Safety Assessment, Product Applications and Recommended Dosage of Pueraria Lobata Extract

Pueraria Lobata Extract (also known as Kudzu Extract) is a concentrated natural active ingredient produced from the dried roots of *Pueraria lobata (Willd.) Ohwi* or *Pueraria thomsonii Benth.* of the Leguminosae family. It is manufactured through processes including crushing, ethanol reflux extraction, macroporous resin purification, refining, concentration and low-temperature drying. The main functional components are puerarin and total isoflavones, supplemented by kudzu polysaccharides, amino acids, minerals and other nutritional ingredients.

As a traditional homologous material of medicine and food in China, it is listed in the *Chinese Pharmacopoeia* and the National Catalogue of Homologous Substances of Food and Medicine. It is mainly used for cardiovascular and cerebrovascular protection, metabolic regulation, liver protection against alcohol damage, antioxidation and endocrine regulation. It is widely applied in health foods, ordinary foods, pharmaceuticals, cosmetics and other fields. It exhibits excellent safety at conventional dosages with no obvious toxic or side effects. Appropriate control of addition levels and target populations is required to avoid mild gastrointestinal discomfort.

1. Safety Assessment of Pueraria Lobata Extract

1.1 Conclusions of Toxicological Studies

1.1.1 Acute Toxicity

According to GB 15193-2003 *Procedures and Methods for Toxicological Assessment of Food Safety*, oral gavage tests in mice showed that the oral maximum tolerated dose (MTD) of Pueraria Lobata Extract was >20,000 mg/kg bw. In rats, the oral MTD was >15,000 mg/kg bw. No mortality or obvious toxic symptoms were observed in test animals within two weeks. Behavioral activities, food and water intake, body weight gain were normal, and no abnormal pathological changes were found in visceral organs. The extract is classified as **practically non-toxic**, with no risk of acute poisoning at conventional dosages, complying with safety standards for natural food and health food raw materials.

1.1.2 Subchronic Toxicity

In a 90-day feeding study in rats, standardized Pueraria Lobata Extract (total isoflavones ≥30%, puerarin ≥8%) was administered by gavage at 500, 1000 and 2000 mg/kg bw/day. No significant abnormalities were found in growth, food intake, hematology, serum biochemistry or organ coefficients in either male or female rats. No organic lesions, inflammation, degeneration or necrosis were observed in histopathological sections. The no-observed-adverse-effect level (NOAEL) was >2000 mg/kg bw/day.

Long-term moderate intake presents no cumulative toxicity and does not damage vital organs including liver, kidney, spleen and gastrointestinal tract. At high doses (>5000 mg/kg bw/day), only mild abdominal distension and soft stools occurred in a few animals, with no irreversible damage and rapid recovery after cessation of administration.

1.1.3 Genotoxicity and Carcinogenicity

Multiple tests including Ames test, mouse bone marrow cell chromosome aberration test and mouse sperm malformation test demonstrated that Pueraria Lobata Extract has no mutagenicity or chromosome damage, and does not induce gene mutation. Long-term animal feeding studies showed no evidence of tumor induction or dose-dependent increase in tumor incidence. The extract poses no carcinogenic or mutagenic risk, complying with strict genotoxicity standards for food-grade, health-grade and pharmaceutical-grade natural raw materials.

1.1.4 Reproductive and Developmental Toxicity

Animal studies showed that Pueraria Lobata Extract at conventional doses (≤1000 mg/kg bw/day) had no adverse effects on reproductive organs, embryonic development or offspring growth, with no embryo malformation, fetal death or developmental retardation. At high doses (>3000 mg/kg bw/day), no obvious reproductive system damage was observed, only accompanied by mild gastrointestinal discomfort. Due to insufficient large-scale human clinical data, pregnant women, lactating women and young children are advised to use cautiously, avoiding long-term high-dose intake, and professional guidance should be sought if necessary.

1.2 Hazardous Substances and Limit Control

1.2.1 Core Impurities and Limits

Kudzu raw material contains small amounts of starch and crude fiber with no natural allergenic toxins. Invalid impurities can be completely removed by multi-stage membrane separation and macroporous resin purification, resulting in non-irritating finished products. Food-grade and health-grade Pueraria Lobata Extract shall strictly control impurities: crude fiber ≤5%, total ash ≤5.0%, moisture ≤7.0%, to prevent gastrointestinal discomfort and ensure purity and safety.

1.2.2 Heavy Metals and Harmful Elements

The product shall comply with national food safety limits and *Chinese Pharmacopoeia* standards. Key controlled indexes: Pb ≤1.0 mg/kg, As ≤0.3 mg/kg, Hg ≤0.1 mg/kg, Cd ≤0.3 mg/kg, total heavy metals ≤10 ppm. Kudzu raw materials from non-polluted areas with standardized cultivation are preferred to eliminate harmful element residues at the source.

1.2.3 Pesticide Residues and Microorganisms

The product shall meet GB 2763 (pesticide residues), GB 4789 (microbial limits) and pharmacopoeial requirements. *Salmonella*, *Staphylococcus aureus*, *Shigella* and other pathogenic bacteria shall not be

detected. Molds ≤10^2 cfu/g, yeasts ≤10^2 cfu/g, total aerobic plate count ≤10^3 CFU/g. No microbial contamination or mildew deterioration is allowed, in accordance with food and pharmaceutical production hygiene specifications.

1.2.4 Allergenicity and Irritation

Pueraria Lobata Extract has extremely low allergenicity and no allergic risk at conventional doses. Oral administration shows no mucosal irritation and does not damage esophagus or gastrointestinal mucosa. Topical application causes no skin irritation. Only a very small number of people with idiosyncratic constitution may experience slight rash or itching, which can be relieved by discontinuation without severe allergic risk.

1.2.5 Risks for Special Populations

- **Hypotensive individuals**: The extract can dilate blood vessels and assist in blood pressure regulation. Hypotensive patients must strictly control dosage to avoid dizziness, fatigue, palpitations and other discomforts.
- **Individuals with coagulation disorders**: Puerarin inhibits platelet aggregation. People with poor coagulation function or taking anticoagulants shall use under physician guidance.
- **People with spleen-stomach cold deficiency**: Kudzu is slightly cold in nature. High-dose fasting intake may aggravate cold deficiency symptoms such as abdominal distension and loose stools. Postprandial administration or dosage reduction is recommended.
- **Pregnant and lactating women**: Insufficient human safety data; self-administration is not recommended. Use under medical supervision if necessary.
- **Infants and children**: Not recommended for infants under 3 years old due to immature digestive function. Children over 3 years old shall take strictly controlled dosages under adult supervision.

1.3 Safety Conclusions from Authoritative Institutions

- **China**: Listed in the National Catalogue of Homologous Substances of Food and Medicine and the *Chinese Pharmacopoeia* 2020 Edition. Permitted for use in various foods, health foods and Chinese patent medicines, complying with GB 2762, GB 2763, GB 15193 and pharmacopoeial standards. Widely applied with officially recognized safety.
- **United States**: Listed in dietary supplement raw material catalog and accepted by FDA filing. Permitted as natural plant extract for dietary supplements and functional foods. Safe daily intake for adults ≤3 g.
- **European Union**: Included in the list of herbal and food supplement raw materials, approved for foods and health products. Based on animal NOAEL, the acceptable daily intake (ADI) for humans is 50 mg/kg bw, with safe and controllable conventional health doses.

2. Product Applications of Pueraria Lobata Extract

2.1 Health Food Industry

2.1.1 Core Value

As a natural raw material for cardiovascular protection and metabolic regulation, it contains no pharmaceutical ingredients, acts mildly without dependence, and is suitable for long-term consumption. It can be used as single-ingredient preparation or combined with other natural components for synergistic effects. Main health functions include assisting in lowering blood pressure, blood lipid and blood glucose, liver protection against alcohol, antioxidation, menopausal regulation and immune enhancement. It meets health demands of the elderly, business entertainment groups, menopausal women and subhealthy populations, with wide market application and large consumer base.

2.1.2 Mechanism of Action

- **Cardiovascular and cerebrovascular protection**: Puerarin dilates coronary and cerebral vessels, improves microcirculation, reduces vascular resistance, inhibits platelet aggregation, stabilizes blood pressure and lipid, protects myocardium and brain tissue, and prevents atherosclerosis.
- **Metabolic balance regulation**: Improves insulin sensitivity, delays sugar absorption, stabilizes postprandial blood glucose, regulates lipid disorders, accelerates alcohol metabolism and relieves liver burden.
- **Endocrine regulation**: Daidzin, daidzein and other components bidirectionally regulate estrogen levels, relieve menopausal symptoms such as hot flashes, insomnia and irritability, improve bone metabolism and prevent osteoporosis.
- **Antioxidation and anti-aging**: Eliminates excess free radicals, reduces oxidative damage, delays cell senescence, brightens skin tone and improves subhealth status.

2.1.3 Recommended Dosage Forms / Products

- Recommended forms: pressed candy, hard capsule, soft capsule, powder, oral liquid, granule, meal replacement shake. Tablets and capsules are portable; oral liquid has high absorption; powder is suitable for brewing.
- Specific products: kudzu heart-protective capsules, antihypertensive and lipid-lowering tablets, anti-alcohol liver-protective tablets, menopausal oral liquid, antioxidant powder. Many blue-hat health foods have been approved in China, focusing on assisting in lowering blood pressure, blood lipid and protecting against chemical liver injury.

2.1.4 Application Solutions

- **Single-ingredient maintenance solution**: Standard extract with total isoflavones ≥30% formulated into tablets/capsules for daily cardiovascular care and liver protection for

entertainment groups.

- **Compound enhancement solution**: Combined with mulberry leaf extract, bitter melon extract, salvia miltiorrhiza extract, probiotics and collagen for comprehensive regulation of blood lipid, glucose, vascular and skin health.
- **Mild regulation solution**: Reduced single dose combined with jujube, ginger powder and other warm ingredients to neutralize cold nature for people with spleen-stomach cold deficiency.

2.2 Ordinary Food and Beverage Industry

2.2.1 Core Value

Endows foods with health-preserving functions, enhances healthy added value, and meets public demands for wellness, mild nourishment, anti-aging and liver protection without changing original flavor. Suitable for beverages, snacks, meal replacements, baked foods and other categories, realizing functional upgrading of ordinary foods.

2.2.2 Mechanism of Action

Stably retains active ingredients during food processing. Rapidly absorbed in the digestive tract to exert antioxidant, metabolic and vascular protective effects, reducing metabolic burden without affecting taste, color or texture. Compatible with mild industrial processing with high activity retention.

2.2.3 Recommended Dosage Forms / Products

- Recommended form: powder with good water solubility, no precipitation and mild bitter taste, suitable for various food applications.
- Specific products: health beverages (kudzu tea, plant drinks, anti-alcohol drinks, solid drinks), leisure snacks (cereal bars, gummies, biscuits), meal replacements (powder, shakes, congee), baked foods (bread, pastries).

2.2.4 Application Solutions

- **Health beverage solution**: Added to plant drinks, solid drinks and anti-alcohol beverages for daily care of workplace and entertainment groups.
- **Mild nourishment snack solution**: Added to cereal bars, gummies and biscuits to provide antioxidant and liver-protective effects while maintaining taste.
- **Meal replacement wellness solution**: Added to meal replacement powder and shakes for satiety and metabolic regulation, suitable for weight management and health-conscious groups.

2.3 Dietary Supplement Industry

2.3.1 Core Value

As a natural botanical dietary supplement designed for wellness and subhealthy populations, daily supplementation provides cardiovascular care, metabolic regulation and antioxidation. Convenient for

daily carry, it compensates for nutritional deficiencies and supports long-term health.

2.3.2 Mechanism of Action

Multi-component synergy regulates body systems without affecting normal diet or metabolism, gently improving physical function and preventing or alleviating hypertension, hyperlipidemia, hyperglycemia, liver damage from staying up late, menopausal discomfort and skin aging.

2.3.3 Recommended Dosage Forms / Products

- Recommended forms: portable tablets, individually packaged powder, chewable tablets, easy to carry and administer without water.
- Specific products: imported botanical supplements, domestic portable wellness tablets for daily care, post-alcohol repair and menopausal relief.

2.3.4 Application Solutions

- **Portable emergency solution**: Individually wrapped tablets for use before/after entertainment to relieve burden from staying up late, drinking and high-oil/salt diets.
- **Daily nourishment solution**: Combined with multivitamins and minerals for comprehensive nutrition and long-term daily conditioning.

2.4 Special Dietary Foods

2.4.1 Core Value

Suitable for special dietary foods for people with hypertension, hyperlipidemia, hyperglycemia, menopausal women, the elderly and those at risk of chemical liver injury. Provides safe and mild conditioning without pharmaceutical side effects, suitable for long-term use.

2.4.2 Mechanism of Action

Stabilizes blood pressure and lipid, regulates glucose metabolism, protects liver, relieves menopausal discomfort without affecting normal nutrient supply, gently improving physical function for long-term wellness.

2.4.3 Recommended Dosage Forms / Products

- Recommended forms: meal replacement powder, special dietary biscuits, nutritional powder, elderly congee.
- Specific products: special dietary foods for the elderly, special meal replacements for three-high populations, menopausal nutritional diets complying with special dietary food standards.

2.5 Cosmetics and Topical Applications

2.5.1 Core Value

As a natural antioxidant skincare raw material, it scavenges free radicals, relieves inflammation and repairs skin. Added to skincare products to delay aging, brighten skin tone, soothe sensitive skin and

enhance natural efficacy.

2.5.2 Mechanism of Action

Topical application penetrates the skin surface, eliminates free radicals, reduces oxidative damage, soothes inflammation, improves dullness and sensitivity, moisturizes and repairs, delaying skin aging.

2.5.3 Recommended Products

Essence, cream, facial mask, toner, soothing repair lotion and other skincare formulations.

3. Recommended Dosage by Field

The following dosages are based on standard food/health-grade Pueraria Lobata Extract with **total isoflavones ≥30%, puerarin ≥8%**. High-purity products (puerarin ≥40%, total isoflavones ≥60%) may be reduced proportionally.

3.1 Health Food Industry

1. **Single-ingredient preparations (tablets, capsules, chewables)**: 100–300 mg per unit, recommended daily intake 200–800 mg in 1–2 doses; 200–500 mg/day for daily care, 500–800 mg/day for intensive conditioning, max ≤1000 mg/day.
2. **Oral liquids, granules**: 50–200 mg per unit, daily intake ≤800 mg, better absorption after meals.
3. **Blue-hat health foods**: Follow registered approval documents, daily intake 100–600 mg for labeled functions.

3.2 Ordinary Food and Beverage Industry

1. **Liquid beverages**: 0.05%–0.3% by finished weight, ≤300 mg per serving.
2. **Solid drinks, meal replacements, cereal powder**: 0.3%–1.0% by weight.
3. **Baked foods**: 0.1%–0.4% by weight.
4. **Leisure snacks**: 0.2%–0.5% by weight.

3.3 Dietary Supplement Industry

1. **Tablets, chewables**: 100–200 mg per tablet, 1–2 tablets/day, total ≤400 mg/day.
2. **Individual powder packets**: 200–500 mg per packet, 1 packet/day.

3.4 Special Dietary Foods

0.2%–0.8% by finished weight, 100–300 mg per serving, total daily intake ≤600 mg.

3.5 Cosmetic Topical Applications

1. **Creams and lotions**: 0.5%–2.0%
2. **Essences and serums**: 1.0%–3.0%
3. **Masks and toners**: 0.3%–1.5%

Topical formulations should maintain pH 4.0–7.5 to avoid strong acid/alkali environments and ensure stability.

4. Application Precautions and Quality Control

4.1 Raw Material Standards

High-quality kudzu roots with sufficient growth cycle, no mildew, no insect damage and no pollution are preferred. Food/health-grade products shall meet: total isoflavones ≥30%, puerarin ≥8%; high-activity grade: total isoflavones ≥60%, puerarin ≥40%. Heavy metals, microorganisms and pesticide residues comply with national and pharmacopoeial standards. Odorless, slightly sweet and bitter, no caking, uniform color. Impurities such as crude fiber and starch are thoroughly removed.

4.2 Extraction Process

Ethanol reflux extraction + macroporous resin purification + low-temperature drying is preferred, mild and environmentally friendly with extremely low organic solvent residue, maximizing retention of isoflavones and puerarin. Filtration, concentration and refining remove impurities and bitterness. Processing temperature controlled within 60℃ to avoid thermal degradation.

4.3 Compatibility and Contraindications

- As a mild conditioning agent, long-term regular intake is required for effects. It is not a substitute for medicines in treating three-high disorders or liver diseases.
- Users taking anticoagulants, antihypertensives or hypoglycemics should administer at intervals and monitor indicators regularly.
- People with spleen-stomach cold deficiency are recommended to take after meals. Avoid long-term overdosage to prevent abdominal distension or loose stools.
- Skin sensitivity test is required before topical application.

4.4 Storage Conditions

Store sealed, light-proof, in a cool and dry place, temperature ≤25℃, relative humidity ≤60%, protected from moisture, caking and oxidation. Avoid direct sunlight and high humidity. Shelf life of sealed powder: 24 months. After opening, seal promptly and use within 3 months.

5. Summary

Pueraria Lobata Extract is a traditional homologous material of medicine and food with complete toxicological data and high safety. It shows very low acute and subchronic toxicity, no genotoxicity, carcinogenicity or reproductive toxicity. No serious adverse reactions occur at conventional dosages; only mild gastrointestinal discomfort may appear at high doses or on an empty stomach, which is reversible upon cessation or dosage reduction.

With clear core efficacy covering cardiovascular care, metabolic regulation, liver protection, antioxidation and endocrine modulation, it contains no pharmaceutical ingredients and acts mildly without dependence. It is widely used in health foods, ordinary foods, dietary supplements, special dietary foods and cosmetics, suitable for all-age wellness populations.

In practical application, strict adherence to recommended dosages, selection of high-purity, high-activity qualified raw materials, control of extraction process and production hygiene, and avoidance of risks in special populations are essential. Dosage control or avoidance is required for hypotensive individuals, those with spleen-stomach cold deficiency, pregnant women and children.

Overall, Pueraria Lobata Extract is natural, safe, comprehensive in efficacy and widely compatible, conforming to current health trends of wellness and mild nourishment. It is an excellent natural raw material for cardiovascular care, subhealth management and daily health preservation. Standardized use and reasonable addition ensure optimal conditioning effects, satisfying public health demands with broad market prospects.