Xylitol Safety Assessment, Product Application and Recommended Dosage

1. Basic Information

1.1 Product Definition

Xylitol (CAS: 87-99-0), a five-carbon sugar alcohol, naturally exists in birch trees, corn cobs, sugarcane bagasse, as well as fruits and vegetables such as strawberries, spinach and pumpkins. It is a classic low-calorie functional sweetener. Its sweetness reaches **90%~100%** of sucrose, with an energy coefficient of approximately **2.4 kcal/g**. Its metabolism is insulin-independent, with a glycemic index (GI) of only **7~13**. It delivers a pure and refreshing taste with a cooling sensation due to heat absorption during dissolution.

1.2 Production Processes

1. **Chemical Synthesis (Mainstream Process)**: Taking agricultural and forestry wastes such as corn cobs, sugarcane bagasse and birch bark as raw materials, xylose is extracted via acid hydrolysis, followed by catalytic hydrogenation, concentration, crystallization and drying. The final purity can reach **98.5%~101.0%**.
2. **Biological Transformation (Emerging Process)**: Microorganisms are used to ferment lignocellulosic hydrolysate, and xylitol is produced through enzymatic hydrolysis, fermentation, purification and other procedures. It features outstanding environmental performance yet higher production costs.
3. **Direct Extraction**: Directly extracted from natural fruits and vegetables. Restricted by low natural content and high costs, it is only applied in a small number of high-end products.

2. Safety Assessment

2.1 Toxicological Evaluation

1. **Acute Toxicity**: The oral LD_{50} of rats > **15 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-day)**: The oral gavage NOAEL for rats = **5000 mg/kg·bw/day**, with no organ damage or abnormal biochemical indicators.

4. **Chronic Toxicity and Carcinogenicity**: Long-term animal feeding tests confirm no carcinogenicity or target organ toxicity, with normal body weight and hematological parameters.
5. **Reproductive and Developmental Toxicity**: No parental reproductive damage or offspring developmental abnormalities are observed under test doses, with a wide safety margin for reproductive toxicity.
6. **Human Tolerance**: Adults show good tolerance with daily intake ≤**50 g**; excessive intake (> **60 g/day**) may cause transient gastrointestinal reactions such as abdominal distension, borborygmus and mild diarrhea in some populations, which can be relieved rapidly after discontinuation.

2.2 Safety Recognition by Global Authoritative Institutions

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

- Approved as a sweetener for appropriate use in all types of foods according to production demands, with no upper limit on daily intake.
- Safe for regular consumption by infants, pregnant women, lactating women and diabetic populations in fortified foods.
- Food safety indicators comply with national standard limits for heavy metals, microorganisms and reducing sugars.

2. United States (FDA)

- Recognized as GRAS in 1986 (21 CFR 172.395), permitted for full-category applications including beverages, baked goods, confectionery and oral care products.

3. Europe (EFSA)

- Safety verified in the 2011 assessment; sugar alcohols are confirmed to reduce dental demineralization and postprandial blood glucose response, with no specified ADI limit.

4. Others

- Approved for widespread use as a food sweetener by FSANZ (Australia and New Zealand), Japan, South Korea, Canada and other regions; listed in food additive standards by the Codex Alimentarius Commission (CAC) with INS No. 967.

2.3 Safety Conclusion

Xylitol possesses complete toxicological data, a long global application history and excellent human tolerance, with zero safety risks under normal consumption doses. Excessive intake may only cause mild gastrointestinal discomfort. It has no cumulative toxicity and low metabolic burden, with no strict dietary restrictions for special groups, making it a widely recognized high-safety sugar substitute.

Note: **Xylitol is toxic to dogs and strictly prohibited in pet food**.

3. Functional Characteristics and Product Applications

3.1 Core Functional Characteristics

1. **Sucrose-comparable Sweetness**: 90%~100% sweetness of sucrose, featuring a cooling taste without bitterness, metallic aftertaste or unpleasant residual flavor, and natural sweetness release.
2. **Low Calorie & Low GI**: Only 60% of sucrose's calorie content, non-stimulatory to insulin secretion, suitable for blood sugar control, weight management and diabetic groups.
3. **High Stability**: High temperature resistance (no decomposition under 150℃ baking), acid and alkali resistance (stable at pH 3~7), non-participation in Maillard reaction and low browning tendency.
4. **Anti-caries Property**: Unable to be fermented into acid by oral cariogenic bacteria, inhibits dental plaque formation and protects oral health.
5. **Moisturizing & Texture Modification**: Excellent moisturizing performance, capable of improving product texture, delaying starch retrogradation and extending shelf life.

3.2 Beverages (Calculated by Finished Product Mass)

1. Sugar-free Beverages / Sparkling Water / Functional Drinks

- Recommended Dosage: **3%–8%**
- Functions: Delivers refreshing sweetness, masks bitter and astringent tastes, enhances palatability and avoids blood glucose elevation.

2. Fruit & Vegetable Juices / Plant Protein Beverages

- Recommended Dosage: **2%–6%**
- Functions: Softens sour taste, improves flavor stability and does not interfere with nutritional components.

3. Solid Beverages / Instant Drinks

- Recommended Dosage: **5%–12%**
- Functions: Ensures good fluidity and low moisture absorption, with natural sweetness and cooling mouthfeel after reconstitution.

3.3 Baked Foods (Calculated by Total Formula Mass)

1. Biscuits / Cookies / Pastries

- Recommended Dosage: **6%–15%**
- Functions: Optimizes crispness, reduces moisture absorption, prevents browning and cuts calories by over 40%.

2. Bread / Cakes / Western Pastries

- Recommended Dosage: **5%–12%**
- Functions: Improves texture, reduces excessive sweetness, delays aging and adapts to sugar-controlled products.

3. Moon Cakes / Chinese-style Pastries

- Recommended Dosage: **8%–15%**
- Functions: Moderates sweetness, reduces oil exudation, prolongs shelf life and delivers a fresh non-greasy taste.

3.4 Dairy & Frozen Foods (Calculated by Finished Product Mass)

1. Yogurt / Fermented Milk / Flavored Milk

- Recommended Dosage: **3%–7%**
- Functions: Regulates acidity, ensures smooth texture, does not affect fermentation and improves product stability.

2. Ice Cream / Ice Bars / Frozen Desserts

- Recommended Dosage: **6%–12%**
- Functions: Inhibits ice crystal formation, creates dense texture without ice residue and ensures strong freezing stability.

3. Cheese / Cream / Flavored Dairy Products

- Recommended Dosage: **2%–5%**
- Functions: Softens flavor, optimizes texture and realizes sugar & calorie control.

3.5 Confectionery & Preserved Fruits (Calculated by Finished Product Mass)

1. Chewing Gum / Hard Candy / Tablet Candy

- Recommended Dosage: **60%–95%**

- Functions: Ensures good moldability and low moisture absorption, delivers anti-caries effect, cooling sensation and long-lasting sweetness.

2. Chocolate / Filled Candy

- Recommended Dosage: **5%–15%**
- Functions: Enhances sweetness, does not interfere with fat crystallization, ensures smooth taste and reduces calorie content.

3. Dried Fruits / Preserves / Jelly

- Recommended Dosage: **4%–8%**
- Functions: Reduces total sugar content, retains moisture and color, relieves excessive sweetness and extends shelf life.

3.6 Condiments & Sauces (Calculated by Finished Product Mass)

1. Jam / Salad Dressing / Ketchup

- Recommended Dosage: **3%–8%**
- Functions: Balances sweet and sour taste, inhibits browning, strengthens stability and optimizes mouthfeel.

2. Oyster Sauce / Barbecue Sauce / Seasoning Sauce

- Recommended Dosage: **2%–6%**
- Functions: Enhances sweetness and umami, improves product fluidity, prevents moisture-induced deterioration and extends shelf life.

3.7 Other Food Applications

1. Tabletop Sweetener: Add as required

- Scope of Application: Directly replaces sucrose in coffee, tea and daily meals for low-calorie and healthier diets.

2. Meal Replacement Bars / Protein Powder / Health Foods

- Recommended Dosage: **4%–12%**
- Functions: Controls sugar and calorie intake, improves taste, masks peculiar odors and enhances product stability.

3.8 Non-food Applications

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

- Recommended Dosage: **5%–35%**
- Functions: Prevents dental caries, freshens breath, inhibits dental plaque and provides mild care without oral mucosal irritation.

2. Pharmaceutical Excipients / Cosmetics

- Recommended Dosage: **2%–10%**
- Serves as a flavor corrector and humectant to improve the palatability of pharmaceuticals and the skin-feel of cosmetics with mild and skin-friendly properties.

4. Usage Specifications & Precautions

1. Intake Recommendation

The daily recommended intake for adults is ≤**50 g**, with a single intake ≤**20 g**; excessive consumption may trigger gastrointestinal symptoms such as abdominal distension and diarrhea.

2. Population Applicability

No restricted groups; infants, pregnant women, lactating women and diabetic patients can consume normally. Strictly forbidden in dog food.

3. Compound Formula Suggestion

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

4. Process Tips

Due to non-participation in the Maillard reaction, a small amount of fructose or food coloring can be matched to achieve a golden color for baked goods; 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; shelf life: **24 months**.