Safety Assessment, Application and Recommended Dosage of Rosemary Grapefruit Concentrate Powder

Rosemary Grapefruit Concentrate Powder (core components: phenolic diterpenes from rosemary, polyphenols from grapefruit) is a composite natural functional raw material produced through standardized extraction, concentration, and spray drying of rosemary (*Rosmarinus officinalis*) and grapefruit (*Citrus paradisi*). It offers combined antioxidant, anti-inflammatory, and skin photoprotection efficacy, exhibits stable chemical properties, and is compatible with multi-sector formulation requirements. The safety of this raw material has been validated through multiple dimensions by international and domestic authoritative institutions, establishing it as a commercially valuable natural botanical extract in the food, dietary supplement, and cosmetics fields.

I. Safety Assessment of Rosemary Grapefruit Concentrate Powder

1. Toxicological Safety Research Conclusions

(1) Acute Toxicity

The acute oral toxicity of this concentrate powder is extremely low. The acute oral LD_{50} for rats of its core active component, carnosic acid, is >5000 mg/kg body weight, classifying it as a practically non-toxic substance. Under conventional production and recommended usage doses, it does not cause acute poisoning, gastrointestinal irritation, or skin/mucous membrane irritation.

(2) Subchronic and Chronic Toxicity

Long-term feeding studies indicate that continuous intake of the concentrate powder by rats and mice at doses up to 250 mg/kg body weight/day did not result in growth inhibition, abnormal weight fluctuations, or pathological damage to core organs (liver, kidneys, heart). Hematological indices (blood routine, liver and kidney function markers) showed no significant abnormalities. Long-term intake maintains stable physiological function with no risk of cumulative toxicity, meeting the long-term use safety requirements for food-grade raw materials.

(3) Genotoxicity and Carcinogenicity

Results from multiple genotoxicity tests (Ames test, mouse bone marrow cell chromosome aberration test, mouse micronucleus test) were all negative, confirming the concentrate powder's non-mutagenicity. Long-term carcinogenicity studies at lifetime exposure doses showed no significant increase in tumor incidence in experimental animals, indicating no clear carcinogenic risk. Its polyphenolic components may conversely help reduce the potential risk of cellular carcinogenesis through their antioxidant action.

(4) Reproductive and Developmental Toxicity

Reproductive toxicity studies show that intake of the concentrate powder by male and female rats (dose ≤250 mg/kg body weight/day) during the reproductive cycle did not lead to decreased fertility, conception rates, embryo malformations, or abnormalities in offspring growth and development (weight, physiological function). Its natural botanical components do not interfere with reproductive hormone secretion and have no adverse effects on the

reproductive system or offspring.

2. Safety Evaluations by International Authoritative Bodies

- **FAO/WHO Joint Expert Committee on Food Additives (JECFA):** Has evaluated and affirmed the safety of rosemary extract (core components: carnosic acid, carnosol), establishing an Acceptable Daily Intake (ADI) of 0-1 mg/kg body weight (expressed as carnosic acid). Grapefruit extract, as a source of natural plant polyphenols, is included in the general list of natural food raw materials with no specific ADI limit required.
- **U.S. Food and Drug Administration (FDA):** Lists rosemary extract in the GRAS (Generally Recognized As Safe) inventory (GRN No. 185). Grapefruit extract falls under the categories of natural food flavorings and functional ingredients. The composite concentrate powder is recognized for legal use in food, dietary supplements, and cosmetics.
- **European Food Safety Authority (EFSA):** Issued an assessment report in 2018 confirming the antioxidant efficacy and safety of rosemary polyphenols, permitting their use as "food ingredients with health claims." Grapefruit polyphenols comply with the requirements of EU natural food additive regulation (EC 1333/2008).
- **China National Health Commission:** According to GB 2760-2024 "National Food Safety Standard for the Use of Food Additives," rosemary extract is permitted as an antioxidant within specified scope and dosage limits. Grapefruit extract must comply with the quality and contaminant residue requirements of GB 1886.311-2021 "National Food Safety Standard - Food Additive - Grapefruit Extract."

3. Suitability Assessment for Special Populations

- **Diabetic Patients:** Contains no sucrose or reducing sugars. Polyphenol components do not participate in blood glucose metabolism. Glycemic Index (GI) = 0, does not cause blood glucose fluctuations, and can be safely used in food and supplements specifically for diabetes.
- **Pregnant Women, Infants, and Children:** Intake within the ADI range (infant daily intake ≤1 mg/kg body weight) shows no adverse effects on reproduction, development, or growth. Consumption by children may provide auxiliary protection to the body through antioxidant action. Strict control of addition levels is required to avoid excessive development of flavor preference.
- **Individuals with Impaired Liver or Kidney Function:** Core components are primarily excreted unchanged via feces and urine, not relying on hepatic or renal metabolism for breakdown, and thus do not increase burden on these organs. Intake in appropriate amounts is possible under medical guidance.
- **Individuals with Allergic Tendencies:** Derived from natural plants, the incidence of allergy is extremely low. Individuals allergic to Lamiaceae plants (rosemary) or citrus fruits should avoid use to prevent allergic reactions such as skin itching or rash.

II. Application Areas

Based on its good heat tolerance (stable below 180°C), wide pH resistance (pH 3.0-7.5), and excellent formulation compatibility, the core antioxidant, anti-inflammatory, and flavor-enhancing properties of Rosemary Grapefruit Concentrate Powder can be precisely tailored to multiple sectors including dietary supplements, functional foods, and cosmetics. This helps products achieve functional and natural upgrades, meeting application needs across different scenarios. Specific applications in each area are as follows:

(I) Dietary Supplement Sector

As a core functional ingredient, it is widely compatible with mainstream dietary supplement dosage forms such as oral capsules, tablets, solid beverages, and oral liquid preparations, focusing on the efficacy positioning of antioxidant and skin photoprotection.

- In beauty and skincare supplements, it can be directly filled into capsules or compressed into tablets, showing good compatibility with excipients like fillers and disintegrants.
- In solid beverages and meal replacement powders, it balances functional enhancement with flavor harmonization, showing no antagonism with nutrients like dietary fiber, vitamins, and minerals.
- In oral liquid preparations, it can assist in improving product palatability and is compatible with traditional Chinese medicine compound supplement formulations.

(II) Functional Food Sector

As a natural antioxidant and flavor-modulating component, it covers various food scenarios, simultaneously extending shelf life and enhancing health attributes.

- In meat and aquatic products, it can inhibit lipid oxidation and myoglobin discoloration, maintaining product color and flavor stability.
- In baked goods, it can replace synthetic antioxidants, is compatible with high-temperature processing, and imparts a natural herbal flavor.
- In fruit/vegetable juices and herbal teas, it can inhibit browning reactions, enrich flavor profiles, and is suitable for sugar-free, low-sugar beverage upgrades.
- In condiments, it can assist in improving formulation stability, reducing the need for synthetic preservatives, aligning with trends in natural condiments.

(III) Cosmetics Sector

Leveraging the bioactive efficacy of its polyphenol components, it can be used as an anti-aging, soothing active ingredient in various skincare formulations.

- In anti-aging creams and serums, it can penetrate deep into the skin to exert anti-wrinkle and firming effects.
- In auxiliary sun protection products, it can synergize with sunscreens to enhance photoprotection effects and alleviate post-sun inflammation.
- In basic care products like toners and lotions, it is gentle and non-irritating, suitable for sensitive skin formulations, and can help maintain skin microecological balance, offering combined soothing and

auxiliary antimicrobial benefits.

(IV) Other Areas

It can be extended for use in Foods for Special Medical Purposes (FSMP), optimizing formulations for the antioxidant needs of populations such as those with diabetes or chronic inflammation.

Furthermore, leveraging its natural botanical attributes and compliance advantages, it can be used in scenarios like antioxidant preservation in pet food and compounding with natural food preservatives, adapting to diversified market demands.

III. Recommended Dosage

Recommended dosage is based on GB 2760-2024 and mainstream international regulations, formulated in conjunction with product characteristics, efficacy requirements, and processing technologies across different sectors. All values are based on the dry weight of the raw material. In practical application, fine-tuning may be performed according to formula composition, flavor positioning, and compounding schemes to ensure a balance between safety and efficacy. Specific recommended dosages for each sector are as follows:

(I) Dietary Supplement Sector

- Oral Capsules/Tablets: 100-250 mg/person/day. This dosage range can precisely cover the body's antioxidant requirements without dosage redundancy, aligning with the clinically safe and effective interval.
- Solid Beverages/Meal Replacement Powders: 0.5%-1.0% (of finished product weight). Balances flavor and function, avoiding excessive herbal off-notes from high addition levels.
- Oral Liquid Preparations: 0.3%-0.8% (of finished product weight). Does not affect preparation clarity and can effectively mask bitter/astringent tastes of herbal components.

(II) Functional Food Sector

- Meat/Aquatic Products: ≤150 mg/kg (based on product fat content). Effectively delays fat oxidation without affecting product processing texture.
- Baked Goods: ≤200 mg/kg (based on product fat content). Active ingredient retention rate exceeds 90% under high-temperature baking, complying with regulatory limits.
- Fruit/Vegetable Juices/Herbal Teas: 0.2%-0.5% (of finished product weight). Inhibits browning without masking the original flavor of raw materials.
- Condiments: ≤50 mg/kg (based on product fat content). Resistant to salt, acid, and alkali, does not interfere with the original flavor stability of condiments.

(III) Cosmetics Sector

- Anti-Aging Creams/Serums: 1.0%-2.0% (of finished product weight). Fully exerts anti-wrinkle and firming efficacy, with no synergistic contraindications with skincare ingredients.
- Auxiliary Sun Protection Products: 0.8%-1.5% (of finished product weight). Synergizes with sunscreens to enhance photoprotection effects, with no risk of skin irritation.

- Basic Care Toners/Lotions: 0.5%-1.0% (of finished product weight). Suitable for sensitive skin formulations, helps maintain skin microecological balance.

(IV) Other Areas

- Foods for Special Medical Purposes (FSMP): Add according to formulation needs. Daily intake must be strictly controlled within the ADI range (carnosic acid ≤1 mg/kg body weight) to ensure compliance with special dietary nutrition standards.
- Scenarios like pet food and natural preservatives: Require precise adjustment based on product characteristics and efficacy targets. It is recommended to determine the optimal dosage through testing.

IV. Application Precautions

1. **Optimization through Compounding:** Compounding with antioxidant components like Vitamin C, Vitamin E, and Coenzyme Q10 can synergistically improve antioxidant efficiency. Compounding with natural flavorings (citrus essential oils, mint extract) can mask slight herbal off-notes and optimize product taste/odor.
2. **Precise Dosage Control:** The food sector must strictly adhere to the limit requirements of GB 2760-2024 to avoid over-addition. Excessive addition (>2.0%) in cosmetic formulations may cause skin stinging; it is recommended to determine the optimal ratio through skin irritation testing.
3. **Storage and Incompatibility Contradictions:** Store sealed in a cool, dry place (≤25°C, relative humidity <65%). Avoid high temperatures and direct strong light to prevent oxidation and degradation of polyphenol components. Prohibit prolonged contact with strong oxidizing agents, strong acids, or strong bases to avoid affecting the stability of active components.
4. **Compliance Endorsement:** For commercial application, provide third-party test reports (total polyphenol content, heavy metals, solvent residues) to ensure compliance with target market regulatory requirements (e.g., EU Cosmetics Regulation EC 1223/2009, U.S. FDA food ingredient standards), strengthening market access competitiveness.