Safety Assessment, Application and Recommended Dosage of Mogrosides

Ⅰ. Basic Information

1. Product Definition

Mogrosides (the main sweet component is **Mogroside V**, CAS: 88901-36-4, EINECS: 695-005-3, CNS: 19.015) is a natural triterpenoid saponin sweetener extracted from the fruit of *Siraitia grosvenorii* of the Cucurbitaceae family. Its chemical name is **(24R)-3β-[6-O-(β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy-24-[2-O,6-O-di(β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy-cucurbita-5-ene**, molecular formula $C_{60}H_{102}O_{29}$, molecular weight 1287.43.

Its sweetness is 240~425 times that of sucrose (Mogroside V is about 300~425 times). Calorie ≈ 0 kcal/g (hardly involved in human metabolism with no calorie contribution), Glycemic Index GI ≈ 0. It cannot be fermented by oral cariogenic bacteria with no dental caries risk. It features natural pure sweetness, no after-bitterness, excellent thermal stability, acid and alkali resistance (pH 2~10), good water solubility, ability to mask astringency/balance flavor and antioxidant properties. It has pure taste close to sucrose without peculiar odor, appearing as pale yellow to white powder with natural monk fruit fragrance.

2. Production Processes

2.1. Boiling Extraction - Chromatographic Purification Method (Mainstream Industrial Process)

Taking dried mature monk fruit as raw material: multiple hot water extraction at 80~100℃ → filtration and residue removal → vacuum concentration → macroporous adsorption resin adsorption/desorption → membrane separation for impurity removal → ion exchange desalination → activated carbon decolorization → spray drying / vacuum drying → refined powder. Product purity ≥95% (Mogroside V ≥20%, complying with GB 1886.77-2016). With mature process, natural source and high safety, it accounts for over 90% of industrial production capacity, covering food grade, health product grade and beverage grade full categories.

2.2. Enzymolysis-Assisted Extraction Method (Optimized Process)

Raw material pretreatment followed by adding pectinase/cellulase (45~55℃, pH 4.5~6.0, 2~4h) for cell wall breaking → hot water extraction → subsequent procedures consistent with mainstream process. The extraction rate increases by 15%~25% with fewer impurities, purity **≥97%** and purer flavor, suitable for high-end food and health products.

2.3 Supercritical CO_2 Extraction Method (High-End Process)

Using supercritical CO_2 as solvent, extraction under low temperature (31~45℃) and high pressure (15~30MPa) → separation and purification → drying. No solvent residue, complete activity retention, purity ≥98%. However, it requires high equipment investment and cost, mostly applied in high-end natural food, infant food and pharmaceutical excipients.

2.4. Biosynthesis Method (R&D Stage)

Synthesize mogroside precursors via fermentation of recombinant yeast/Escherichia coli, then prepare by enzyme-catalyzed glycosylation. It has renewable raw materials and environmental friendliness, yet suffers from low conversion rate, complicated separation and high cost, not yet applied in large-scale industrial production.

Ⅱ. Safety Assessment

2.1 Toxicological Evaluation

Acute Toxicity

Oral LD_{50} in rats/mice > 10000 mg/kg·bw, classified as practically non-toxic grade; the maximum tolerated dose in mice **＞15 g/kg·bw**. No death, organ damage or acute poisoning symptoms occurred after single high-dose administration, showing extremely high animal tolerance.

Genetic Toxicity

Ames test, in vitro mammalian cell chromosome aberration test, mouse bone marrow micronucleus test and sperm abnormality test all showed negative results. It has no risk of mutagenicity, teratogenicity or chromosome damage; no genetic toxicity risk at conventional dosage (≤1 g/kg·bw).

Subchronic Toxicity (90-day)

Oral NOAEL for rats ≥7000 mg/kg·bw/day, NOAEL for dogs ≥3000 mg/kg·bw/day. During the test period, no pathological damage or cumulative toxicity was observed in animal body weight, blood biochemistry, liver, kidney, gastrointestinal and other target organs.

Chronic Toxicity and Carcinogenicity

Verified by 2-year long-term animal feeding and over 300 years of human consumption history, it has no carcinogenicity, chronic toxicity or organ damage. It is recognized as GRAS (Generally Recognized As Safe) substance by FDA, and approved for appropriate use according to production requirements with no upper limit in China GB 2760-2024.

Safety for Special Populations

Safe for infants, pregnant women, lactating women, diabetic patients and obese people. It is not absorbed in the human body, does not affect blood sugar/insulin, does not increase liver and kidney burden, with no allergy, dependence or metabolic interference.

2.2 Stability and Compatibility Safety

Thermal Stability:

No decomposition, browning or sweetness attenuation after heating at 100℃ for 25h and high-temperature sterilization at 120℃, suitable for baking, sugar boiling, spray drying and high-temperature sterilization processes.

Acid-Base Stability:

Stable structure and unchanged flavor under pH 2~10 environment, compatible with acidic beverages, alkaline food and fermented products.

Compatibility:

Compound with erythritol, xylitol, steviol glycosides, L-arabinose and maltitol to complement taste, enhance sweetness, reduce cost and relieve gastrointestinal discomfort; no adverse reaction with vitamins, minerals, protein and oil, without affecting product quality.

III. Product Application Fields

1. Beverages (Core Application)

- Sugar-free/low-sugar fruit and vegetable juice, tea beverages, carbonated drinks, functional beverages: 0.05~0.5 g/kg, replacing 95%~100% of sucrose. Zero-calorie pure sweetness, stable flavor, masking astringency, enhancing mellowness, no browning and no turbidity.
- Solid beverages, coffee, milk tea, plant protein beverages: 0.02~0.3 g/kg, good solubility, pure sweetness without greasiness, blood sugar control friendly, suitable for instant and cold brew formulas.
- Fermented milk beverages, lactic acid bacteria drinks: 0.03~0.4 g/kg, no impact on fermentation, balanced sour and sweet taste, low-sugar smooth texture and extended shelf life.

2. Bakery and Cereal Products

- Sugar-free bread, cakes, biscuits, mooncakes, pastries: 0.1~0.8 g/kg, replacing 90%~100% of sucrose. Moist and soft texture, natural color, delayed aging, no bitter burnt taste and pure flavor.

- Oatmeal, meal replacement powder, cereal bars, puffed food: 0.05~0.6 g/kg, low-sugar pure sweetness, improved taste, anti-caking, enhanced chewiness, blood sugar control and satiety.

3. Candy and Chocolate Products

- Sugar-free hard candy, soft candy, chewing gum, gum base candy: 0.2~1.0 g/kg, anti-caries, non-sticky teeth, fresh and sweet taste, moisturizing and anti-drying, inhibiting crystallization and high stability.
- Sugar-free chocolate, cocoa products: 0.1~0.7 g/kg, reduced glycemic load, improved taste, inhibiting blooming and enhanced storage stability.

4. Dairy and Cold Drink Products

- Yogurt, modified milk, milk powder, plant-based drinks: 0.05~0.5 g/kg, no impact on fermentation, smooth flavor, moisturizing and anti-caking, suitable for blood sugar control and high-protein formulas.
- Ice cream, ice cream bar, smoothie, jelly: 0.03~0.4 g/kg, inhibiting ice crystal formation, delicate and dense texture, low-calorie pure sweetness, good melt resistance and no peculiar flavor.

5. Health Products and Dietary Supplements

- Throat-soothing, lung-clearing, laxative health products: 0.5~3.0 g/kg, medicinal and edible homology, natural and safe, core functional ingredients with synergistic efficacy.
- Blood sugar control, fat reduction, antioxidant and immune regulation products: 0.3~2.0 g/kg, zero calorie, no blood sugar rise, suitable for all populations with safe and non-side effects.
- Infant formula food, special medical purpose formula food: 0.02~0.2 g/kg, GRAS certified, natural and mild, safe and non-irritating, complying with stringent standards.

6. Other Food and Oral Care Products

- Condiments, sauces, pickled products, convenience food: 0.05~0.4 g/kg, enhancing freshness and inhibiting bitterness, balancing flavor, moisturizing and antisepsis, extending shelf life.
- Toothpaste, mouthwash, oral lozenges: 0.1~0.5 g/kg, anti-caries, fresh breath, sugar-free and safe, mild tooth protection.

Ⅴ. Recommended Dosage (GB 2760-2024 + Industrial Practice)

Food Category	Recommended Dosage (g/kg)	Sucrose Replacement Ratio
Beverages (Fruit & Vegetable Juice / Tea / Functional / Carbonated)	0.05~0.5	95%~100%
Bakery Pastries (Bread / Cake / Biscuit / Mooncake)	0.1~0.8	90%~100%
Candy / Chewing Gum / Chocolate	0.2~1.0	95%~100%
Dairy Products (Yogurt / Modified Milk / Milk Powder)	0.05~0.5	90%~100%
Cold Drinks (Ice Cream / Ice Cream Bar / Smoothie / Jelly)	0.03~0.4	90%~100%
Solid Beverage / Coffee / Milk Tea / Meal Replacement	0.02~0.3	95%~100%
Health Products (Throat-Soothing / Blood Sugar Control / Antioxidant)	0.3~3.0	—
Oral Care Products (Toothpaste / Mouthwash)	0.1~0.5	—

Notes

• Extremely high sweetness. Start with the lower recommended limit when used alone to avoid excessive sweetness; compound formula (e.g. Mogrosides + Erythritol + Steviol Glycosides) can optimize taste and reduce dosage by 20%~40%.

• The recommended daily human intake **≤1.0 g** (pure mogrosides, equivalent to the sweetness of 300g sucrose); adult (60kg) ≤1.0 g/day, child (30kg) ≤0.5 g/day, single intake **≤0.3 g** to prevent gastrointestinal flatulence and diarrhea.

• Strictly abide by GB 2760-2024 and GB 1886.77-2016, use appropriately according to production requirements; reduce dosage properly for people with deficient cold of spleen and stomach and intestinal sensitivity.

• Compliant with FDA GRAS, EU, Japan, Canada and other international safety standards, suitable for export food, high-end natural food and infant food formulas.