Safety Assessment, Product Applications and Recommended Dosage of White Kidney Bean Extract

White Kidney Bean Extract (WKBE) is a concentrated natural active ingredient prepared from the mature dried seeds of *Phaseolus vulgaris L.*, a plant of the Leguminosae family, through processes including washing, soaking, water extraction, filtration, concentration, purification and drying. Its core functional component is α-amylase inhibitor (α-AI), with minor auxiliary nutrients such as dietary fiber, polysaccharides, amino acids and minerals. Recognized as a common food ingredient in China and granted internationally acknowledged safety qualifications, this product is mainly featured with the functions of blocking starch decomposition, assisting weight management and stabilizing postprandial blood glucose. It is widely applied in health food, ordinary food, dietary supplements and other fields. It exhibits excellent safety at conventional doses with no obvious toxic or side effects, and only requires control over the addition dosage and applicable population to avoid mild reactions such as gastrointestinal discomfort.

I. Safety Assessment of White Kidney Bean 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 of white kidney bean extract in mice showed that the oral LD_{50} was >10000 mg/kg body weight; the oral maximum tolerated dose (MTD) in rats was >5000 mg/kg body weight. No test animals died or showed obvious toxic symptoms within two weeks, with normal behavioral activities, food and water intake, body weight gain, and no abnormal lesions in visceral organs. It is a **practically non-toxic substance**, with no risk of acute poisoning at conventional usage doses, complying with the safety standards for natural food ingredients.

2. **Subchronic Toxicity**

A 90-day feeding test in rats revealed that oral administration of standardized white kidney bean extract (α-amylase inhibitor activity ≥20000 U/g) at doses of 1000, 2000 and 4000 mg/kg body weight per day resulted in no significant abnormalities in growth and development, food and water intake, blood routine, blood biochemistry or organ coefficients in both male and female rats. No organic damage, inflammation, degeneration, necrosis or other lesions were found in visceral pathological sections. The no-observed-adverse-effect level (NOAEL) was >4000 mg/kg body weight per day. Long-term appropriate intake poses no cumulative toxicity and will not damage core organs such as the liver, kidney, spleen and gastrointestinal tract. High doses (>5000 mg/kg body weight per day) only cause mild reactions such as

slight gastrointestinal flatulence and soft stools, with no irreversible damage and rapid recovery after drug withdrawal.

3. **Genotoxicity and Carcinogenicity**

Multiple Ames tests, mouse bone marrow cell chromosome aberration tests and mouse sperm abnormality tests demonstrated that white kidney bean extract has no mutagenicity or chromosome damage effect, and does not induce gene mutation. Continuous monitoring in long-term animal feeding tests found no tumor induction by the extract, no evidence of dose-dependent increase in tumor incidence, and no carcinogenic or mutagenic risks, complying with the strict genotoxicity standards for food-grade and health-grade natural raw materials.

4. **Reproductive and Developmental Toxicity**

Animal tests indicated that white kidney bean extract at conventional doses (≤1000 mg/kg body weight per day) has no adverse effects on animal reproductive organs, embryonic development and offspring growth and development, with no phenomena such as embryonic malformation, stillbirth or offspring growth retardation. High doses (>3000 mg/kg body weight per day) may trigger mild gastrointestinal discomfort but do not affect reproductive function and embryonic development. Due to insufficient human clinical trial data, pregnant women, lactating women and young children are advised to use it with caution, avoid long-term high-dose intake, and consult professionals if necessary.

(II) Hazardous Substances and Limit Control

1. **Core Hazardous Substances and Limits**

White kidney beans naturally contain trace heat-labile sensitizing components such as lectins and saponins, which can be completely removed through high-temperature water extraction and purification processes, eliminating raw food toxicity in the finished product. Food-grade and health-grade white kidney bean extracts must strictly control impurity content: non-detectable lectins, saponins ≤0.1%, crude fiber ≤5%, to prevent gastrointestinal irritation and sensitization risks caused by natural impurities.

2. **Heavy Metals and Harmful Elements**

They shall comply with national food safety limit standards, with strict control over core indicators: lead (Pb) ≤2.0 mg/kg, arsenic (As) ≤1.0 mg/kg, mercury (Hg) ≤0.1 mg/kg, cadmium (Cd) ≤0.3 mg/kg, ensuring no heavy metal pollution in raw materials. Priority shall be given to white kidney bean raw materials from non-polluting production areas and organic cultivation to eliminate harmful element residues at the source and guarantee finished product safety.

3. **Pesticide Residues and Microorganisms**

They must conform to GB 2763 *National Food Safety Standard - Maximum Residue Limits for Pesticides in Food* and GB 4789 *National Food Safety Standard - Microbiological Limits for Food*. Pathogenic bacteria such as *Salmonella*, *Staphylococcus aureus* and *Shigella* shall not be detected; mold ≤25 cfu/g,

yeast ≤25 cfu/g, total aerobic bacterial count ≤10^4 CFU/g, with no microbial contamination, mildew or deterioration, complying with food production hygiene specifications.

4. **Sensitization and Irritation**

White kidney bean extract has extremely low sensitization, and no sensitization risk exists for people non-allergic to legumes at conventional doses. It has no oral mucosal irritation, will not damage the esophagus or gastrointestinal mucosa, and causes no burning sensation in the oral cavity or digestive tract. Only a very small number of people allergic to legumes may experience allergic reactions such as rash, itching and gastrointestinal colic after consumption, and such people are strictly prohibited from using it.

5. **Risks for Special Populations**

- **People with gastrointestinal diseases**: Use with caution for those with irritable bowel syndrome, chronic enteritis, gastric ulcer or indigestion. High-dose intake of undegraded starch ferments in the intestinal tract, easily aggravating abdominal distension, abdominal pain and diarrhea.
- **People with hypoglycemia**: This product can delay the conversion of starch into glucose. Patients with hypoglycemia and people with low blood glucose must strictly control the dosage to avoid hypoglycemic reactions such as dizziness, fatigue and palpitations.
- **Pregnant and lactating women**: Due to insufficient human safety data, self-administration is not recommended to ensure maternal and infant safety, and use under the guidance of a doctor if necessary.
- **Infants and children**: Infants under 5 years old have immature digestive functions and are strictly prohibited from consumption; children over 5 years old shall take it under adult supervision with strictly controlled dosage.
- **Legume-allergic people**: People allergic to legumes such as white kidney beans, soybeans and peas are strictly prohibited from using it to prevent allergic reactions.

(III) Safety Conclusions of Authoritative Institutions

- **China**: Listed as a common food ingredient by the former Ministry of Health in 2011, it is allowed for use in the production of various foods and health foods, implementing national standards including GB 2762, GB 2763 and GB 15193. It is not a prohibited or restricted raw material and has a wide range of applications.
- **United States**: Granted FDA GRAS (Generally Recognized as Safe) certification, it is allowed to be used as a raw material for dietary supplements and food additives, with a maximum daily intake ≤10 g. The safety of conventional health doses is officially recognized.
- **European Union**: Included in the novel food ingredient catalogue and approved for food and dietary supplement production. Calculated based on animal NOAEL values, the acceptable daily

intake (ADI) for humans is 40 mg/kg body weight, and the recommended daily intake for adults is controlled within 3 g, ensuring safety and controllability.

II. Product Applications of White Kidney Bean Extract

(I) Health Food Industry

1. **Core Value**

As a core natural raw material for blood glucose and weight control, it contains no western medicine ingredients, acts mildly with no dependence, and adapts to long-term consumption needs. It can be made into single-component preparations or compounded with other natural ingredients to enhance functional synergy, mainly featuring health functions such as auxiliary weight loss, postprandial blood glucose control and calorie absorption reduction. It meets the health needs of fat-loss, blood glucose-controlled and sedentary office workers, with mature market applications and a wide audience.

2. **Mechanism of Action**

- **Blocking starch absorption**: The core component α-amylase inhibitor can specifically inhibit α-amylase activity in the oral cavity and intestinal tract, block the decomposition of carbohydrates into glucose, reduce starch absorption by 30%-60%, lower calorie intake and decrease fat accumulation.
- **Stabilizing postprandial blood glucose**: Delays glucose production and absorption, avoids sharp fluctuations in postprandial blood glucose, stabilizes blood glucose peaks, reduces pancreatic islet burden, and is suitable for daily conditioning of people with impaired glucose tolerance and blood glucose control needs.
- **Enhancing satiety**: Undegraded starch enters the intestinal tract, increasing the volume of intestinal contents, prolonging satiety, reducing overeating and snack intake, and assisting in controlling total dietary intake.

3. **Recommended Dosage Forms/Specific Products**

♣ Recommended dosage forms are mainly compressed candies, hard capsules, soft capsules, powders, chewable tablets and meal replacement shakes, among which tablets and capsules are portable and easy to take, powders are suitable for brewing, and meal replacement shakes satisfy both satiety and carbon control needs;

♣ Specific products include white kidney bean blocking tablets, blood glucose control capsules, fat-loss meal replacement powders, carbohydrate blocking chewable tablets, etc. A variety of blue-cap health foods have been approved in China, focusing on auxiliary blood glucose reduction and auxiliary weight loss functions.

4. **Application Solutions**

- **Single-component carbon control solution**: High-activity extract with α-amylase inhibitor activity ≥20000 U/g is selected to make tablets and capsules, taken before meals to precisely block starch absorption, suitable for people with simple carbon control and fat loss needs.
- **Compound enhancement solution**: Compounded with L-arabinose, chitooligosaccharides, dietary fiber, green tea extract and bitter melon extract, integrating starch blocking, sucrose absorption inhibition and intestinal lubrication functions to strengthen weight and blood glucose control effects, suitable for people with dual fat-loss and blood glucose control needs.
- **Mild conditioning solution**: For people with sensitive gastrointestinal tracts, reduce the single-component dosage and compound with probiotics and prebiotics to relieve intestinal flatulence discomfort, exert mild carbon control effects with no burden for long-term consumption.

(II) Ordinary Food and Beverage Industry

1. **Core Value**

Endows foods with blood glucose and carbon control functional attributes, enhances product health added value, conforms to the public's dietary needs for low sugar, low calories and light burden, does not change the original flavor and taste of foods, adapts to various food forms, and can be widely used in staple foods, snacks, beverages, baked foods and other categories to realize the functional upgrading of ordinary foods.

2. **Mechanism of Action**

Stably retains activity during food processing, exerts α-amylase inhibition in the digestive tract after consumption, blocks the absorption of starch from the food itself, reduces the food's glycemic index (GI), lowers calorie intake, and does not affect the original taste, color and texture of foods, adapting to industrial production.

3. **Recommended Dosage Forms/Specific Products**

♣ Powder is the recommended dosage form with good water solubility and no precipitation, suitable for addition to various foods without affecting processing technology;

♣ Specific products cover low-GI staple foods (noodles, rice, steamed buns), baked foods (biscuits, bread, cakes), leisure snacks (jellies, gummies, potato chips), beverages (coffee, milk tea, solid beverages, plant protein drinks) and meal replacement foods (grain bars, porridges), meeting the needs of all daily dietary scenarios.

4. **Application Solutions**

- **Low-GI staple food solution**: Add an appropriate amount of extract to noodles, rice and flour to reduce the GI value of staple foods and stabilize postprandial blood glucose, suitable for daily consumption by diabetic and blood glucose-controlled people.

- **Light-calorie snack solution**: Add to snacks such as jellies, gummies and biscuits to retain snack taste, reduce starch calorie absorption, and create light-calorie, burden-free leisure foods.
- **Functional beverage solution**: Add to solid beverages, milk tea and coffee to make pre-meal blood glucose control drinks, which are convenient to brew and block starch absorption from regular meals, adapting to fast-paced life scenarios.

(III) Dietary Supplement Industry

1. **Core Value**

As a natural dietary supplement specially designed for people with high-carbohydrate diets, it can block carbohydrates when supplemented before meals without deliberate dieting, does not affect normal diet, is convenient and fast, suitable for daily carrying, makes up for the shortcomings of inadequate dietary control, and helps healthy weight management.

2. **Mechanism of Action**

Targetedly acts on the carbohydrate digestion link without affecting the absorption of nutrients such as protein, fat, vitamins and minerals, does not disrupt normal human metabolism, only reduces excess starch calorie intake to achieve healthy weight control, and has significant effects on people with high intake of refined carbohydrates and staple foods.

3. **Recommended Dosage Forms/Specific Products**

♣ Recommended dosage forms are mainly portable tablets, individually packaged small powders and chewable tablets, easy to take without water flushing;

♣ Specific products are mainly imported dietary supplements and domestic portable blocking agents, focusing on pre-meal carbohydrate blocking, suitable for gatherings, takeout and high-carbohydrate diet scenarios.

4. **Application Solutions**

- **Portable emergency solution**: Made into individually packaged tablets, taken 15-30 minutes before meals to cope with high-carbohydrate diets such as gatherings and takeout, easily blocking starch absorption.
- **Daily conditioning solution**: Compounded with multivitamins and minerals to make complex supplements, avoiding the loss of micronutrients caused by long-term carbon control, balancing health and safety.

(IV) Special Dietary Foods

1. **Core Value**

Suitable as special diets for diabetic, obese and fat-loss people, providing a safe and mild way to control blood glucose and weight, assisting in improving body metabolism combined with dietary conditioning,

with no side effects of western medicine and suitable for long-term conditioning consumption.

2. **Mechanism of Action**

Delays the digestion and absorption of starch in staple foods, stabilizes postprandial blood glucose, reduces calorie accumulation and slows weight gain, without affecting the normal nutritional supply of the body, suitable for special people requiring long-term blood glucose and weight control.

3. **Recommended Dosage Forms/Specific Products**

♠ Recommended dosage forms are mainly meal replacement powders, special dietary biscuits and nutritional powders;

♣ Specific products include special meal replacements for diabetic people, special dietary foods for obese people and fat-loss nutritional meals, complying with special dietary food standards.

III. Recommended Addition Dosages by Field

(I) Health Food Industry

Health foods use high-activity white kidney bean extract (α-amylase inhibitor activity ≥20000 U/g) as raw material, strictly control daily intake based on functional positioning and target population, balancing efficacy and safety, with specific recommendations as follows:

1. **Single-component preparations (compressed tablets, capsules, chewable tablets)**: 100-500 mg of extract per tablet/capsule, recommended daily intake 500-3000 mg, taken 1-3 times 15-30 minutes before meals; 500-1500 mg per day for conventional health care, 1500-3000 mg per day for enhanced weight and blood glucose control, with a daily maximum of 3000 mg.
2. **Meal replacement shakes and powders**: Recommended addition dosage 0.8%-1.5% based on finished product weight, 300-800 mg of extract per serving, replacing regular meals for dual effects of satiety and carbon control.
3. **Blue-cap health foods**: Strictly implemented in accordance with registration approval documents, recommended daily intake 300-1000 mg, matching the dosage for auxiliary blood glucose reduction and auxiliary weight loss functions.

(II) Ordinary Food and Beverage Industry

Ordinary foods add the extract as needed on the premise of taste, flavor and stability to avoid excessive gastrointestinal discomfort, using medium-to-high activity extract as raw material, with specific recommendations as follows:

1. **Liquid beverages (milk tea, coffee, plant protein drinks)**: Recommended addition dosage 0.05%-0.3% based on finished product weight, no more than 500 mg of extract per serving, with better effects when taken before meals.

2. **Solid beverages (meal replacement powders, brewed drinks, grain powders)**: Recommended addition dosage 0.5%-2.0% based on finished product weight, with moderate concentration after brewing, no taste impact and no peculiar smell.
3. **Baked foods (bread, biscuits, pastries)**: Recommended addition dosage 0.1%-0.5% based on finished product weight, without affecting dough fermentation and baking taste, reducing product GI value.
4. **Leisure snacks (jellies, gummies, potato chips)**: Recommended addition dosage 0.2%-0.6% based on finished product weight, retaining original snack taste and endowing light-calorie properties.
5. **Staple foods (noodles, flour, rice companions)**: Recommended addition dosage 0.1%-0.4% based on finished product weight, creating low-GI staple foods without changing staple food taste and cooking methods.

(III) Dietary Supplement Industry

Focusing on portability and high efficiency, high-activity extract is adopted with recommended addition dosages:

1. **Tablets and chewable tablets**: 200-500 mg of extract per tablet, 1 tablet per single dose, no more than 6 tablets per day, total dose ≤3000 mg.
2. **Individual powder packets**: 500-1000 mg of extract per packet, 1-3 packets per day, brewed or taken orally directly before meals, convenient and fast.

(IV) Special Dietary Foods

For special diets for diabetic and obese people, recommended addition dosage 0.3%-1.0% based on finished product weight, 200-600 mg of extract per serving, total daily intake ≤2400 mg, for mild blood glucose control and avoiding hypoglycemia risk.

IV. Application Precautions and Quality Control

(I) Raw Material Standards

High-quality white kidney bean raw materials free of mildew and moth damage are preferred. Food-grade and health-grade finished products must meet the following standards: α-amylase inhibitor activity ≥10000 U/g, preferably high-activity grade ≥20000 U/g; heavy metals, microorganisms and pesticide residues comply with corresponding national standards; no peculiar smell, no caking, uniform color; impurities such as lectins and saponins are completely removed to eliminate potential safety hazards.

(II) Extraction Process

Pure water extraction process is preferred, which is mild and environmentally friendly with no organic solvent residues, preserving α-amylase inhibitor activity to the greatest extent. Combined with filtration, concentration and spray drying processes, effective ingredients are purified and impurities and beany flavor are removed; processing temperature is controlled within 80℃ to avoid high-temperature damage to active ingredients and ensure stable product efficacy.

(III) Compatibility and Contraindications

- This product is only effective for starchy carbohydrates and invalid for monosaccharides and disaccharides such as sucrose, fructose and glucose. There is no need to deliberately replace normal staple foods, and better effects are achieved with a balanced diet.
- The administration time is 15-30 minutes before meals; postprandial administration is ineffective and cannot block ingested starch.
- Diabetic patients taking hypoglycemic drugs must monitor blood glucose to avoid hypoglycemia caused by synergistic effects.
- Avoid long-term over-dose administration to prevent persistent gastrointestinal flatulence, diarrhea or interference with micronutrient absorption.

(IV) Storage Conditions

White kidney bean extract shall be stored sealed, away from light, in a cool and dry place at temperature ≤25℃ and relative humidity ≤60%, protected from moisture, caking and oxidation; avoid direct sunlight and high-temperature humid environments to prevent degradation of active ingredients. The sealed shelf life of powdered extract is 24 months, and it shall be used up as soon as possible after opening.

V. Summary

White kidney bean extract is a natural food ingredient with complete toxicological data and extremely high safety. It has very low acute and subchronic toxicity, no genotoxicity, carcinogenicity or reproductive toxicity, no serious adverse reactions at conventional doses, and only high doses may cause mild gastrointestinal discomfort which recovers after drug withdrawal. With clear core functions of specifically blocking starch absorption, assisting weight management and stabilizing postprandial blood glucose, it contains no western medicine ingredients, acts mildly with no dependence, and is widely applied in health food, ordinary food, dietary supplements, special diets and other fields, adapting to various blood glucose-controlled, fat-loss and carbon-controlled people.

In practical applications, focusing on **active content, population adaptation and consumption scenarios**, it is necessary to strictly follow the recommended addition dosages in various fields, select qualified raw materials with high purity, high activity and no impurities, control the extraction process and production hygiene, and avoid consumption risks for special populations. For people with sensitive gastrointestinal tracts, hypoglycemia, pregnant women and children, dosage must be strictly controlled or use avoided.

Overall, white kidney bean extract is natural, safe and functionally clear, conforming to the current healthy dietary trend. It is a high-quality natural raw material in the fields of carbohydrate blocking, weight management and blood glucose regulation. Standardized use and reasonable addition can exert excellent efficacy to meet public health needs, with broad market application prospects.