Safety Assessment, Application and Recommended Dosage of Lactitol

I. Basic Information

(I) Product Definition

Lactitol (Lactositol, CAS: 585-86-4) is a low-calorie sugar alcohol sweetener, produced by catalytic hydrogenation of lactose. Its chemical name is 4-O-β-D-galactopyranosyl-D-sorbitol, with the molecular formula of $C_{12}H_{24}O_{11}$. It owns a sweetness level of 30%~40% of sucrose and a calorie content of approximately 2.4 kcal/g (60% of sucrose). With a glycemic index GI=0, its metabolism is insulin-independent. It is non-cariogenic and possesses prebiotic activity, featuring pure taste without after-bitterness, low hygroscopicity and excellent stability.

(II) Production Processes

1. **Lactose Catalytic Hydrogenation Method (Mainstream Process)**: Adopting natural lactose as raw material, it is prepared through high-pressure hydrogenation reaction → concentration and crystallization → centrifugal separation → drying under the action of nickel/palladium catalysts. The product purity reaches ≥99%. As the mainstream food-grade production process, it features mature technology and controllable costs.
2. **Enzymatic Conversion Method (Improved Process)**: β-galactosidase is used to catalyze the synthesis of lactitol from lactose and sorbitol. This process has mild reaction conditions and few impurities, with product purity up to 99.5%+, which is suitable for high-end food and pharmaceutical-grade applications.
3. **Biosynthesis Method (R&D Stage)**: Synthesized by microbial fermentation engineering, it is eco-friendly with high purity, yet limited by low production capacity and high cost, and has not been widely industrialized.

II. Safety Assessment

(I) Toxicological Evaluation

1. **Acute Toxicity**: The oral LD_{50} in mice/rats > 10 g/kg·bw, classified as practically non-toxic. Single high-dose administration (10 g/kg·bw) causes no death or visceral damage with good tolerance.
2. **Genotoxicity**: Ames test, in vitro mammalian cell chromosome aberration test, mouse bone marrow micronucleus test and sperm aberration test all show negative results, with no risks of mutagenicity, teratogenicity or chromosomal damage.

3. **Subchronic Toxicity (90-day)**: In oral gavage tests on rats, the no-observed-adverse-effect level (NOAEL) = 1000 mg/kg·bw/day. No abnormal weight changes, normal hematological/biochemical indicators and no pathological damage to target organs such as liver and kidney were observed.
4. **Chronic Toxicity and Carcinogenicity**: A 2-year lifelong feeding test on rats and mice (at a dose 200 times the daily intake) confirmed no carcinogenicity or cumulative toxicity. No pathological changes were found in the liver, kidney and reproductive system, ensuring safety for long-term consumption.
5. **Reproductive and Developmental Toxicity**: Three-generation reproductive toxicity test showed no parental reproductive damage and no malformation/developmental retardation in offspring. Administration to pregnant rats until delivery resulted in normal body weight and skeletal development of fetal rats without embryotoxicity.
6. **Human Tolerance**: Adults have good tolerance with daily intake **≤20 g**; excessive intake (> 25 g/day) may cause transient gastrointestinal reactions such as abdominal distension, borborygmus and mild diarrhea in some groups**. Symptoms can be relieved rapidly within 24~48 hours after stopping intake. No allergic cases have been reported, and it is suitable for diabetics, obese people, children, pregnant women and lactating women.

(II) Safety Certification by Global Authoritative Institutions

1. China (National Health Commission / GB 2760-2024 / GB 1886.98)

- Approved as a food additive (sweetener, stabilizer, humectant), allowed for appropriate use according to production demands in all food categories including beverages, baked goods, confectionery, dairy products, frozen drinks and condiments.
- Applicable to diabetics, obese people, children, pregnant women and lactating women. Normal consumption of added food is safe with no contraindicated groups.
- Food safety indicators: heavy metals (Lead ≤1 mg/kg), microorganisms (Total bacterial count ≤1000 CFU/g) and purity ≥99%, complying with national standard limits.

2. Codex Alimentarius Commission (CAC/JECFA)

- First assessed in 1983 and re-evaluated for safety confirmation in 2006. Its ADI value is not specified, recognized as a generally safe sweetener.

3. European Food Safety Authority (EFSA)

- Certified with a health claim for maintaining normal defecation function in 2015. Daily intake ≥10 g can promote intestinal peristalsis and relieve constipation without potential safety risks.

III. Functional Characteristics and Applications of Products

(I) Product Application Characteristics

1. **Low Calorie, Zero Glycemic Index and Anti-Cariogenic**: With only 60% calories of sucrose and GI=0, it does not stimulate insulin secretion, meeting the demands of low-sugar/sugar-free, blood sugar control and weight management. It cannot be fermented and acidified by oral bacteria, delivering significant anti-caries effects.
2. **High Stability and Excellent Processing Adaptability**: Stable at high temperature (stable at 180℃) and acid-base environment (stable at pH 2~10). It will not decompose, brown or affect flavor during baking, sterilization, spray drying and other processing procedures.
3. **Good Moisturizing Performance and Extended Shelf Life**: It has excellent water retention capacity, preventing baked goods from hardening and confectionery from sanding, so as to extend product shelf life. Being non-fermentable and unavailable for microbial utilization, it can inhibit mold growth.
4. **Prebiotic Activity and Good Compatibility**: It selectively promotes the proliferation of beneficial intestinal bacteria such as bifidobacteria and lactic acid bacteria, inhibits harmful bacteria and optimizes intestinal microecology. Compound use with erythritol, stevia and maltitol can enhance sweetness, improve taste and reduce costs.

(II) Product Application Fields

1. Bakery and Cereal Products (Core Application)

• Sugar-free bread, cakes, biscuits and pastries: 10~50 g/kg, replacing 30%~80% of sucrose, keeping products moist and soft, high temperature resistant, non-browning and shelf-life extended.

• Cereals, meal replacement powder and puffed food: 5~30 g/kg, low sugar and high fiber, meeting health demands and improving product taste and texture.

2. Confectionery and Chocolate Products

• Sugar-free hard candy, gummy candy and chewing gum: 50~200 g/kg, anti-cariogenic, non-sticky teeth, long-lasting sweetness, moisturizing and anti-hardening.

• Sugar-free chocolate: 30~80 g/kg, improving taste, reducing calories, inhibiting blooming and enhancing product stability.

3. Dairy Products and Cold Drinks

• Sugar-free yogurt, flavored fermented milk and modified milk: 20~100 g/kg, non-interfering with fermentation, optimizing taste and promoting probiotic colonization.

• Ice cream, ice lolly and smoothie: 15~50 g/kg, low-calorie and non-greasy, good melting resistance, improved texture and inhibited ice crystal growth.

4. Beverages

• Fruit and vegetable juice, tea drinks, functional beverages and plant protein beverages: 5~30 g/kg, acid and heat resistant, stable flavor, zero sugar and low calorie to meet

health needs.

• Bottled water, sugar-free coffee/milk tea: 2~15 g/kg, zero calorie, flavor-neutral and synergistic with prebiotic efficacy.

5. Condiments and Other Products

• Soy sauce, vinegar, sauce, chicken essence/monosodium glutamate: 5~20 g/kg, enhancing freshness, inhibiting bitterness, balancing flavor, reducing sweetness and adapting to low-sugar formulas.

• Health products, dietary supplements and oral care products: 10~50 g/kg, natural and safe with prebiotic activity, suitable for sugar-free formulas.

(III) Recommended Dosage (GB 2760-2024 + Industrial Practice)

Food Category	Recommended Dosage (g/kg)	Sucrose Replacement Ratio
Baked Pastries (Bread/Cake/Biscuit)	10~50	30%~80%
Confectionery / Chewing Gum / Chocolate	50~200	60%~100%
Dairy Products (Yogurt/Modified Milk/Milk Powder)	20~100	40%~70%
Cold Drinks (Ice Cream/Ice Lolly/Smoothie)	15~50	50%~90%
Beverages (Fruit & Vegetable Juice/Tea Drink/Functional Drink)	5~30	30%~70%
Condiments (Soy Sauce/Vinegar/Sauce)	5~20	20%~50%
Meal Replacement Powder / Cereals / Puffed Food	5~30	40%~80%

Notes

• When used alone, the dosage can be reduced by 10%~20% from the upper limit in the table to avoid insufficient sweetness;

• Compound application (e.g. lactitol + erythritol + stevia) can reduce the dosage of lactitol by 30%~50% with better taste and lower cost;

• The daily human tolerance is **≤20 g**, the maximum daily intake for adults (60kg) is **≤20 g**, and for children (30kg) ≤10 g;

• Strictly comply with the provisions of GB 2760-2024 and use appropriately according to production needs. Special groups (such as people with sensitive intestines) shall control the intake.