and synergy.

Overall, garlic extract has broad application prospects due to its natural, safe and multi-functional properties. Rational and standardized use supports the replacement of synthetic additives, antibiotics and flavors, enhancing product quality and competitiveness in line with green, healthy and sustainable development trends.