Safety Assessment, Product Applications and Recommended Dosage of Polydextrose

Overview

Polydextrose is a water-soluble dietary fiber produced from glucose, sorbitol and citric acid through processes including high-temperature melt polymerization, refining and decolorization, ion exchange, concentration and drying. As a functional food ingredient with low calorie and low glycemic index, it possesses physiological functions such as regulating intestinal flora, promoting intestinal peristalsis, improving constipation, assisting in glycemic and lipid control, and enhancing satiety. It is a widely recognized food additive and dietary fiber fortification ingredient at home and abroad, listed in authoritative standards including GB 2760, FDA and EU food regulations. With high safety and good tolerance, it can be widely used in common foods, health foods, special dietary foods, infant foods and other fields.

1 Safety Assessment of Polydextrose

1.1 Conclusions of Toxicological Tests

1.1.1 Acute Toxicity

In accordance with GB 15193 *Procedures and Methods for Toxicological Assessment of Food Safety*, oral acute toxicity tests in mice and rats show that the oral maximum tolerated dose (MTD) of polydextrose is much higher than the conventional edible dose. No test animals died or showed toxic manifestations, and no abnormalities were observed in behavior, food intake, body weight or visceral organs. It is a practically non-toxic substance with no risk of acute poisoning from conventional intake.

1.1.2 Subchronic and Chronic Toxicity

90-day and long-term feeding tests in rats indicate that under high-dose intake conditions, no significant abnormalities are found in animal growth and development, blood routine, blood biochemistry or organ coefficients, with no organic visceral damage or cumulative toxicity. The no-observed-adverse-effect level (NOAEL) is much higher than the recommended human intake, and long-term consumption exerts no adverse effects on the liver, kidneys, intestines and other organs.

1.1.3 Genotoxicity and Carcinogenicity

Multiple genotoxicity tests including Ames test, chromosome aberration test and micronucleus test are all negative, showing no mutagenicity or chromosome damage. Long-term animal carcinogenicity tests reveal no increased tumor incidence, and there is no risk of carcinogenicity, mutagenicity or teratogenicity, meeting the safety requirements for food-grade raw materials.

1.1.4 Reproductive and Developmental Toxicity

Animal tests confirm that polydextrose at conventional doses has no adverse effects on the reproductive system, embryonic development or offspring growth, with no embryonic malformations, stillbirths or developmental retardation. It is safe for pregnant women and infants at recommended doses; only mild flatulence may occur at

high doses, with no irreversible damage.

1.2 Risk Substances and Limit Control

1.2.1 Purity and Impurity Control

The finished product shall control free glucose ≤4.0%, anhydrous sorbitol ≤2.0%, and 5-hydroxymethylfurfural (5-HMF) ≤0.1% to ensure stable polymerization degree, reduce gastrointestinal discomfort caused by hypertonic impurities, and improve tolerance.

1.2.2 Heavy Metals and Harmful Elements

It complies with the national food safety standard GB 2762, with lead ≤0.5mg/kg, arsenic ≤0.3mg/kg, mercury ≤0.1mg/kg, cadmium ≤0.2mg/kg, posing no risk of heavy metal contamination.

1.2.3 Microbiological Indicators

It meets the relevant requirements of GB 4789, with total aerobic bacterial count ≤10^3CFU/g, molds and yeasts ≤10^2CFU/g, and no detection of pathogenic bacteria such as *Salmonella* and *Staphylococcus aureus*, complying with food production hygiene specifications.

1.2.4 Sensitization and Irritation

Polydextrose is non-sensitizing and non-irritating to the gastrointestinal mucosa when taken orally, causing no allergic reactions. A very small number of people may experience intestinal adaptive reactions such as abdominal distension, increased flatus and loose stools when taking high doses initially, which can be quickly relieved with continuous consumption or dose reduction.

1.2.5 Risks for Special Populations

- Intestinally sensitive people: It is recommended to start with a low dose for initial consumption to avoid flatulence caused by a large single intake.
- Diabetic patients: It does not significantly increase blood glucose and can be used safely, but shall be included in total carbohydrate management.
- Infants: Infants over 6 months of age can be supplemented in accordance with standards with no safety risks.
- Pregnant and lactating women: Safe for use within recommended doses with no adverse effects.

1.3 Safety Conclusions of Authoritative Institutions

- China: Approved as a food additive (GB 2760) and nutritional fortifier, which can be used appropriately in various foods according to production needs and is permitted for use in infant formula foods.
- United States: Recognized as a Generally Recognized as Safe (GRAS) substance by FDA, with no strict upper limit for average daily intake, and widely used in low-sugar and low-calorie foods.
- European Union: Approved as a dietary fiber and food ingredient with no acceptable daily intake (ADI) limit, supporting health claims related to intestinal health and weight management.
- Japan: Listed in the *Japan's Specifications and Standards for Food Additives* (9th Edition), approved for use as a food additive and dietary fiber raw material, complying with the food safety standards of the

Consumer Affairs Agency of Japan. There is no strict limit on daily intake, allowing wide application in various foods. Its safety is recognized by the Food Safety Commission of Japan, adapting to the consumption demand of low-sugar and high-fiber foods in Japan.

2 Product Applications of Polydextrose

2.1 Health Food Industry

2.1.1 Core Value

As a high-quality water-soluble dietary fiber, it is used in health foods for intestinal health, auxiliary regulation of blood glucose and lipids, weight management and defecation promotion. It is natural, mild and non-dependent, suitable for long-term consumption.

2.1.2 Mechanism of Action

- Proliferates beneficial bacteria such as *Bifidobacterium*, regulates intestinal microecology, promotes intestinal peristalsis and improves functional constipation.
- Delays glucose absorption, reduces postprandial blood glucose fluctuations, decreases fat absorption, and assists in regulating blood lipids.
- Enhances satiety, reduces total energy intake, and supports weight control.
- Low in calories (approximately 1kcal/g) and non-cariogenic, suitable for people with glycemic and weight control needs.

2.1.3 Recommended Dosage Forms and Products

Pressed candy, hard capsules, dietary fiber powder, probiotic compound powder, laxative oral liquid, meal replacement milkshake, etc.; typical products: dietary fiber tablets, intestinal care powder, health foods for glycemic and lipid control.

2.1.4 Application Schemes

- Single-ingredient intestinal care: High-purity polydextrose made into powder/tablets for quantitative daily supplementation to improve constipation and maintain intestinal health.
- Compound fortification: Compounded with probiotics, resistant dextrin, inulin and collagen to enhance intestinal barrier and metabolic regulation functions.
- Weight and glycemic control formula: Combined with white kidney bean extract and L-arabinose to synergistically block sugar and fat absorption.

2.2 Common Food and Beverage Industry

2.2.1 Core Value

Improves the dietary fiber content of foods, realizes the upgrading of low-sugar, low-calorie and high-fiber properties, optimizes taste and texture without significantly affecting flavor, and adapts to industrial production.

2.2.2 Mechanism of Action

Good water solubility and strong stability, resistant to acid, heat and processing. It can replace part of sugar and fat,

improve product bulkiness, moisture retention and smooth taste, while endowing products with the health attribute of dietary fiber.

2.2.3 Recommended Product Types

- Beverages: Lactic acid bacteria drinks, carbonated drinks, fruit juices, dietary fiber water, solid beverages.
- Baked goods: Bread, cakes, biscuits, pastries.
- Candy and snacks: Sugar-free hard candies, gummies, chocolate, meal replacement bars, jelly.
- Dairy products: Yogurt, modified milk, milk drinks, ice cream.

2.3 Infant Formula and Special Dietary Foods

2.3.1 Core Value

As a compliant source of dietary fiber, it is used in infant formula foods, supplementary foods and formula foods for special medical purposes to promote intestinal development, reduce constipation, and meet national standard nutritional fortification requirements.

2.3.2 Applicable Products

Infant formula milk powder, supplementary food nutritional supplements, special medical foods for premature/low birth weight infants, complete nutritional formula powder.

2.4 Sugar-Free and Reduced-Sugar Food Sector

As an excellent sugar substitute filler, it is used in sugar-free and low-sugar foods to improve sweet taste, reduce calories, enhance product texture, and does not raise blood glucose, suitable for diabetic and glycemic control populations.

2.5 Meat Products and Condiments Sector

Improves water retention, tenderness and slicing properties of meat products; increases viscosity and stability in sauces and condiments, while boosting dietary fiber content.

3 Recommended Dosage by Field

Based on food-grade/health-grade polydextrose (purity ≥90%), high-purity products can be used directly on a mass basis.

3.1 Health Foods

- Dietary fiber tablets/capsules: 200–500mg per tablet/capsule, total daily intake 3–10g.
- Dietary fiber powder/solid beverages: 3–6g per sachet, 1–2 times daily.
- Defecation/intestinal care products: 5–12g recommended daily, taken in divided doses.
- Glycemic and lipid control products: 4–8g daily, taken with meals.

3.2 Common Foods and Beverages

- Liquid beverages: 0.5%–3.0%
- Solid beverages/meal replacement powder: 3.0%–10.0%
- Baked foods (biscuits, bread): 2.0%–5.0%

- Candy/jelly/chocolate: 3.0%–8.0%
- Yogurt/dairy products: 1.0%–4.0%
- Ice cream/frozen drinks: 2.0%–6.0%

3.3 Infant Formula and Supplementary Foods

- Infant formula foods: Added in accordance with GB 10765/10767, generally 0.5%–3.0%.
- Infant cereal supplementary foods, nutrition packets: 1.0%–5.0%.

3.4 Formula Foods for Special Medical Purposes

Complete nutritional formula powder, special medical foods: 2.0%–8.0%, adjusted according to product positioning and intestinal tolerance.

3.5 Meat Products and Condiments

- Meat products: 0.5%–2.0%
- Sauces/condiments: 1.0%–3.0%

4 Application Precautions and Quality Control

4.1 Raw Material Quality Standards

- Appearance: White or off-white powder, odorless, readily soluble in water.
- Purity: Polydextrose content ≥90%.
- Impurities: Free sugars, 5-HMF, heavy metals and microorganisms meet national standard requirements.
- Solubility: Good water solubility, clear and transparent solution with no precipitation.

4.2 Processing and Compatibility

- Heat-resistant and acid-resistant, suitable for high-temperature sterilization and acidic beverage systems with stable activity.
- Good compatibility with probiotics, vitamins and minerals, no antagonistic reactions.
- Control moisture when used at high concentrations to avoid moisture absorption and caking.

4.3 Consumption Recommendations

- It is recommended to gradually increase the dose from a small amount for initial consumption to help intestinal adaptation and reduce flatulence.
- Drink an appropriate amount of water during consumption to improve defecation effect.
- Cannot replace drugs in the treatment of intestinal diseases, diabetes, hyperlipidemia, etc.

4.4 Storage Conditions

Store sealed in a cool and dry place at temperature ≤25℃, protected from moisture and sunlight; unopened shelf life is 24 months, use as soon as possible after opening.

5 Summary

Polydextrose is a water-soluble dietary fiber with sufficient toxicological data and extremely high safety. It is non-toxic, non-sensitizing and non-carcinogenic/mutagenic, with good tolerance in special populations. Only mild intestinal adaptive reactions may occur at high initial doses. With clear physiological functions, it has multiple values including intestinal health promotion, metabolic regulation, glycemic and weight control, and food texture improvement. It can be widely used in health foods, common foods, infant foods, special dietary foods and other fields, serving as a core ingredient for the upgrading of low-sugar, low-calorie and high-fiber foods.

In practical applications, the dosage shall be controlled according to product type, population characteristics and consumption scenarios. Qualified raw materials with high purity, low impurities and qualified microorganisms shall be preferred, and production processes shall be standardized. Polydextrose is suitable for all age groups, conforms to the trend of modern healthy diet, and has broad application prospects in intestinal health, weight management, reduced-sugar foods and other segments.