Operation Guidelines for Addition Methods of Lactitol in Application Fields

Preface

This guideline aims to provide professional operational instructions on the application and processing technologies of **lactitol** for technicians, R&D engineers and production managers in downstream industries including food, pharmaceuticals and feed. As a safe sweetener, **lactitol** is also a multi-functional food ingredient with moisturizing, filling, prebiotic and other properties. A correct understanding of its characteristics and mastery of scientific addition methods are the keys to ensuring product quality, optimizing production costs and realizing technological innovation.

This guideline systematically elaborates the whole application process of **lactitol** from five dimensions: regulatory basis, physical property selection, scenario-based process key points, compounding strategies and risk control, striving to serve as a directly referential technical manual for your production practices.

Chapter 1 Cornerstone of Global Regulatory Compliance

The global safety of **lactitol** has been confirmed by **JECFA** (Joint FAO/WHO Expert Committee on Food Additives) with the specification of "**no ADI (Acceptable Daily Intake) limit required**", and it is used in most countries in accordance with **GMP (Good Manufacturing Practice)**. Nevertheless, regulatory differences across regional markets must be strictly distinguished in specific applications.

1.1 China (GB Standard System)

- Regulatory Basis: Compliant with **GB 1886.98 National Food Safety Standard – Food Additive: Lactitol**.
- Scope of Application: In accordance with **GB 2760 Standards for the Use of Food Additives**, **lactitol** is allowed for moderate addition as required by production (GMP principle) in various foods as a sweetener, stabilizer and humectant with no specific limit value.
- Label Warning: Per **GB 7718**, if the product contains a high content of **lactitol** (generally recommended for a single intake exceeding 20g), the warning statement **"Excessive consumption may cause diarrhea"** shall be labeled on packaging.

1.2 Codex Alimentarius Commission (CAC / Codex Alimentarius)

- **Regulatory Basis:** Assigned with **INS No. 966**. JECFA has formulated clear specifications for lactitol (e.g., FNP 52 Add 4).
- **Scope of Application:** Listed in Table 3 of **GSFA (General Standard for Food Additives)**, **lactitol** is permitted for GMP-based addition in multiple food categories such as syrups and condiments.
- **Core Reminder:** CAC standards serve as the benchmark for international trade. Export to developing countries adopting CAC regulatory frameworks shall generally

comply with this system.

1.3 European Union (EU Regulation)

- **Regulatory Basis:** EU Food Additive Regulation **(EC) No 1333/2008** and its annexes.
- **Scope of Application:** In food categories permitting sweetener use, **lactitol** is generally added following the **quantum satis** principle (moderate addition as required).
- **Special Provisions:** In the field of dietary supplements, the EU has clarified through regulations including **(EU) 2017/450** and **(EU) 2024/1023** that the maximum daily intake of **lactitol** in adult dietary supplements is limited to 20 grams. Meanwhile, the health claim of **"increasing defecation frequency to maintain normal intestinal function"** is permitted under specified conditions.

1.4 United States (FDA)

- **Regulatory Basis:** Recognized as a **GRAS (Generally Recognized As Safe)** substance.
- **Scope of Application:** Allowed for on-demand addition in various foods in compliance with GMP requirements.
- **Label Warning:** In accordance with **21 CFR 101.80**, if the daily intake under normal consumption conditions may exceed 50 grams (or other lower specific thresholds), the mandatory label statement **"Excess consumption may have a laxative effect"** is required.

Compliance Red Line: For export products, it is mandatory to verify specific food classification standards (e.g., EU sweetener directives, U.S. GRAS notice numbers) and labeling warning requirements in line with destination country regulations. It is prohibited to directly apply China's "on-demand addition" rule to all international markets.

Chapter 2 Scientific Selection: Characteristics and Application Orientation of Different Crystal Forms

The physical properties of **lactitol**, especially solubility, melting point and hygroscopicity, are closely correlated with its crystal water content. Selecting the appropriate crystal form based on processing demands is the first step for successful application.

1. Anhydrous Lactitol

- Physical Properties: Presented as anhydrous crystalline powder with a high melting point (approximately 146℃), extremely low hygroscopicity (stable at 20℃ and 80% relative humidity) and low heat of solution.
- Core Application Scenarios: Recommended for high-temperature processes (e.g., baking, hard candy boiling), products requiring strict moisture control (e.g., direct compression tablets, powder products) and scenarios with strict fluidity requirements.

2. Monohydrate / Dihydrate Lactitol

- Physical Properties: Presented as hydrated crystalline powder with a low melting point (approx. 95℃ for monohydrate and approx. 70℃ for dihydrate), low hygroscopicity and significant endothermic effect during dissolution to deliver a refreshing cooling taste.
- Core Application Scenarios: Suitable for conventional processing, especially products requiring a cooling mouthfeel such as chewing gum, cooling candies and ice cream; also widely applied in common confectionery and liquid formulations.

Selection Decision Tree

1. Does the product require high-temperature treatment (>120℃)?

- Yes → Priority selection: **Anhydrous Lactitol** (for baking, high-temperature confectionery, etc.).
- No → Proceed to the next step.

2. Does the product have strict requirements on fluidity and moisture control?

- Yes (e.g., direct compression tablets, powder products) → Priority selection: **Anhydrous Lactitol**.
- No → Proceed to the next step.

3. Does the product need a cooling taste?

- Yes (e.g., chewing gum, cooling candies, ice cream) → Priority selection: **Monohydrate / Dihydrate Lactitol**.
- No → Both forms are applicable, selected based on cost and solubility demands.

Chapter 3 Scenario-Based Processing Technologies and SOP Key Points

3.1 Sugar-Free Confectionery and Chocolate Products

3.1.1 Hard Candy

- **Function & Dosage:** Sucrose substitute and excipient; recommended addition ratio: **30%-50% of total dry matter**.
- **Processing Technology:**

1. **Addition Timing:**

   Added into the sugar dissolving tank together with other liquid raw materials such as alternative sweeteners, syrup and water at the initial stage of sugar melting.

2. **Operational Key Points:**

- Dissolution: Turn on stirring and heat to 85-95℃ to ensure complete dissolution. **Lactitol** features high solubility; slow feeding is recommended to avoid dust emission and caking and accelerate dissolution.
- Boiling: Filter the solution and transfer to the boiling pot. Leveraging its high glass transition temperature, the final vacuum boiling temperature can be set at 160-170℃. High-temperature boiling effectively removes residual moisture, prevents product sanding, and endows finished products with favorable gloss and brittleness.
- Cooling & Forming: Rapidly cool the boiled candy mass to an appropriate plastic temperature (generally 30-40℃ lower than the boiling endpoint temperature), followed by timely stripping, forming and cooling.

● **Notes:**

Strictly control vacuum degree and temperature curve during boiling to prevent caramelization. As **lactitol** does not participate in the Maillard reaction, finished products present a light color; permitted edible pigments can be added at this stage if specific coloration is required.

3.1.2 Soft Candy / Gel Candy

● **Function & Dosage:** Sweetener and humectant; recommended addition ratio: **20%-40%**.

● **Processing Technology:**

1. **Addition Timing:**

Added during mixing with liquid ingredients such as syrup after complete hydration and dissolution of colloids.

2. **Operational Key Points:**

- Dissolution & Mixing: Mix **lactitol** with partial water or syrup in a jacketed pot or sugar dissolving tank, heat to 75-85℃ under stirring until fully dissolved. Slowly pour the prepared lactitol solution into the colloid solution and stir evenly.
- Boiling: Conduct atmospheric or vacuum boiling of the mixed liquid; set the final temperature at 105-115℃ based on product moisture requirements. Its excellent moisturizing property maintains the soft texture of finished products.
- Depositing & Drying: Deposit the boiled liquid, cool for gel formation, and then transfer to the drying room. Its low hygroscopicity stabilizes the dehydration rate and shortens the drying cycle.

● **Notes:**

Ensure uniform mixing with colloid solution to avoid excessive local concentration that damages the gel structure; maintain stable humidity in the drying environment.

3.1.3 Compressed Candy

- **Function & Dosage:** Major filler and binder; addition ratio: **40%-90%**.
- **Processing Technology:**

1. **Addition Timing:**

   Put into the mixer together with all other powder raw materials in the total mixing process.

2. **Operational Key Points:**

- Direct Compression: **Anhydrous Lactitol** is the preferred option. Mix all powder materials (including lactitol, acidulant, flavor, pigment, magnesium stearate, etc.) in a three-dimensional mixer or V-type mixer for 20-30 minutes to achieve uniform mixing. Its ultra-low hygroscopicity and excellent fluidity are critical for successful direct compression. The particle size D50 is recommended to be controlled at 80-120μm.
- Wet Granulation: Adopt wet granulation if other ingredients in the formula have poor fluidity. Mix **lactitol** with active ingredients or other powders, prepare soft materials with its aqueous solution or ethanol aqueous solution as the binder, sieve for granulation, dry at 60-80℃, size the granules, and finally mix with external lubricants.

- **Notes:**

  Control production environmental humidity at **RH＜45%**. Test the fluidity (angle of repose) and compressibility of intermediates before tableting, and adjust tablet press pressure accordingly.

3.1.4 Chocolate

- **Function & Dosage:** Sweetener and filler; recommended addition ratio: **30%-50% of non-fat cocoa solids**.
- **Processing Technology:**

1. **Addition Timing:**

   Put into the refiner together with all dry raw materials such as cocoa mass, cocoa butter and milk powder at the initial refining stage.

2. **Operational Key Points:**

- Crystal Form Selection & Temperature Control: **Anhydrous Lactitol** withstands higher refining temperatures (70-80℃); for monohydrate lactitol, the refining temperature must be strictly controlled **≤60℃** to prevent precipitation of crystal water, sharp increase of material viscosity and impairment of refining and subsequent tempering effects.

- Refining: Conduct long-term refining (24-72 hours) at the set temperature to reduce particle size for a delicate mouthfeel (generally < 25μm). The non-reducing property of **lactitol** avoids Maillard reaction with milk protein, serving as a core advantage for maintaining the light color of dark chocolate and stable tone of milk chocolate.
- Tempering: Apply standard tempering procedures to refined chocolate slurry. The addition of **lactitol** barely affects the crystallization behavior of cocoa butter; the original tempering curve is applicable after verification via small-scale trials.

Notes:

Temperature control is the top priority when using hydrated lactitol. Monitor viscosity changes of materials during refining. Due to the low sweetness of **lactitol**, pre-mix evenly with high-intensity sweeteners (e.g., sucralose) before addition.

3.2 Baked Foods

3.2.1 Biscuits

Function & Dosage: Sweetener and texture modifier for partial sucrose replacement; recommended addition ratio: **3%-8% based on flour weight**.

Processing Technology:

1. **Addition Timing:**

   Added into the dough mixer together with dry raw materials such as flour and baking soda during dough preparation.

2. **Operational Key Points:**

   Pre-mix all dry powder ingredients (flour, lactitol, leavening agent, salt, etc.) for 1-2 minutes to ensure even distribution, then add wet raw materials including oil, eggs and water for dough kneading. Its low hygroscopicity preserves the crisp texture of biscuits during baking and storage.

Notes:

Limited Maillard reaction caused by **lactitol** results in light surface coloration. Adjustment solutions: a) Increase baking temperature or extend baking time (avoid coking); b) Add a small amount of high-fructose corn syrup or malt syrup; c) Supplement appropriate baking soda (sodium bicarbonate) to promote caramelization; d) Spray diluted syrup on the surface or use permitted edible pigments.

3.2.2 Cakes / Bread

- **Function & Dosage:** Humectant and softener; recommended addition ratio: **2%-5% based on flour weight**.
- **Processing Technology**:

1. **Addition Timing:**

   Added together with dry raw materials such as sucrose and flour at the initial stage of batter or dough stirring.

2. **Operational Key Points:**

   Whip **lactitol** with sucrose and oil during cake batter preparation; mix evenly with dry ingredients (flour, yeast, improver, etc.) before water addition for bread dough production. Its powerful moisturizing capacity locks moisture, delays starch retrogradation and effectively extends shelf life.

- **Notes:**

  The sweetness of **lactitol** is only 30%-40% of sucrose. For complete sucrose replacement, compound with high-intensity sweeteners (e.g., aspartame, sucralose) and ensure absolute uniform mixing in the dry powder pre-mixing stage. Adjust coloration following the same methods for biscuits.

3.3 Beverages, Dairy Products and Frozen Desserts

3.3.1 Flavored Beverages / Yogurt

- Function & Dosage: Sweetener, prebiotic and flavor carrier; recommended addition ratio: **0.5%-5%**.
- Processing Technology:

1. **Addition Timing:**

- Neutral or high-pH products: Dissolve in the sugar dissolving tank with other saccharides and stabilizers at the early batching stage.
- Low-pH products: For acidic beverages with pH < 3.5 (e.g., fruit juice drinks, lactic acid bacteria beverages), add in the post-blending stage or after sterilization and cooling to minimize potential hydrolysis under high-temperature acidic conditions.

2. **Operational Key Points:**

   Add treated water to the sugar dissolving tank, heat to 60-70℃, slowly add **lactitol** under stirring until completely dissolved to a clear state, then add other heat-resistant ingredients in sequence. Mix with the main liquid after dissolution and filtration.

- **Notes:** Strictly control dissolution temperature and time to avoid prolonged high-temperature boiling. Ensure sanitary conditions of pipelines and mixing equipment for post-addition in acidic products; conduct sterile filtration or short-term pasteurization for mixed liquid if necessary.

3.3.2 Ice Cream

- **Function & Dosage:** Anti-crystallizing agent and sweetener; recommended addition ratio: **2%-8% of total mixed materials**.
- **Processing Technology:**

1. **Addition Timing:**

   Dissolve together with other sweeteners, stabilizers and milk solids in the material preparation stage.

2. **Operational Key Points:**

   Mix dry powder raw materials including **lactitol**, granulated sugar and stabilizers evenly in the batching tank, sprinkle into liquid raw materials (water, milk, cream, etc.) at 40-50℃ under stirring for sufficient hydration and dissolution. Heat up to 70-75℃ for pasteurization, maintain the temperature for a specified duration, homogenize and rapidly cool to 4℃ for aging.

- **Notes:**

  Compound with monohydrate lactitol to enhance the cooling taste of finished products. Its excellent anti-crystallizing property refines ice cream structure, requiring compatible matching with ice cream stabilizer systems.

3.4 Pharmaceuticals and Feed

3.4.1 Oral Tablets / Granules

- **Function & Dosage:** Filler and corrigent; wide addition range: **5%-90%**.
- **Processing Technology:**

1. **Addition Timing:**

   Put into mixing equipment together with active pharmaceutical ingredients and other excipients in the total mixing process.

2. **Operational Key Points:**

- Direct Compression: Preferred processing method. Mix **anhydrous lactitol** (recommended D50: 80-120μm), active ingredients and auxiliary materials (disintegrant, lubricant, etc.) in the mixer to uniform content. Its superior fluidity and compressibility adapt to high-speed tableting production.
- Wet Granulation: Adopt wet granulation to improve the uniformity or mask the odor of active pharmaceutical ingredients. Mix **lactitol** with raw drugs, prepare soft materials with purified water or ethanol aqueous solution, sieve and granulate, dry at ≤80℃, size granules and conduct total mixing with external disintegrants and lubricants.

- Notes:

  Strictly control production humidity (RH < 45% recommended). Test content uniformity, moisture content and fluidity of intermediates before tableting. **Lactitol** presents favorable chemical inertness; verify its long-term stability with specific alkaline active ingredients through compatibility tests.

3.4.2 Functional Feed

- **Function & Dosage:** Phagostimulant; recommended addition ratio: **1%-3%**.
- **Processing Technology:**

1. Addition Timing:

   Add together with trace components such as vitamin and mineral premixes in the mixing process, or pre-mix with partial carriers (e.g., bran) in advance.

2. Operational Key Points:

   Adopt the **equal incremental method** or carrier pre-mixing method. Fully mix a small proportion (1-2%) of bulk raw materials (e.g., corn flour) with the required dosage of **lactitol** to prepare premixes, then add the premix into the main mixer and blend with remaining raw materials for uniform distribution.

- **Notes:**

  Avoid direct and long-term mixing with high-concentration and high-activity trace elements (e.g., copper sulfate, ferrous sulfate). Implement separate addition or adopt coated trace elements to prevent physicochemical reactions that affect product color and potency.

Chapter 4 Compound Synergy Scheme and Troubleshooting for Common Problems

4.1 Sweetness Synergy and Flavor Improvement

The relative sweetness of **lactitol** is equivalent to **30%-40% of sucrose**. Scientific compounding with high-intensity sweeteners is required to achieve the same sweetness as traditional products. Reference optimal compound ratios are as follows:

- **Lactitol + Sucralose**:

Compound 10% lactitol with 0.015% sucralose to reach the comprehensive sweetness equivalent to 10% sucrose solution.

- **Lactitol + Aspartame**:

Compound 10% lactitol with 0.03% aspartame to reach the comprehensive sweetness equivalent to 10% sucrose solution.

● **Lactitol + Rebaudioside A Stevioside**:

Compound 10% lactitol with 0.02% Reb A stevioside to reach the comprehensive sweetness equivalent to 10% sucrose solution.

Operational Suggestion: To ensure the uniform distribution of high-intensity sweeteners in finished products, follow the equal incremental principle: conduct small-proportion pre-mixing with a small amount of lactitol powder first, then gradually expand the mixing proportion with remaining raw materials.

4.2 Texture and Functional Synergy

● Compounding with Dietary Fiber:

Combination with water-soluble dietary fibers such as inulin and resistant dextrin synergistically enhances prebiotic effects to improve intestinal health and support nutritional claims of **"high fiber"** or **"prebiotic"** for products.

● Compounding with Other Sugar Alcohols:

Blending with a small amount of sorbitol (high hygroscopicity) precisely adjusts the overall hygroscopicity of product systems, widely applied in products requiring soft and tough texture such as the inner crumb of soft bread and pastries.

● Compounding with Hydrocolloids:

In gel confectionery, **lactitol** features good compatibility with hydrophilic colloids including gelatin, pectin and carrageenan, jointly forming a stable and elastic gel network structure.

Chapter 5 Red Lines for Quality and Risk Control

1. Excessive Intake Risk Control

- Risk Description: Low intestinal absorption rate of **lactitol** leads to gastrointestinal discomforts such as bloating, borborygmus and diarrhea caused by osmotic pressure when consumed in excess (generally more than 20g per adult single intake).
- Operational Specification: Clearly label the warning statement **"Excessive consumption may cause diarrhea"** or equivalent prompts on terminal product packaging in compliance with regulatory requirements. This requirement is particularly critical for candies, chocolates, beverages and other products with potential large single consumption volume.

2. Key Processing and Storage Prohibitions

- Maillard Reaction Characteristics: As a non-reducing sugar alcohol, **lactitol** does not participate in Maillard browning reactions. This property acts as a prominent advantage for color-protecting products (e.g., light-colored chocolate, cream products), while it becomes a disadvantage for baked goods relying on Maillard reaction for color and flavor formation (e.g., bread crust, barbecue sauce). Adjust final coloration by adding glucose syrup, malt syrup, baking soda or permitted edible pigments.
- Storage Conditions: Store raw materials in a cool, dry and ventilated warehouse away from direct sunlight. Although anhydrous lactitol has low hygroscopicity, hermetic sealing is mandatory after opening to prevent caking. Long-term storage of monohydrate/dihydrate lactitol under high temperature and high humidity may cause agglomeration; sieving treatment is recommended before use.

3. Compatibility Stability Precautions

- Avoid prolonged high-temperature treatment of lactitol-containing materials under strong acid (pH < 2) and strong oxidizing environments to prevent degradation.
- For special applications such as feed compounding with high-concentration mineral premixes, conduct short-term compatibility stability tests in advance to monitor potential physical and chemical changes.

Appendix 1 Quick Reference Table: Functional Attribute Comparison between Lactitol and Sucrose

Attribute	**Sucrose**	**Lactitol**
Relative Sweetness	1.0	0.3-0.4
Calorie (kcal/g)	4.0	2.0 (recognized by partial national regulations)
Glycemic Index (GI)	65	~2
Hygroscopicity	Moderate	Extremely low (anhydrous form)
Maillard Reaction	Occurs	Non-reactive
Solubility (20°C)	Highly soluble	Highly soluble
Prebiotic Effect	None	Available

Appendix 2 Quick Troubleshooting Table for Common Problems

- **Phenomenon: Abnormal viscosity increase of candy or chocolate slurry**
  - Possible Causes: 1. Excessively high refining/boiling temperature with monohydrate lactitol adopted; 2. Improper control of system moisture content.
  - Solutions: 1. Immediately lower processing temperature (≤60℃ recommended) or replace with anhydrous lactitol; 2. Inspect raw material moisture and production environmental humidity.
- **Phenomenon: Insufficient surface coloration and pale tone of baked products (bread, biscuits, etc.)**
  - Possible Causes: No Maillard reaction participation of **lactitol**, resulting in insufficient browning.
  - Solutions: Add appropriate saccharides supporting Maillard reaction (e.g., glucose syrup, malt syrup), adjust the dosage of leavening agents such as baking soda, or use compliant edible pigments (e.g., caramel color) for color modification.
- **Phenomenon: Insufficient tablet hardness, cracking or lamination**
  - Possible Causes: 1. Excessive moisture content of hydrated raw materials or over-humid tableting environment; 2. Unreasonable tableting pressure parameters or raw material particle size distribution.
  - Solutions: 1. Strictly control tableting workshop humidity (RH < 45% recommended) and prioritize anhydrous lactitol; 2. Optimize tablet press parameters and ensure lactitol raw materials meet the particle size requirements for direct compression (D50: 80-120μm recommended).
- **Phenomenon: Significant insufficient sweetness of finished products**
  - Possible Causes: Inadequate compounding with high-intensity sweeteners or uneven mixing.
  - Solutions: Add high-intensity sweeteners in accordance with the reference ratios in Chapter 4, and adopt pre-mixing procedures to realize uniform dispersion of sweeteners in materials.

Conclusion

As a multi-functional and high-safety food ingredient, **lactitol** presents continuously expanding application value. Successful industrial application relies on in-depth comprehension of raw material characteristics, precise control of processing key points and scientific formula design. All data and suggestions specified in this guideline are summarized from universal industrial experience. Strict small-scale and pilot-scale trials are indispensable before large-scale mass production, with targeted optimization adjusted according to enterprise-specific equipment and process parameters.

It is expected that this guideline can serve as a powerful tool for you to develop innovative products, improve product quality and control production costs.