Sorbitol Safety Assessment, Product Applications and Recommended Dosage

1. Basic Information

1.1 Product Definition

Sorbitol (D-Sorbitol, CAS: 50-70-4, E420) is a natural polyol sweetener and humectant. Its chemical name is **(2S,3R,4R,5R)-hexane-1,2,3,4,5,6-hexaol**, with a molecular formula of $C_6H_{14}O_6$ and a molecular weight of 182.17. It delivers 60%~70% of the sweetness of sucrose with a calorie content of approximately 2.6 kcal/g (65% of sucrose) and a glycemic index GI≈9. Its metabolism is insulin-independent and it is non-cariogenic. It features mild moisturizing performance and metal ion chelating properties, with a pure, refreshing taste and no after-bitterness. The crystalline type has low hygroscopicity while the liquid type offers strong moisturizing capacity, alongside excellent thermal stability and acid-base stability.

1.2 Production Processes

1. Catalytic Hydrogenation of Glucose (Mainstream Industrial Process): Prepared using starch-hydrolyzed glucose as raw material. The process includes medium and high-pressure hydrogenation reaction (120~150℃, 4~8MPa) under Raney nickel/palladium catalyst → impurity removal via ion exchange → concentration → crystallization/drying → refining. The product purity is **≥99%**. With mature technology, controllable costs and the largest production capacity, this process covers full ranges of food-grade and pharmaceutical-grade products.
2. Electrochemical Reduction Method (Improved Process): Adopting glucose/fructose as substrates for preparation through electrolytic reduction reaction. It features mild reaction conditions, no catalyst residue and few impurities, with product purity of **≥99.5%**. It is suitable for high-end food, cosmetics and injection-grade pharmaceutical applications.
3. Microbial Fermentation Method (R&D Stage): Synthesizes sorbitol by directly converting glucose using microorganisms such as genetically engineered yeast and lactic acid bacteria. It is eco-friendly with no high temperature and high pressure requirements and few by-products. However, it has a long fermentation cycle, low conversion rate and high cost, and has not yet been applied in large-scale industrial production.

2. Safety Assessment

2.1 Toxicological Evaluation

1. Acute Toxicity: The oral LD_{50} in rats is 15.9~17.5 g/kg·bw, and the oral LD_{50} in mice is 17.8~23.2 g/kg·bw, classifying it as practically non-toxic. Single high-dose administration (10 g/kg·bw) causes no death, organ damage or acute poisoning symptoms, indicating extremely high animal tolerance.
2. Genetic Toxicity: Ames test, in vitro mammalian cell chromosome aberration test, mouse bone marrow micronucleus test and sperm aberration test all show negative results. It poses no risks of mutagenicity, teratogenicity or chromosome damage, with no hidden genetic toxicity hazards.
3. Subchronic Toxicity (90-day): In oral gavage tests on rats, the NOAEL is 2000 mg/kg·bw/day. During the test period, animals showed normal weight gain, normal blood and biochemical indicators, and no pathological damage to target organs such as liver, kidney, gastrointestinal tract, with no subchronic cumulative toxicity.
4. Chronic Toxicity and Carcinogenicity: A 2-year lifelong feeding test on rats (at a dose 150 times the daily intake level) and mouse carcinogenicity tests found no carcinogenicity, chronic toxicity or pathological changes. No damage was observed in the liver, kidney, hematopoietic system or reproductive system, ensuring extremely high safety for long-term consumption.
5. Reproductive and Developmental Toxicity: Two-generation reproductive toxicity tests showed no parental reproductive damage, no fetal malformation, developmental retardation or fetal death. Administration to pregnant mice until delivery resulted in normal weight, bone and organ development of fetal rats, with no embryonic toxicity or teratogenic toxicity.
6. Human Tolerance: Adults show good tolerance with a daily intake **≤30 g**. Excessive intake (> 50 g/day) may cause transient gastrointestinal reactions such as abdominal distension, borborygmus and mild diarrhea in some gut-sensitive populations, which can be completely relieved within 24~48 hours after intake cessation. It causes no allergies, teratogenic effects or cumulative risks, and is suitable for diabetics, obese people, children, pregnant women and lactating women.

2.2 Safety Recognition by Global Authoritative Institutions

1. China (National Health Commission / GB 2760-2024 / GB 1886.187)

- Approved as a food additive (sweetener, humectant, stabilizer, thickener, emulsifier), allowed for appropriate use according to production needs in all food categories except salt and salt substitutes, and spices.
- Suitable for diabetics, obese people, children, pregnant women and lactating women. Foods with normal addition are safe with no special contraindicated groups.
- Food safety indicators: Heavy metals (Lead ≤1.0 mg/kg), microorganisms (Total viable count ≤1000 CFU/g), reducing sugar ≤0.2%, purity ≥99%, all complying with

national standard limits.

2. Codex Alimentarius Commission (CAC/JECFA)

● First evaluated in 1965 with multiple reviews confirming its safety. Its ADI value is Not Specified, ranking it as a sweetener with the highest safety level with no safety limit when used in accordance with GMP specifications.

3. European Food Safety Authority (EFSA)

● Confirmed that sorbitol has no genetic toxicity, carcinogenicity or reproductive and developmental toxicity, and is safe and reliable at daily intake levels. It is stipulated that foods containing **≥10%** sorbitol must be labeled with the warning "Excessive consumption may cause diarrhea".

4. U.S. Food and Drug Administration (FDA)

● Listed in the **GRAS (Generally Recognized As Safe)** inventory, permitted for use in food, health products and pharmaceuticals based on production needs with no mandatory daily intake limit. Only high-dose products require gastrointestinal warning labeling.

3. Functional Characteristics and Applications

3.1 Functional Application Characteristics

1. Low-Calorie & Sugar Control, Anti-Cariogenic: With only 65% of sucrose's calories and a GI value of approximately 9, it does not stimulate insulin secretion, making it ideal for sugar-free/low-sugar, sugar-controlled and weight-loss foods. It cannot be fermented and acidified by oral Streptococcus mutans, inhibits enamel demineralization and delivers significant anti-caries effects.
2. Powerful Moisturizing & Shelf-Life Extension: Possesses excellent water retention capacity to prevent baked goods from hardening, candies from sugar blooming and meat products from dehydration. Being non-fermentable and unavailable for mold/yeast utilization, it inhibits microbial reproduction and extends product shelf life by 30%~50%.
3. High Stability & Wide Processing Adaptability: Resists high temperature (no decomposition at 200℃) and acid-base conditions (stable at pH 2~12). It avoids browning and decomposition during baking, sterilization, spray drying and sugar boiling processes without affecting flavor. It chelates metal ions to prevent turbidity and precipitation in beverages and sauces.
4. Excellent Compatibility & Synergistic Functions: Blended with erythritol, xylitol, steviol glycosides and mogroside, it optimizes taste balance, enhances sweetness, reduces costs and alleviates gastrointestinal reactions. It also has emulsifying, thickening and shaping functions, adapting to multi-category food processing.

3.2 Product Application Fields

1. Bakery & Cereal Products (Core Application)

- Sugar-free bread, cakes, biscuits, mooncakes and pastries: 10~50 g/kg, replacing 30%~80% of sucrose. It maintains soft texture, prevents browning, delays staling and extends shelf life.
- Cereal flakes, meal replacement powder, puffed foods and cereal bars: 5~30 g/kg, supporting low-sugar and high-fiber formulas, improving taste, preventing caking and enhancing chewiness.

2. Confectionery & Chocolate Products

- Sugar-free hard candy, gummy candy, chewing gum and gum base candy: 50~200 g/kg, providing anti-caries effects, non-sticky texture, refreshing sweetness, moisturizing and anti-hardening properties, and inhibiting crystallization.
- Sugar-free chocolate and cocoa products: 30~80 g/kg, reducing calories, optimizing taste, inhibiting blooming and improving storage stability.

3. Dairy & Frozen Dessert Products

- Sugar-free yogurt, modified milk, condensed milk and milk powder: 20~100 g/kg, compatible with fermentation processes, improving flavor, preventing caking and adapting to sugar-controlled formulas.
- Ice cream, ice lollies, smoothies and vegetable cream: 15~50 g/kg, delivering low-calorie and non-greasy texture, improving melting resistance, inhibiting ice crystal growth and refining texture.

4. Beverage Products

- Fruit and vegetable juice, tea drinks, functional beverages and plant protein beverages: 5~30 g/kg, featuring acid and heat resistance, stable flavor, zero sugar and low calories, preventing turbidity and chelating metal ions.
- Sugar-free coffee, milk tea and solid beverages: 2~15 g/kg, zero-calorie, flavor-neutral, improving solubility and synergizing moisturizing effects.

5. Condiments & Other Foods

- Soy sauce, vinegar, sauces, chicken essence and pickled products: 5~20 g/kg, enhancing freshness, suppressing bitterness, balancing flavor, reducing sweetness, preventing deterioration and adapting to low-sugar formulas.
- Surimi products (fish balls, crab sticks): ≤0.5 g/kg, inhibiting freezing denaturation, maintaining elasticity and optimizing taste.
- Health products, dietary supplements and oral care products (toothpaste, mouthwash): 10~50 g/kg, natural and safe, anti-cariogenic, moisturizing and shaping, suitable for sugar-free formulas.

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

Food Category	Recommended Dosage (g/kg)	Sucrose Replacement Ratio
Baked Pastries (Bread/Cake/Biscuit/Mooncake)	10~50	30%~80%
Confectionery / Chewing Gum / Chocolate	50~200	60%~100%
Dairy Products (Yogurt/Modified Milk/Condensed Milk/Milk Powder)	20~100	40%~70%
Frozen Desserts (Ice Cream/Ice Lolly/Smoothie/Vegetable Cream)	15~50	50%~90%
Beverages (Fruit & Vegetable Juice/Tea/Functional/Plant Protein)	5~30	30%~70%
Condiments (Soy Sauce/Vinegar/Sauce/Pickled Products)	5~20	20%~50%
Meal Replacement Powder / Cereal Flakes / Puffed Foods	5~30	40%~80%
Surimi Products	≤0.5	—

Notes

- When used alone, the dosage can be reduced by 10%~20% from the upper limit in the table to avoid excessive sweetness;
- Compound application (e.g. Sorbitol + Erythritol + Steviol Glycosides) can cut dosage by 30%~50%, with better taste, lower cost and improved gastrointestinal tolerance;
- The daily human tolerance intake is **≤30 g**. The maximum daily intake for adults (60kg) is **≤30 g**, and for children (30kg) ≤15 g;
- Strictly comply with the provisions of GB 2760-2024 for appropriate use according to production needs; gut-sensitive groups and infants and young children shall control single intake.