Safety Assessment, Application and Recommended Dosage of Maltitol

I. Basic Information

(I) Product Definition

Maltitol (CAS: 585-88-6), a dihydric alcohol, is produced by hydrogenation and reduction of maltose. It naturally exists in small amounts in some fermented foods and serves as a classic low-calorie functional sweetener. Its sweetness is **75%~90%** of sucrose, with an energy coefficient of approximately 2.1 kcal/g. Its metabolism is insulin-independent, and the glycemic index (GI) is only 35~40. It features pure and mild taste without unpleasant aftertaste, as well as excellent moisture retention and stability.

(II) Production Processes

1. **Starch Hydrolysis and Hydrogenation Method (Mainstream Process)**: Using corn starch and cassava starch as raw materials, maltose liquid is generated via enzymatic hydrolysis, followed by catalytic hydrogenation, concentration, crystallization and drying. The product purity can reach **98.0%~100.0%**.
2. **Hydrogenated Glucose Syrup Method (Commonly Used Process)**: Starch is fully hydrolyzed into glucose and then hydrogenated. The product contains about 50% maltitol + 20% maltotriitol + 30% sorbitol. It features low cost and is suitable for mid-to-low-end products.
3. **Bioconversion Method (R&D Stage)**: Microbial fermentation of starch hydrolysate combined with enzymatic catalysis is adopted to produce maltitol. It boasts outstanding environmental performance yet suffers from high cost and low conversion rate, without large-scale industrial application.

II. Safety Assessment

(I) Toxicological Evaluation

1. **Acute Toxicity**: The oral LD_{50} of rats > 20 g/kg·bw, classified as a practically non-toxic substance.
2. **Genotoxicity**: Ames test, in vitro mammalian cell chromosome aberration test and mouse bone marrow micronucleus test all show negative results, with no mutagenic or teratogenic risks.
3. **Subchronic Toxicity (90 Days)**: The oral NOAEL of rats is 3000 mg/kg·bw per day, with no organ damage, abnormal biochemical indicators or target organ toxicity.
4. **Chronic Toxicity and Carcinogenicity**: Long-term 2-year animal feeding tests confirm no carcinogenicity or cumulative toxicity, with normal body weight and

hematological indicators.

5. **Reproductive and Developmental Toxicity**: No parental reproductive damage or offspring developmental abnormalities are observed at tested doses, presenting a wide safety margin for reproductive toxicity.
6. **Human Tolerance**: Adults have good tolerance with daily intake ≤40 g; excessive intake (> 50 g/day) may cause transient gastrointestinal reactions such as abdominal distension, borborygmus and mild diarrhea in some populations, which can be relieved rapidly after stopping intake.

(II) Safety Recognition by Global Authoritative Institutions

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

- Approved as a sweetener that can be appropriately used in various foods according to production requirements, with no upper limit on daily intake.
- Safe for infants, pregnant women, lactating women and diabetic populations under normal dietary consumption of added foods.
- Food safety indicators comply with national standard limits for heavy metals, microorganisms and reducing sugars.

2. United States (FDA)

- Recognized as GRAS (21 CFR 172.845), permitted for use in all categories of foods including beverages, baked goods, confectionery and oral care products.

3. Europe (EFSA)

- Safety confirmed in the 2011 assessment. Sugar alcohols are verified to reduce dental demineralization and postprandial blood glucose response, with no specific ADI restriction.

4. Other Regions

- Approved for widespread use as a food sweetener by FSANZ (Australia and New Zealand), Japan, South Korea, Canada and other regions; included in food additive standards by the Codex Alimentarius Commission (CAC) with the code INS 965.

(III) Safety Conclusion

Maltitol possesses complete toxicological data, a long global application history and excellent human tolerance, with no safety risks under normal consumption doses. Only excessive intake may cause mild gastrointestinal discomfort. It has no cumulative toxicity and low metabolic burden, with no strict dietary restrictions for special crowds, and is widely recognized as a high-safety sugar substitute.

Note: It is toxic to dogs and strictly prohibited for addition in pet food.

III. Product Application Characteristics and Applications

(I) Product Application Characteristics

1. **Sucrose-like Sweetness**: With sweetness of **75%~90%** of sucrose, it delivers mild and pure taste without bitterness, metallic taste or unpleasant aftertaste, and natural sweet taste release.
2. **Low Calorie & Low GI**: The calorie value is only 50% of sucrose. It does not stimulate insulin secretion, making it suitable for sugar control, weight management and diabetic groups.
3. **Powerful Moisture Retention & Stability**: Moderate hygroscopicity delays starch retrogradation, maintains product moisture and extends shelf life.
4. **Non-Cariogenic**: Hardly fermented by oral bacteria to produce acid, inhibits dental plaque formation and reduces dental caries risks.
5. **Excellent Physical and Chemical Stability**: High temperature resistance, acid and alkali resistance, and no Maillard reaction, suitable for high-temperature processed foods.

(II) Beverages (Calculated by Finished Product Mass)

1. Sugar-Free Carbonated Drinks / Tea Beverages / Sports Drinks

- Dosage: 2%–5%
- Function: Provides mild sweetness, ensures flavor stability, low calorie and low blood glucose response.

2. Fruit & Vegetable Juices / Plant Protein Beverages

- Dosage: 3%–6%
- Function: Softens sour taste, improves taste smoothness and does not interfere with nutrient absorption.

3. Solid Beverages / Instant Drinks

- Dosage: 6%–12%
- Function: Ensures good fluidity and low moisture absorption, with natural sweetness and mild taste after reconstitution.

(III) Baked Foods (Calculated by Total Formula Mass)

1. Biscuits / Cookies / Pastries

- Dosage: 5%–12%
- Function: Ensures crisp texture and moisture resistance, avoids browning with stable color, and reduces calories by over 40%.

2. Bread / Cakes / Western Pastries

- Dosage: 4%–10%
- Function: Improves texture, reduces cloying sweetness, delays staling, extends shelf life and adapts to sugar-controlled products.

3. Moon Cakes / Chinese Pastries

- Dosage: 6%–15%
- Function: Reduces excessive sweetness and oil exudation, prolongs shelf life and delivers fresh non-cloying taste.

(IV) Dairy and Frozen Foods (Calculated by Finished Product Mass)

1. Yogurt / Fermented Milk / Flavored Milk

- Dosage: 2%–6%
- Function: Regulates acidity, ensures smooth taste, does not affect fermentation process and enhances product stability.

2. Ice Cream / Popsicles / Frozen Desserts

- Dosage: 5%–10%
- Function: Inhibits ice crystal formation for dense and smooth texture without ice residue, with strong freezing stability and good melting resistance.

3. Cheese / Cream / Flavored Dairy Products

- Dosage: 2%–5%
- Function: Softens flavor, optimizes texture, controls sugar and calories, and increases product added value.

(V) Confectionery and Preserves (Calculated by Finished Product Mass)

1. Chewing Gum / Hard Candy / Tablet Candy

- Dosage: 50%–90%
- Function: Good moldability and low hygroscopicity, anti-cariogenic, mild taste and long-lasting sweetness.

2. Chocolate / Filled Candy

- Dosage: 10%–25%
- Function: Enhances sweetness without affecting fat crystallization, ensures smooth texture, prevents blooming and reduces calories.

3. Dried Fruits / Preserves / Jelly

- Dosage: 5%–10%
- Function: Reduces total sugar content, retains moisture and color, relieves cloying sweetness and extends shelf life.

(VI) Condiments and Sauces (Calculated by Finished Product Mass)

1. Jam / Salad Dressing / Ketchup

- Dosage: 4%–10%
- Function: Balances sweet and sour taste, inhibits browning, improves stability and optimizes taste.

2. Oyster Sauce / Barbecue Sauce / Seasoning Sauce

- Dosage: 3%–8%
- Function: Enhances sweetness and freshness, improves texture, prevents moisture absorption and deterioration, and prolongs shelf life.

(VII) Other Food Fields

1. Tabletop Sweetener: Add as required

- Scope of Application: Directly replace sucrose in coffee, tea and meals for low-calorie and healthier consumption.

2. Meal Replacement Bars / Protein Powder / Health Foods

- Dosage: 5%–15%
- Function: Controls sugar and calorie intake, improves taste, masks peculiar odors and enhances product stability.

(VIII) Non-Food Applications

1. Oral Care Products (Toothpaste / Mouthwash / Lozenges)

- Dosage: 5%–30%
- Function: Prevents dental caries, refreshes breath, inhibits dental plaque and is mild and non-irritating to oral mucosa.

2. Pharmaceutical Excipients / Cosmetics

- Dosage: 3%–12%
- Serves as flavoring agent and humectant to improve the palatability of medicines and skin feel of cosmetics, featuring mild skin friendliness and high stability.

IV. Usage Specifications and Precautions

1. Intake Recommendation

The recommended daily intake for adults is ≤40 g, with single intake ≤15 g; excessive intake may induce gastrointestinal reactions such as abdominal distension and diarrhea.

2. Population Applicability

There are no strictly restricted groups. Infants, pregnant women, lactating women and diabetic patients can consume normally; strictly prohibited for dog food.

3. Compound Formula Suggestion

Compound with erythritol, steviol glycosides and mogroside to optimize the sweet taste profile, improve taste and reduce production costs.

4. Process Tips

Due to the absence of Maillard reaction, a small amount of fructose or food colorants can be added for golden color of baked products; sealed storage is required in high-humidity environments.

5. Storage Conditions

Store in a sealed, cool and dry place, protected from moisture and sunlight to avoid caking. The shelf life is 24 months.