Safety Assessment, Product Applications and Recommended Dosage of D-Allulose

I. Basic Information

(I) Product Definition

D-Allulose (D-Allulose, CAS: 551-68-8) is a hexoketose and epimer of fructose. It naturally exists in trace amounts in plants such as figs, kiwifruits and wheat, and is a novel low-calorie functional rare sugar.

It has **70% of the sweetness of sucrose**, with an energy coefficient of approximately **1.67 kJ/g** (only 10% that of sucrose). About 90% is not metabolized or absorbed by the human body but excreted directly via the kidneys, with no significant effect on blood glucose or insulin levels.

(II) Production Process

1. **Enzymatic Conversion Method**: Using fructose as raw material, catalyzed by D-allulose 3-epimerase, followed by decolorization, separation, purification, crystallization and drying (mainstream process).
2. **Microbial Fermentation Method**: Using glucose/sucrose as raw material, fermented by *Escherichia coli* AS10, then purified, crystallized and dried.
3. **Product Standard**: D-Allulose content ≥ 98 g/100 g.

II. Safety Assessment

(I) Toxicological Assessment

1. **Acute Toxicity**: Oral LD_{50} in rats > 15 g/kg·bw, classified as **practically non-toxic**.
2. **Genotoxicity**: Negative results in Ames test, chromosome aberration test and micronucleus test; no mutagenicity.
3. **Subchronic Toxicity (90 days)**: NOAEL (No-Observed-Adverse-Effect Level) in rats = 5000 mg/kg·bw/day.
4. **Chronic Toxicity (18 months)**: NOAEL in rats = 1280 mg/kg·bw/day. Only high doses caused slight body weight reduction in some animals, with no organ damage

or pathological abnormalities.

5. **Reproductive and Developmental Toxicity**: No adverse effects on parental and filial generations at 2000 mg/kg·bw in rats; no teratogenicity at 5000 mg/kg·bw in teratogenicity tests.
6. **Human Tolerance**: Single maximum tolerated dose = 0.4 g/kg·bw; daily maximum tolerated dose = 0.9 g/kg·bw. Excessive intake (> 1.0 g/kg·bw/day) may cause gastrointestinal symptoms such as bloating, diarrhea and abdominal pain.

(II) Global Safety Approvals by Authoritative Bodies

1. **China (NHCC Announcement No. 4 of 2025)**

- Approved as a **novel food ingredient**, with recommended daily intake ≤ 20 g per person.
- Contraindicated populations: infants, pregnant women, lactating women (insufficient safety data).
- Food safety indicators: comply with limits for heavy metals, microorganisms and solvent residues specified in the announcement.

2. **United States (FDA)**

- Repeatedly designated as GRAS (Generally Recognized as Safe) in 2012 (GRN 400) and 2019, permitted for use in various foods as needed for production.

3. **Europe (EFSA)**

- Evaluated twice in 2021 and 2023: no safety risks under intended conditions of use; formal approval planned for 2026.

4. **Others**

- Canada: natural health product ingredient; Australia & New Zealand: novel food ingredient; Republic of Korea, Japan: permitted for food use.

(III) Safety Conclusion

D-Allulose has **complete toxicological data**, **authoritative approvals in multiple countries** and **good human tolerance**, with extremely high safety within recommended dosages. Only excessive intake carries a risk of gastrointestinal discomfort, and special populations should avoid use.

III. Product Application Properties and Applications

(I) Application Properties

1. **Pure Sweetness**: Similar to sucrose, with no bitter, metallic or aftertaste. Suitable for all food categories without additional masking agents.
2. **Low Calorie & Low GI**: Only 10% of the energy of sucrose; does not participate in blood glucose metabolism or stimulate insulin secretion, suitable for glycemic control, weight management and diabetic populations. GI value < 10.
3. **Excellent Processing Stability**: Heat-resistant (stable under long-term heating above 180 °C) and acid-alkali resistant (stable at pH 3.0–7.0), suitable for baking, high-temperature sterilization, acidic beverages and other processes.
4. **Strong Maillard Reaction Activity**: Efficiently undergoes caramelization and Maillard reactions, providing baked goods with golden color, rich caramel aroma and soft texture, superior to common sugar substitutes such as erythritol and steviol glycosides.
5. **Significant Texture Improvement**: Enhances moisture retention and anti-aging properties, extending the shelf life of pastries, sauces and other products; lowers the freezing point of frozen foods, reduces ice crystal formation and optimizes texture in ice cream, sorbet and similar products.
6. **Anti-cariogenic Property**: Not fermented by oral microorganisms such as *Streptococcus mutans* to produce acid, does not damage tooth enamel; can replace sucrose in anti-caries food development.
7. **Good Compatibility in Blends**: Can be combined with erythritol, steviol glycosides, mogrosides and other sugar substitutes to synergistically improve sweetness and taste, while reducing costs and side effects of single sweeteners.

(II) Product Applications

1. Core Value

Centered on **low calorie, glycemic control and high compatibility**, it replaces traditional sucrose and high-GI sweeteners to resolve the core conflict between “high sugar, high calorie” and “taste demand” in foods. With both processing adaptability and functional properties, it can be widely used in general foods, functional foods and some non-food fields, balancing flavor, health and process feasibility to match current health consumption trends (glycemic control, weight management, healthy diets).

2. Mechanism of Action

- **Sweetness Mechanism**: Similar molecular structure to sucrose; binds to sweet taste receptors on human taste buds to produce pure sweetness at 70% of sucrose intensity, with no unpleasant aftertaste and moderate sweetness threshold to meet sweetness needs of various foods.

- **Low-Calorie Mechanism**: Humans lack specific enzyme systems to break down D-allulose. Approximately 90% is not absorbed by the gastrointestinal tract and is excreted directly via urine through the kidneys; only about 10% is metabolized, giving an energy coefficient of only 1.67 kJ/g, much lower than sucrose (16.7 kJ/g).
- **Glycemic Control Mechanism**: Not regulated by insulin and does not participate in blood glucose synthesis or metabolism. Intake does not cause significant fluctuations in blood glucose or insulin levels, making it suitable for diabetics and glucose-sensitive individuals.
- **Processing Function Mechanism**: Stable at high temperatures and participates in Maillard and caramelization reactions to form desired color and flavor; hydrophilicity improves moisture retention and delays water loss; lowers freezing point in frozen systems to reduce ice crystal size and optimize texture.
- **Anti-cariogenic Mechanism**: Not fermented by oral bacteria to produce lactic acid and other acids, preventing enamel demineralization; inhibits growth of harmful oral bacteria and reduces caries risk.

3. Recommended Dosage Forms and Typical Products

Application Category	Recommended Dosage Form	Typical Products
Beverages	Powder, liquid (after dissolution)	Sugar-free carbonated drinks, zero-calorie juices, glycemic-control teas, sugar-free coffee, protein drinks, low-alcohol fruit wines
Baked Foods	Powder, crystalline granules	Sugar-free bread, glycemic-control cakes, low-calorie biscuits, sugar-free cookies, low-sugar mooncakes, Chinese pastries
Dairy & Frozen Foods	Powder, crystalline granules	Sugar-free yogurt, fermented milk, zero-calorie ice cream, low-sugar sorbet, low-fat cheese, sugar-free cream
Confectionery & Preserved Fruits	Powder, crystalline granules, syrup	Sugar-free hard candies, low-calorie gummies, sugar-free nougat, cocoa butter substitute chocolate, low-sugar preserved fruits, sugar-free jams
Condiments & Sauces	Powder, syrup	Low-sugar tomato sauce, sugar-free jam, zero-calorie salad dressing, low-fat barbecue sauce, sugar-free oyster sauce, compound seasonings
Functional Foods	Powder, granules, capsules (small addition)	Meal replacement bars, glycemic-control meal replacement powder, weight-loss foods, diabetic-specific foods, nutritional supplements
Non-Food Fields	Powder, liquid	Moisturizing creams, nourishing lotions, hair conditioners, enzyme fermentation media, pet feed

4. Application Schemes

Targeted application schemes are formulated based on D-allulose properties, processing requirements and product positioning across sectors, balancing taste, process and cost. Core schemes are as follows:

- **Beverage Application Scheme**
  - Single use: For juices and tea drinks at 3%–8% (based on finished product weight), directly replacing sucrose without flavor modifiers, maintaining refreshing taste and reducing calories by over 30%.
  - Blended use: Combined with erythritol (5%–10%) and steviol glycosides (0.05%–0.1%) for carbonated and functional drinks to improve sweetness coordination and reduce costs.
  - Processing notes: Dissolution at 40–60 °C with complete mixing; stable in acidic drinks (pH 3.0–4.0); no degradation after high-temperature sterilization (121 °C, 15 min).
- **Baked Food Application Scheme**
  - Single use: For bread and cakes at 5%–12% (based on flour weight), replacing 30%–50% sucrose. Maillard reaction improves color and aroma, enhances moisture retention, delays staling and extends shelf life by 2–3 days.
  - Blended use: Combined with erythritol (4%–8%) and maltitol (2%–5%) for biscuits and cookies to improve crispness and control calories.
  - Processing notes: Baking temperature ≤ 200 °C; mix evenly with flour and fats before dough preparation.
- **Dairy & Frozen Food Application Scheme**
  - Yogurt/fermented milk: 2%–6% (finished product weight), added after fermentation (below 40 °C) to avoid affecting probiotics, balancing acidity and improving smoothness.
  - Ice cream: Blended with erythritol (6%–10%) at 3%–8% (finished product weight), lowering freezing point, reducing ice crystals and solving hardness/shrinkage issues.
- **Confectionery & Preserved Fruit Application Scheme**
  - Hard candy/gummies: 5%–15% (finished product weight), blended with maltitol and isomaltulose to improve transparency, reduce hygroscopicity and extend shelf life.

- Preserved fruits: 3%–8% (finished product weight), added during pickling to retain moisture, protect color and reduce sucrose content.

- **Functional Food & Non-Food Application Scheme**
  - Meal replacement/nutrition bars: 3%–10% (total formula weight), blended with dietary fiber and protein powder to mask off-flavors and support glycemic/calorie control.
  - Cosmetics: 1%–3% (total formula weight) in creams and lotions for moisturization and skin feel improvement; in conditioners to reduce dryness.
  - Biological fermentation: 5%–15% as carbon source to promote microbial growth and fermentation efficiency without affecting product purity.

IV. Field Applications and Recommended Dosages

(I) Beverages (based on finished product weight)

1. **Carbonated / juice / tea drinks: 3%–8%**

● Function: Replaces sucrose, reduces calories; balances sweet-sour taste, enhances refreshment; no impact on flavor or color.

2. **Coffee / functional drinks: 2%–5%**

● Function: Masks bitterness and astringency, smooths taste; does not interfere with active ingredient stability.

3. **Protein drinks (soy milk / whey): 2%–6%**

● Function: Reduces beany/milky off-notes, enhances fullness.

4. **Alcoholic drinks (low-alcohol / fruit wine): 1%–4%**

● Function: Balances alcohol irritation, softens taste, lowers calories.

(II) Baked Foods (based on flour / total formula weight)

1. **Bread / cake / pastries: 5%–12%**

● Function: Color and aroma enhancement via Maillard reaction; improves softness and moisture retention, delays staling; calorie reduction >30%.

2. **Biscuits / cookies: 4%–10%**

● Function: Crisp texture, golden color, reduced sucrose usage.

3. **Mooncakes / Chinese pastries: 6%–15%**

- Function: Improves oil return and moisture retention, lowers sweetness and calories.

(III) Dairy & Frozen Foods (based on finished product weight)

1. **Yogurt / fermented milk: 2%–6%**

- Function: Balances acidity, improves smoothness, does not interfere with fermentation.

2. **Ice cream / sorbet / slush: 3%–8%**

- Function: Lowers freezing point, reduces ice crystals, creates creamy texture; blended with erythritol to solve shrinkage and hardness.

3. **Cheese / cream products: 2%–5%**

- Function: Softens flavor, improves texture, controls calories.

(IV) Confectionery & Preserved Fruits (based on finished product weight)

1. **Hard candy / gummies / nougat: 5%–15%**

- Function: Pure sweetness, low hygroscopicity, stable form; anti-cariogenic, low calorie.

2. **Chocolate / cocoa butter substitute products: 4%–10%**

- Function: Enhances sweetness and smoothness, does not affect crystallization.

3. **Preserved fruits: 3%–8%**

- Function: Assists moisture retention and color protection, reduces total sugar content.

(V) Condiments & Sauces (based on finished product weight)

1. **Tomato sauce / jam / salad dressing: 2%–8%**

- Function: Balances sweet-sour taste, inhibits dehydration and gassing, extends shelf life.

2. **Barbecue sauce / oyster sauce / compound seasoning: 1%–5%**

- Function: Boosts sweetness and umami, improves color and viscosity.

(VI) Other Food Fields

1. **Tabletop sweetener (powder/granule): added as needed (≤20 g/day)**

- Direct replacement for sucrose in coffee, tea and cooking.

2. **Nutrition bars / meal replacements / health foods: 3%–10%**

- Glycemic and calorie control, improved taste and texture.

3. **Pet food / feed: 2%–6%**

- Low calorie, anti-cariogenic, improves palatability.

(VII) Non-Food Applications

1. **Cosmetics: 1%–3%**

- Moisturizer and skin feel modifier for creams, lotions and hair conditioners.

2. **Biological Fermentation: 5%–15% as medium carbon source**

- For enzymes, probiotics and organic acid fermentation.

V. Usage Specifications and Precautions

1. **Daily Limit**: Adults ≤ 20 g/day, single dose ≤ 0.4 g/kg·bw to avoid gastrointestinal discomfort.
2. **Contraindicated Populations**: Infants, pregnant women, lactating women.
3. **Blending Recommendation**: Combine with erythritol, steviol glycosides and mogrosides to improve sweetness, texture and cost efficiency.
4. **Process Adaptation**: Baking temperature ≤ 200 °C; avoid ultra-high-temperature long-time sterilization for beverages.