Safety Assessment, Product Applications and Recommended Dosage of FOS

Overview

Fructo-oligosaccharides (FOS) are water-soluble dietary fibers and prebiotics synthesized from sucrose via catalysis of fructosyltransferase, or extracted and refined from plants such as Jerusalem artichoke and chicory. As functional oligosaccharides indigestible by human digestive enzymes, they exert multiple physiological functions including efficiently proliferating intestinal beneficial bacteria, regulating intestinal microflora, relieving constipation, promoting mineral absorption, assisting in regulating blood lipids and blood glucose, low calorie and non-cariogenicity.

Recognized globally as safe food ingredients, FOS are listed in authoritative standards including GB 2760, GB 14880, FDA GRAS, EU Food Regulations, and Food for Specified Health Use (FOSHU) by the Ministry of Health, Labour and Welfare of Japan. Featuring high safety and good tolerance, FOS can be widely used in ordinary food, health food, infant food, special dietary foods and pet food.

1 Safety Assessment of Fructo-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 FOS is much higher than the actual human intake level. No test animals died or showed toxic symptoms, and no abnormalities were observed in behavior, food intake, body weight gain or organ morphology. FOS are classified as practically non-toxic substances, with no risk of acute poisoning under normal consumption.

1.1.2 Subchronic and Chronic Toxicity

90-day and long-term feeding tests in rats indicate that under high-dose administration, no significant changes occur in animal growth, hematological parameters, blood biochemical indicators or organ coefficients; no organic lesions or cumulative toxicity in vivo are observed. The no-observed-adverse-effect level (NOAEL) is significantly higher than the recommended human intake, and 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 chromosome aberration test and mouse bone marrow micronucleus test are all negative, showing no mutagenicity or chromosome damage. Long-term animal carcinogenicity tests reveal no increased tumor incidence, and FOS have no carcinogenic, teratogenic or mutagenic effects, 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 FOS within the recommended dosage range have no adverse effects on parental reproductive function, embryonic development or offspring growth, with no embryo malformation, fetal death or growth retardation. Safe for pregnant women and infants at compliant dosages, only excessive intake may cause mild intestinal reactions such as flatulence and loose stools, without irreversible tissue damage.

1.2 Hazardous Substances and Limit Control

1.2.1 Purity and Impurity Control

The final product shall control residual monosaccharides (glucose + fructose) ≤ 5.0% and sucrose ≤ 8.0% to ensure stable active ingredient content, reduce osmotic pressure fluctuations caused by free sugars, lower the risk of gastrointestinal discomfort and improve human tolerance.

1.2.2 Heavy Metals and Harmful Elements

Comply with the national food safety standard GB 2762: 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

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

1.2.4 Sensitization and Irritation

FOS are non-sensitizing and non-irritating to the gastrointestinal mucosa upon oral administration, and do not induce allergic reactions. A small number of people with sensitive intestines may experience intestinal adaptive reactions such as abdominal distension, increased flatus and loose stools after initial high-dose intake, which can be quickly relieved by continuous consumption or dosage reduction.

1.2.5 Risks for Special Populations

- People with sensitive intestines: Start with a low dose for initial consumption to avoid flatulence caused by a large single intake.
- Diabetic patients: Not absorbed or metabolized by the human body, does not significantly raise blood glucose, safe for use and not required to be counted as digestible carbohydrates.
- Infants: Infants over 6 months of age can be supplemented in accordance with national standards, with good safety and benefits for intestinal flora establishment.
- Pregnant and lactating women: Safe for consumption within the recommended dosage, with no adverse reproductive health risks.
- People with irritable bowel syndrome (IBS): Gradual adaptation from an extremely low dose is recommended to avoid abdominal discomfort induced by excessive intake.

1.3 Safety Conclusions of Authoritative Institutions

- China: Approved as food additives, nutritional fortifiers and new food raw materials. GB 2760 allows appropriate use according to production needs, applicable to infant formula foods and supplementary foods.
- United States: Recognized as a GRAS (Generally Recognized as Safe) substance by FDA, with no explicit ADI limit, widely used in infant food, 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 a permitted ingredient for Food for Specified Health Use (FOSHU), approved by the Ministry of Health, Labour and Welfare. Its safety is evaluated and recognized by the Food Safety Commission of Japan, widely used in yogurt, beverages and health foods.

2 Product Applications of Fructo-oligosaccharides

2.1 Health Food Industry

2.1.1 Core Value

As highly effective prebiotics, FOS are used in health foods for intestinal health, defecation promotion, intestinal flora regulation, calcium and iron absorption promotion, and auxiliary regulation of blood lipids and blood glucose. Mild, safe and non-dependent, they are suitable for long-term consumption by people of all ages.

2.1.2 Mechanism of Action

- Specifically proliferate beneficial bacteria such as *Bifidobacterium* and *Lactobacillus*, inhibit harmful bacteria and maintain intestinal microecological balance.
- Promote intestinal peristalsis, soften feces, improve functional constipation and reduce intestinal toxin accumulation.
- Lower intestinal pH, promote absorption of minerals such as calcium, magnesium and iron, and enhance bone health.
- Reduce intestinal absorption of fat and cholesterol, assisting in regulating serum total cholesterol and triglycerides.
- Low calorie (approximately 1.5 kcal/g), non-cariogenic and does not raise blood glucose, suitable for people with blood glucose and weight control needs.

2.1.3 Recommended Dosage Forms and Products

Dietary fiber powder, probiotic complex powder, compressed tablets, soft capsules, oral liquids, meal replacement powder, and health foods for defecation promotion. Typical products: probiotic prebiotic powder, intestinal care tablets, mineral absorption enhancers.

2.1.4 Application Schemes

- Single prebiotic: High-purity FOS made into powder for quantitative daily supplementation to relieve constipation and maintain intestinal health.
- Compound formulation: Combined with probiotics, resistant dextrin, inulin and stachyose to synergistically improve intestinal barrier function.
- Nutritional fortification: Combined with calcium citrate, ferrous glycinate and vitamin D to promote mineral absorption and utilization.

2.2 Ordinary Food and Beverage Industry

2.2.1 Core Value

Enhance dietary fiber and prebiotic content of products, realize the health upgrading of food, improve flavor and taste. Featuring strong stability without masking the original taste, FOS are suitable for large-scale industrial production.

2.2.2 Mechanism of Action

Excellent water solubility, acid resistance, heat resistance and processing resistance. Can partially replace sucrose, improve sweetness and smoothness of products, endow products with intestinal health properties without increasing blood glucose burden.

2.2.3 Recommended Product Categories

- 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, gummies, jellies, 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 prebiotics and dietary fiber sources permitted by national standards, FOS are used in infant formula milk powder, supplementary 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, supplementary 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 foods, low-sugar foods and blood glucose-controlled foods.

2.4.2 Functional Performance

Improve the sweetener system and taste, do not raise blood glucose or cause dental caries, suitable for diabetic patients, weight-loss populations and people sensitive to oral health.

2.5 Pet Food and Feed Sector

2.5.1 Applicable Products

As special prebiotics for pets, added to dog and cat staple food, snacks and nutrition creams.

2.5.2 Functional Performance

Regulate pet intestinal flora, reduce diarrhea and constipation, improve nutrient absorption and enhance immunity.

3 Recommended Dosage by Field

Based on food-grade / health-grade FOS (purity ≥ 90%), high-purity products are directly added by mass percentage.

3.1 Health Food

- Prebiotic / dietary fiber tablets / capsules: 200–500 mg per tablet / capsule, total daily intake 3–10 g.
- Solid beverages / probiotic powder: 2–5 g per sachet, 1–2 times daily.
- Defecation / intestinal care products: 5–10 g recommended daily, taken in divided doses.
- Blood lipid regulation / mineral absorption promotion products: 3–8 g daily, taken with meals.

3.2 Ordinary Food and Beverages

- Liquid beverages: 0.5%–3.0%
- Solid beverages / meal replacement powder: 3.0%–10.0%
- Baked goods (biscuits, bread): 1.5%–5.0%
- Confectionery / jelly / chocolate: 2.0%–7.0%
- Yogurt / dairy products: 0.8%–4.0%
- Ice cream / frozen drinks: 1.5%–5.0%

3.3 Infant Formula and Supplementary Foods

- Infant formula foods: Added in accordance with GB 10765 and GB 10767, generally 0.5%–2.5%.
- Infant rice flour, supplementary food nutrient packages: 1.0%–4.0%.

3.4 Foods for Special Medical Purposes

Complete nutritional formula powders, foods for special medical purposes: 1.5%–7.0%, adjusted according to intestinal tolerance of the population.

3.5 Pet Food and Feed

- Pet staple food / snacks: 0.5%–3.0%
- Pet nutritional supplements: 2.0%–6.0%

4 Application Notes and Quality Control

4.1 Raw Material Quality Standards

- Appearance: White or off-white powder, odorless, with good solubility.
- Purity: FOS content ≥ 90%.
- Impurities: Residual monosaccharides, sucrose, heavy metals and microorganisms meet national standard requirements.
- Solubility: Aqueous solution is clear and transparent, without suspended solids or precipitates.

4.2 Processing and Compatibility

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

4.3 Consumption Recommendations

- Gradually increase the dose from a low level for initial consumption to help intestinal adaptation and reduce flatulence.
- Take with an appropriate amount of water to enhance the defecation effect.
- Cannot replace medicines for the treatment of chronic diseases such as intestinal diseases, diabetes and hyperlipidemia.

4.4 Storage Conditions

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

5. Summary

Fructo-oligosaccharides are water-soluble 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.

With clear and definite physiological functions, FOS possess multiple values including regulating intestinal flora, relieving constipation, promoting mineral absorption, assisting metabolic regulation and improving food texture. They can be widely used in health food, ordinary food, infant food, special dietary foods and pet food, serving as core ingredients for the upgrading of functional foods, reduced-sugar foods and intestinal health products.

In practical applications, the 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. Suitable for people of all ages, FOS conform to modern consumption trends of intestinal health, blood glucose and sugar control, and natural nutrition, boasting broad market application prospects in functional foods, infant foods and pet health foods.