Safety Assessment, Product Applications and Recommended Dosage of XOS

Overview

Xylo-oligosaccharides (XOS) are water-soluble functional oligosaccharides produced from raw materials including corn cobs, bagasse and xylan via endo-xylanase enzymatic hydrolysis, purification and drying. Not decomposed by human digestive enzymes, XOS can reach the hindgut directly to efficiently proliferate beneficial bacteria such as *Bifidobacterium*. It possesses multiple physiological functions including regulating intestinal microecology, improving constipation, reducing harmful intestinal substances, promoting mineral absorption, low calorie, non-cariogenicity, and assisting in regulating blood glucose and blood lipids.

XOS is listed in authoritative standards including GB 2760, GB 14880, FDA GRAS, EU food regulations, and the List of Food for Specified Health Uses (FOSHU) by the Ministry of Health, Labour and Welfare of Japan. With sufficient safety and good tolerance, it can be widely used in general foods, health foods, infant foods, special dietary foods and pet foods.

1 Safety Assessment of Xylo-oligosaccharides

1.1 Conclusions of Toxicological Studies

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 maximum tolerated dose (MTD) of XOS is much higher than the actual human intake level. No test animals died or showed toxic symptoms, and no abnormalities were observed in behavioral activity, food intake, body weight gain or organ morphology. XOS is classified as a practically non-toxic substance with no risk of acute poisoning under normal consumption.

1.1.2 Subchronic and Chronic Toxicity

90-day and long-term feeding studies in rats demonstrate that under high-dose administration, no significant changes occur in animal growth and development, blood routine, blood biochemical parameters or organ coefficients; no organic pathological changes or in vivo cumulative toxicity are observed. Its **NOAEL (No-Observed-Adverse-Effect Level)** is significantly higher than the recommended human intake. Long-term intake exerts no adverse effects on the liver, kidneys, intestines or metabolic system.

1.1.3 Genotoxicity and Carcinogenicity

Multiple genotoxicity tests including Ames test, in vitro mammalian cell chromosome aberration test and mouse bone marrow micronucleus test yield negative results, with no risk of mutagenicity or chromosomal damage. Long-term animal carcinogenicity studies show no increased tumor incidence. XOS is non-carcinogenic, non-teratogenic and non-mutagenic, fully meeting the safety requirements for food-grade raw materials.

1.1.4 Reproductive and Developmental Toxicity

Animal reproductive and developmental toxicity tests confirm that within the recommended dose range, XOS has no adverse effects on parental reproductive function, embryonic development or offspring growth and development, with no embryo malformation, fetal death or growth retardation. It is safe for pregnant women and infants at compliant doses. Only excessive intake may cause mild intestinal reactions such as flatulence and loose stools, with no irreversible tissue damage.

1.2 Hazardous Substances and Limit Control

1.2.1 Purity and Impurity Control

Finished products shall control the content of impurities such as reducing sugars and free monosaccharides to ensure stable active ingredients, reduce osmotic pressure fluctuations, lower the risk of gastrointestinal discomfort and improve tolerance in sensitive populations.

1.2.2 Heavy Metals and Harmful Elements

Compliant with GB 2762 National Food Safety Standard: Pb ≤ 0.5 mg/kg, As ≤ 0.3 mg/kg, Hg ≤ 0.1 mg/kg, Cd ≤ 0.2 mg/kg, with no risk of heavy metal contamination.

1.2.3 Microbiological Indicators

Compliant with relevant hygienic standards of GB 4789: aerobic plate count ≤ 10^3 CFU/g, molds and yeasts ≤ 10^2 CFU/g. Pathogenic bacteria including *Salmonella*, *Staphylococcus aureus* and *Shigella* shall not be detected, meeting GMP standards for food production.

1.2.4 Sensitization and Irritation

XOS is non-sensitizing and non-irritating to the gastrointestinal mucosa upon oral administration, and does not induce allergic reactions. A small number of intestinal-sensitive individuals may experience intestinal adaptive reactions such as abdominal distension, increased flatus and loose stools after initial high-dose intake, which can be rapidly relieved with continuous consumption or dose reduction.

1.2.5 Risks in Special Populations

- Intestinal-sensitive individuals: Start with a low dose for initial consumption to avoid flatulence caused by large single intake.
- Diabetic patients: Not absorbed or metabolized by the human body and does not significantly elevate blood glucose; safe for use and not counted as digestible carbohydrates.
- Infants: Can be added in accordance with national standards for infants over 6 months old, with good safety and benefits for intestinal flora establishment.
- Pregnant and lactating women: Safe for consumption within recommended doses with no adverse reproductive health risks.
- Individuals with irritable bowel syndrome (IBS): Adapt gradually from an extremely low dose to avoid abdominal discomfort induced by excessive intake.

1.3 Safety Conclusions from Authoritative Institutions

- China: Approved as a food additive, nutritional fortifier and novel food ingredient. GB 2760 permits appropriate use according to production needs, including infant formula foods and complementary foods.
- United States: Recognized as a GRAS (Generally Recognized as Safe) substance by FDA with no specified ADI limit, widely used in infant foods, functional beverages and baked goods.
- European Union: Approved as a food ingredient and dietary fiber source with no ADI limit, supporting health claims related to intestinal health and mineral absorption.
- Japan: Listed as an approved ingredient for Food for Specified Health Uses (トクホ, FOSHU) and authorized by the Ministry of Health, Labour and Welfare. Its safety has been evaluated and recognized by the Food Safety Commission of Japan, with wide application in yogurt, beverages and health foods.

2 Product Applications of Xylo-oligosaccharides

2.1 Health Food Industry

2.1.1 Core Value

As a highly efficient prebiotic, it is used in health foods for intestinal health, defecation promotion, intestinal flora regulation, calcium and iron absorption promotion, and auxiliary regulation of blood lipids and glucose. It is mild, safe and non-dependent, suitable for long-term consumption by all age groups.

2.1.2 Mechanism of Action

- Proliferates beneficial bacteria such as *Bifidobacterium* and *Lactobacillus* specifically at very low doses, inhibits harmful bacteria and maintains intestinal microecological balance.
- Promotes intestinal peristalsis, softens feces, improves functional constipation and reduces accumulation of intestinal toxins.
- Lowers intestinal pH, promotes absorption of minerals including calcium, magnesium and iron, and enhances bone health.
- Not involved in human glucose metabolism, extremely low in calories and non-cariogenic, suitable for glucose-controlled and weight-managed populations.

2.1.3 Recommended Dosage Forms and Products

Dietary fiber powder, probiotic complex powder, compressed tablets, oral liquid, meal replacement powder, and defecation-promoting health foods. Typical products: probiotic-prebiotic powder, intestinal care tablets, mineral absorption enhancers.

2.1.4 Application Schemes

- Single prebiotic: Powder formulated with high-purity XOS for daily low-dose supplementation to improve constipation and maintain intestinal health.
- Compound formulation: Combined with probiotics, resistant dextrin, inulin and stachyose to synergistically

enhance intestinal barrier function.

- Nutritional fortification: Combined with calcium citrate, ferrous bisglycinate and vitamin D to promote mineral absorption and utilization.

2.2 General Food and Beverage Industry

2.2.1 Core Value

Enhances dietary fiber and prebiotic content of products, achieves health upgrading of foods, improves flavor and texture. It features strong stability, does not mask the original taste of products, and is suitable for large-scale industrial production.

2.2.2 Mechanism of Action

Excellent water solubility, acid resistance, heat resistance and processing stability. It assists in improving sweetness and smoothness, endows products with intestinal health benefits and imposes no blood glucose burden.

2.2.3 Recommended Product Types

- Beverages: lactic acid bacteria drinks, yogurt drinks, fruit juices, dietary fiber water, sports drinks, solid beverages.
- Baked goods: bread, cakes, biscuits, meal replacement biscuits, pastries.
- Confectionery and snacks: sugar-free hard candies, soft candies, jelly, chocolate, meal replacement bars, milk tablets.
- Dairy products: yogurt, modified milk, milk drinks, ice cream, cheese.

2.3 Infant Formula and Special Dietary Foods

2.3.1 Core Value

As a prebiotic and dietary fiber source permitted by national standards, it is used in infant formula milk powder, complementary foods and foods for special medical purposes to promote intestinal flora establishment in infants, reduce constipation and meet nutritional fortification requirements.

2.3.2 Applicable Products

Infant formula milk powder, complementary food nutrient packages, rice flour, noodles, foods for special medical purposes for premature / low-birth-weight infants, and complete nutritional formula powders.

2.4 Sugar-Free and Reduced-Sugar Food Sector

2.4.1 Applicable products: As an important functional ingredient in sugar-free systems, used in sugar-free, low-sugar and glucose-controlled foods.

2.4.2 Functional performance: Improves sweetener systems and texture, does not raise blood glucose, is non-cariogenic, suitable for diabetics, weight-loss populations and oral health-sensitive individuals.

2.5 Pet Food and Feed Sector

2.5.1 Applicable products: As a dedicated prebiotic for pets, added to dog and cat staple food, treats and nutritional pastes.

2.5.2 Functional performance: Regulates pet intestinal flora, reduces diarrhea and constipation, improves nutrient absorption and enhances immunity.

3 Recommended Dosage by Application Field

Based on food-grade / health-grade XOS (purity ≥ 95%), high-purity products are added directly by mass percentage.

3.1 Health Foods

- Prebiotic / dietary fiber tablets / capsules: 100–300 mg per tablet / capsule, total daily intake 1–3 g.
- Solid beverages / probiotic powder: 0.5–2 g per sachet, 1–2 times daily.
- Defecation / intestinal care products: 1–3 g daily, taken in divided doses.
- Blood lipid regulation / mineral absorption promotion products: 0.8–2 g daily, taken with meals.

3.2 General Foods and Beverages

- Liquid beverages: 0.1%–0.5%
- Solid beverages / meal replacement powders: 0.5%–2.0%
- Baked goods (biscuits, bread): 0.3%–1.0%
- Confectionery / jelly / chocolate: 0.4%–1.5%
- Yogurt / dairy products: 0.2%–0.8%
- Ice cream / frozen desserts: 0.2%–1.0%

3.3 Infant Formula and Complementary Foods

- Infant formula foods: Added in accordance with GB 10765 and GB 10767, typically 0.1%–0.5%.
- Infant rice flour, complementary food nutrient packages: 0.2%–1.0%.

3.4 Foods for Special Medical Purposes

Complete nutritional formula powders, foods for special medical purposes: 0.3%–1.5%, adjusted according to intestinal tolerance of target populations.

3.5 Pet Food and Feed

- Pet staple food / treats: 0.1%–0.5%
- Pet nutritional supplements: 0.5%–2.0%

4 Application Precautions and Quality Control

4.1 Raw Material Quality Standards

- Appearance: White or off-white powder, odorless, with good solubility.
- Purity: XOS content ≥ 95%.
- Impurities: Residual monosaccharides, heavy metals and microorganisms comply with national standards.

- Solubility: Aqueous solution is clear and transparent, free of suspended solids and precipitates.

4.2 Processing and Compatibility

- Good heat resistance, suitable for high-temperature sterilization and baking processes with stable activity.
- Strong acid resistance, applicable to acidic beverages and fermented milk systems.
- Excellent compatibility with probiotics, vitamins, minerals, collagen and other ingredients, no antagonistic reactions.
- Certain hygroscopicity; control ambient humidity during use to prevent caking.

4.3 Consumption Recommendations

- Start with a low dose and gradually increase for initial consumption to facilitate intestinal adaptation and reduce flatulence.
- Take with an appropriate amount of water to enhance defecation effect.
- Not a substitute for drugs in the treatment of chronic diseases such as intestinal disorders, diabetes and hyperlipidemia.

4.4 Storage Conditions

Store sealed in a cool, dry place at temperature ≤ 25°C, protected from moisture, sunlight and odor. Unopened shelf life is 24 months; seal tightly after opening and use as soon as possible.

5 Summary

Xylo-oligosaccharides are highly efficient prebiotic dietary fibers with complete toxicological data and extremely high safety. They are non-toxic, non-sensitizing, non-carcinogenic and non-mutagenic, with good tolerance in special populations. Only excessive intake may cause transient intestinal adaptive reactions.

Its physiological functions are clear and definite, offering multiple values including regulating intestinal flora, improving constipation, promoting mineral absorption, assisting metabolic regulation and improving food texture. It can be widely used in health foods, general foods, infant foods, special dietary foods and pet foods, serving as a core ingredient for upgrading functional foods, reduced-sugar foods and intestinal health products.

In practical applications, dosage should be reasonably controlled according to product category, target population and consumption scenario. High-quality raw materials with high purity, low impurities and qualified microbiological indicators should be prioritized, and production and processing procedures should be standardized. With extremely low addition dosage and significant physiological efficacy, XOS is suitable for all age groups and aligns with modern consumption trends of intestinal health, glucose control and sugar reduction, natural nutrition. It boasts broad market application prospects in functional foods, infant foods and pet health foods.