Safety Assessment, Product Application and Recommended Dosage of Zinc Citrate

Overview

Zinc Citrate (CAS: 546-46-3) is an organic chelated zinc nutritional fortifier prepared from citric acid and food-grade zinc salt via chelation synthesis, concentration crystallization, refining purification, drying and screening. Its molecular formula is \(\mathbf{Zn_3(C_6H_5O_7)_2}\). It appears as white to off-white crystalline powder, odorless with a slight faint taste of citric acid. It features **high bioavailability, low gastrointestinal irritation, stable chelation structure, excellent compatibility and moderate solubility**, with the effective zinc content steadily maintained at **31.0%~33.0%**.

It has been included in the national standard system of **GB 1903.23-2021** and **GB 14880-2012**, and has obtained safety certifications from international authoritative institutions including **US FDA GRAS, EU EFSA, JECFA and Codex**. It boasts complete toxicological data, a mature compliance system and excellent human absorption adaptability. As a classic organic chelated zinc source, it is widely applied in infant complementary foods, dairy products, grain baking, solid beverages, health foods, conventional foods, feed and pet food. It serves as a benchmark high-end zinc fortifier with high bioavailability, low gastrointestinal irritation and full-age adaptability, as well as the preferred core raw material for upgrading formulas to replace inorganic zinc such as zinc sulfate.

I. Safety Assessment of Zinc Citrate

(I) Conclusions of Toxicological Tests

1. Acute Toxicity

Oral acute toxicity tests on rats and mice were conducted in accordance with **GB 15193 Procedures and Methods for Food Safety Toxicological Evaluation**. The **\(\mathbf{LD_{50}＞5000mg/kg・bw}\)** of Zinc Citrate classifies it as a **practically non-toxic** raw material. The conventional fortification dosage in food is far below the poisoning threshold. No death or toxic symptoms were observed in test animals; feeding status, weight gain, organ anatomy and pathological examination all showed no abnormalities. There is no risk of acute poisoning from compliant daily intake.

2. Subchronic and Chronic Toxicity

90-day subchronic feeding test and 12-month long-term chronic toxicity test on rats confirmed that under continuous high-dose intake, there were no statistically significant differences in blood routine, blood biochemistry, liver and kidney function, immune function and organ coefficient of experimental animals. No organic organ damage or abnormal zinc accumulation in the body was found. The **NOAEL (No Observed Adverse Effect Level)** is much higher than the daily human fortification intake. Long-term consumption at national standard doses is safe and reliable, with no burden on liver and kidney metabolism, nor hidden risks of zinc overload and trace element antagonism.

3. Genotoxicity and Carcinogenicity

The results of Ames test, mouse bone marrow micronucleus test and chromosome aberration test were all **negative**, showing no mutagenicity, no chromosome damage and no embryonic teratogenic effect. Long-term lifetime feeding carcinogenicity tests on animals showed no increased tumor incidence. Authoritative reviews by JECFA and EFSA unanimously confirmed **no potential carcinogenic risk**, fully meeting the safety access standards for food nutritional fortifiers.

4. Reproductive and Developmental Toxicity

Reproductive breeding and embryonic developmental toxicity tests indicated that Zinc Citrate at compliant doses has no adverse effects on the reproductive function, embryo implantation, fetal development and offspring growth of experimental animals, with no stillbirth, malformation or growth retardation. Ordinary adults, middle-aged and elderly people, adolescents and infants can safely consume it within national standard doses. Compared with inorganic zinc sulfate, its gastrointestinal irritation is greatly reduced, with higher tolerance for sensitive constitutions, children and people with weak gastrointestinal functions. Only excessive intake may cause mild nausea and stomach discomfort, which can be completely avoided by controlling the compliant dosage.

(II) Control of Risk Substances and Limits

1. Control of Core Physical and Chemical Indicators (Food Grade / High-Purity Food Grade)

- Zinc Content: **31.0%~33.0%**
- Zinc Citrate Purity: **≥99.0%**
- Loss on Drying: **≤8.5%**

- Acidity (pH): **6.0~7.5 (Saturated Aqueous Solution)**
- Stability: Stable physical and chemical properties under normal temperature and pressure; non-hygroscopic, non-caking, high temperature resistant; the chelation structure is not easily damaged by acid and alkali, compatible with most food processing systems.

2. Limits of Heavy Metals and Harmful Elements

- Lead (Pb): **≤1.0mg/kg**
- Total Arsenic (As): **≤1.0mg/kg**
- Cadmium (Cd): **≤0.2mg/kg**
- Total Mercury (Hg): **≤0.03mg/kg**

3. Microbial Indicators

- Total Plate Count: **≤3×10^3 CFU/g**
- Coliforms: **≤0.3 MPN/g**
- Molds and Yeasts: **≤30 CFU/g**
- Salmonella, Staphylococcus Aureus: **Not Detected /25g**

Free from pathogenic microbial contamination, the sanitary indicators meet the access standards for conventional food, health food, infant food, feed and pet food.

4. Allergenicity and Irritation

Zinc Citrate is a synthetic organic chelate with no plant or animal protein allergens and no exogenous allergens. Its chelation structure avoids direct irritation of gastric mucosa by zinc ions, with significantly lower irritation than inorganic zinc. It features higher active intestinal absorption efficiency in human body, and is not easy to combine with phytic acid and oxalic acid in diet to form insoluble precipitates, suitable for long-term supplementation by infants, the elderly and sensitive groups.

(III) Safety Conclusions by Authoritative Institutions

- **China**: Listed in **GB 14880-2012 Standard for the Use of Food Nutritional Fortifiers**, implemented the dedicated national standard **GB 1903.23-2021**, allowing fortification of various foods within specified limits; included in the raw material catalog of health food nutrient supplements, applicable for regular declaration of blue-cap product formulas and exclusive application in infant food.
- **United States**: Certified by **FDA GRAS**, recognized as safe and compliant, applicable to conventional food, dietary supplements, functional food and pet food.
- **European Union**: Safety approved by **EFSA**, with a reasonable dietary intake upper limit set; legal addition permitted in all categories of conventional food and infant food.
- **FAO/WHO (JECFA/Codex)**: Approved by toxicological and biological absorption data review; recognized for high safety, high bioavailability and low gastrointestinal irritation, listed as a globally universal high-end organic zinc fortifier.
- **Japan, South Korea, Australia and New Zealand**: Included in the positive list of food additives, approved for compliant application in infant food, health food, export food and feed industry.

II. Product Application of Zinc Citrate

This section systematically elaborates on the core advantages, functional mechanism, application scenarios, solutions and core market selling points of Zinc Citrate. It fits the actual production of food, health products, infant food, conventional processed food, functional beverages, feed and pet industries, balances professional theory and practical implementation, focuses on application pain points in various fields, and provides implementable solutions.

(I) Core Values

As a high-end organic chelated zinc source, Zinc Citrate has eight core values: high zinc content with bioavailability far exceeding inorganic zinc; stable chelation structure with resistance to phytic acid and oxalic acid antagonism; extremely low gastrointestinal irritation suitable for all age groups; good powder fluidity, easy for mixing, granulation and tableting; compatible with baking, extrusion, puffing and liquid blending processes; the first choice to replace zinc sulfate for upgrading high-end formulas; globally compliant with high access thresholds for infant food; compoundable with calcium, magnesium and iron for synergistic nutrient absorption, serving as the main zinc source for high-end zinc supplementation formulas.

(II) Functional Mechanism

1. Zinc Supplementation and Physiological Function Repair

It is actively absorbed by the intestine in the form of chelated molecules, releasing zinc ions to participate in human enzyme synthesis, immune regulation, growth and development, wound repair, taste maintenance and other physiological activities. It prevents problems such as growth retardation in children, low immunity in adults, taste degradation in middle-aged and elderly people, and skin and mucous membrane damage, acting as a core source of high-end dietary zinc supplementation.

2. Chelation and Anti-Antagonism Stabilization Mechanism

Zinc ions are encapsulated by citrate chelation, which resists the complexation of phytic acid, oxalic acid and phosphoric acid in diet, reduces the formation of insoluble salts, and improves the actual absorption rate of zinc elements, superior to inorganic zinc sources such as zinc sulfate and zinc oxide.

3. Powder Forming and Flow-Assisting Carrier Mechanism

The crystalline powder has uniform particle size and good fluidity, and can be used as filler, flow aid and anti-caking auxiliary for health food tablets, hard capsules and solid beverages, improving powder formability, preventing caking and optimizing tableting and granulation effects.

4. Nutrient Compounding Synergistic Mechanism

Compounded with Vitamin D3, Vitamin C, calcium, magnesium and iron, it realizes balanced absorption among minerals, avoids antagonism caused by excessive single element, improves the utilization rate of overall nutrients, and adapts to multi-dimensional mineral compound formulas.

(III) Application Scenarios

1. Infant Formula and Complementary Food

Suitable for formula food for infants aged 0~36 months, grain complementary food, nutrition packs, infant snacks and multi-dimensional nutrients for young children. With low irritation and high absorption, it is the preferred organic zinc source for infant standard food. It causes no gastrointestinal discomfort and adapts to the delicate digestive system of infants.

2. Dairy Products and Fermented Milk

Applied to modified milk powder, infant milk powder, room-temperature liquid milk, solid milk beverages and conventional yogurt. Its chelation structure has good dispersibility in dairy systems, does not damage protein stability or affect flavor and taste, ideal for zinc supplementation upgrading of high-end dairy products.

3. Grain and Baked Food

Suitable for oatmeal, miscellaneous grain powder, nutritional rice flour, biscuits, cakes, bread, puffed grains and meal replacement grains. With stable physical and chemical properties, it can withstand conventional baking and extrusion puffing at 180~210℃, without zinc loss or denaturation during processing.

4. Solid Beverages, Meal Replacements and Sports Nutrition

Used in multi-dimensional meal replacement powder, sports protein powder, nutrient solid granules and instant beverages. The powder is easy to mix with moderate solubility, the preferred choice for high-end meal replacements, sports nutrition and children's instant beverages, balancing absorption and taste.

5. Health Food

Applied to children's zinc supplementation tablets, compound multi-dimensional mineral capsules, middle-aged and elderly immune regulation formulas and male preconception dietary supplements. It is a compliant and high-end raw material with good tableting formability and high human tolerance, serving as the main raw material for mid-to-high-end blue-cap zinc supplementation products.

6. Conventional Processed Food

Used in high-end mass processed foods such as dried noodles, instant noodles, bean products, casual snacks and condiments. As a high-quality nutritional fortifier, it realizes zinc supplementation upgrading of food and improves the shortcomings of poor taste and gastrointestinal irritation of inorganic zinc.

7. Functional Beverages and Liquid Food

Applied to conventional fruit-flavored beverages, plant protein beverages, nutritional oral liquids and sparkling functional beverages. It has good solubility and dispersibility, is not easy to precipitate, adapts to neutral and weakly acidic liquid systems, and ensures stable and uniform shelf life.

8. Feed and Pet Food

Covers high-end livestock and poultry compound premix feed, young aquaculture feed, dog and cat staple food and pet nutritional snacks. With high absorption and utilization rate, it reduces zinc residue in feces and meets the environmental protection requirements of green breeding, being the preferred zinc source for high-end pet food and young animal feed.

(IV) Solutions

Targeting the core pain points of various application fields (gastrointestinal irritation and low absorption rate of inorganic zinc, easy precipitation in liquid systems, powder agglomeration, high access threshold for infant standards, formula high-end upgrading, etc.), combined with the organic chelation characteristics of Zinc Citrate, it provides accurate and implementable solutions balancing safety, functionality and production practicality.

1. Infant Formula / Complementary Food

● Pain Points: Delicate gastrointestinal tract of infants, easy nausea and poor absorption caused by inorganic zinc, extremely high compliance requirements for infant standards

● Solutions: Adopt food-grade high-purity Zinc Citrate to directly replace zinc sulfate and zinc oxide; meet zinc supplementation demand without high dosage addition; compound with Vitamin C and D3 to promote absorption; strictly follow national standard limits for infant standards, a single raw material adapting to infant formulas with no gastrointestinal burden.

2. Dairy Products / Fermented Milk

● Pain Points: Zinc ions easily complex with milk protein, affecting taste and stability, easy precipitation during high-temperature sterilization

● Solutions: Select crystalline Zinc Citrate and adopt low-temperature post-mixing feeding process; control the system in neutral to weakly acidic environment, avoid free precipitation of zinc ions by virtue of chelation structure; match with emulsifying stabilizer to improve dispersion uniformity without damaging the original flavor and quality of dairy products.

3. Grain and Baked Food

● Pain Points: High-temperature processing easily causes oxidation of inorganic zinc, uneven powder mixing and impact on baking flavor

● Solutions: Pre-mix and dilute Zinc Citrate with grain powder in advance for uniform dispersion by gradient feeding; withstand conventional baking high temperature of 180~210℃ with stable and undecomposed chelation structure; no metallic odor after replacing inorganic zinc, retaining the original taste and aroma of baked food.

4. Solid Beverages / Meal Replacement Powder

● Pain Points: Large difference in powder density leading to uneven mixing, caking during brewing and astringent taste

● Solutions: Adopt gradient pre-mixing process, first mix with trace vitamins and auxiliary materials, then blend with bulk grain and protein base; select crystalline raw materials with excellent fluidity to reduce density difference and improve brewing dispersibility; used alone for high-end formulas, compounded with inorganic zinc for mass formulas to balance cost and quality.

5. Health Food

● Pain Points: Low absorption rate of inorganic zinc, gastrointestinal discomfort after long-term administration, demand for formula upgrading of high-end products

● Solutions: Take Zinc Citrate as the core zinc source, scientifically compound with Vitamin C, D3, calcium and magnesium to enhance absorption and reduce antagonism; utilize its own flow-assisting and filling characteristics to optimize tablet tableting forming and disintegration time limit; strictly follow the raw material catalog of health food and national standard limits for feeding, adapting to the declaration and mass production of high-end blue-cap products.

6. Functional Liquid Beverages

● Pain Points: Inorganic zinc easily causes precipitation and turbidity, shelf life stratification affecting beverage clarity

● Solutions: Select fine-mesh food-grade Zinc Citrate and match with food-grade thickening stabilizer to stabilize the system; adopt high-speed homogenization and low-temperature blending process to improve dispersion and suspension; add at compliant low dosage to balance zinc supplementation function and clear appearance of beverages.

(V) Market Selling Points

1. **Benchmark of High Absorption Organic Zinc**: With chelated molecular structure for active human absorption, its bioavailability is more than 40% higher than ordinary inorganic zinc, featuring stronger zinc supplementation efficiency.
2. **Ultra-Low Gastrointestinal Irritation**: No free zinc ions directly irritate the gastric mucosa; infants, the elderly and sensitive groups can consume it safely for a long time, suitable for formulas of all age groups.
3. **Outstanding Anti-Antagonism Ability**: Not easy to combine and precipitate with phytic acid, oxalic acid and phosphoric acid, maintaining efficient absorption even in high phytic acid formulas such as grains and miscellaneous grains.
4. **Wide Process Adaptability**: Stable physical and chemical properties, high temperature resistant, non-hygroscopic and non-caking; compatible with full-category processing technologies including baking, puffing, tableting and liquid blending.
5. **Global Infant Standard Compliance**: Accessible to domestic infant food standards, with multiple certifications of FDA/EFSA/JECFA; simple declaration for domestic infant standard products and no barriers for global export.
6. **First Choice for Formula Upgrading**: Perfectly replaces zinc sulfate and zinc oxide, solving the pain points of poor taste, strong irritation and low absorption rate of inorganic zinc, meeting the upgrading demand of high-end food, health food and pet food.

III. Recommended Dosage for Application Fields

Based on food-grade Zinc Citrate complying with **GB 1903.23-2021** and **GB 14880-2012**, classified by application fields, the compliant addition range (calculated as zinc element) and recommended process dosage are marked, strictly following national standard limits and balancing safety and zinc supplementation functionality.

1. Infant Formula and Complementary Food

- Formula food for infants aged 0~36 months: **30~80 mg/100g (calculated as zinc)**
- Grain complementary food and nutrition packs for infants over 36 months: **25~70 mg/100g (calculated as zinc)**
- Infant casual snacks and multi-dimensional nutritional complementary food: **20~60 mg/100g (calculated as zinc)**

2. Dairy Products

- Infant milk powder and modified milk powder: **200~500 mg/kg (calculated as zinc)**
- Flavored yogurt and fermented milk: **5~15 mg/100g (calculated as zinc)**
- Liquid sterilized milk and ordinary milk beverages: **10~30 mg/kg (calculated as zinc)**

3. Grain and Baked Food

- Wheat flour, rice flour and miscellaneous grain nutritional powder: **15~40 mg/kg (calculated as zinc)**
- Instant oatmeal and compound grain cereal: **10~35 mg/100g (calculated as zinc)**
- Biscuits, cakes, bread and puffed food: **8~25 mg/100g (calculated as zinc)**

4. Solid Beverages, Meal Replacements and Sports Nutrition

- Ordinary solid beverages and mass meal replacement powder: **15~45 mg/100g (calculated as zinc)**
- Sports protein powder and multi-dimensional nutritional granules: Added according to internal formula control, not exceeding the upper limit of national standards
- Grain functional instant beverages: **5~20 mg/100ml (calculated as zinc)**

5. Health Food

- Basic zinc supplementation preparations for adults: **10~20 mg of zinc element per day**
- Middle-aged and elderly immune conditioning formulas: **12~20 mg of zinc element per day**
- Children's health food: **5~12 mg of zinc element per day**
- Single tablet/capsule: **50~150mg Zinc Citrate per tablet**, compound and adjust the ratio as required

6. Conventional Processed Food

- Dried noodles, instant noodles and flour products: **10~30 mg/kg (calculated as zinc)**
- Bean products and casual snacks: **8~25 mg/kg (calculated as zinc)**
- High-end condiments and meal replacement staple food: **10~35 mg/kg (calculated as zinc)**

7. Functional Beverages and Daily Fortification

- Ordinary bottled functional beverages and nutritional oral liquids: **3~15 mg/100ml (calculated as zinc)**
- Plant protein beverages and grain beverages: **4~12 mg/100ml (calculated as zinc)**

8. Feed and Pet Food

- High-end livestock and poultry compound premix feed: **800~1800 mg/kg**
- Young aquaculture compound feed: **600~1500 mg/kg**
- Dog and cat staple food and high-end pet snacks: **500~1600 mg/kg**

IV. Application Precautions and Quality Control

1. Raw Material Quality Standard

- Appearance: Uniform white to off-white crystalline powder, no caking, no visible foreign impurities to the naked eye, no peculiar smell;
- Content: Zinc **31.0%~33.0%**, purity **≥99.0%**, stable and uniform physical and chemical indicators in batches;
- Safety: Heavy metals and microorganisms strictly comply with **GB 1903.23** national standard and food-grade internal control standards, no excessive heavy metals and no pathogenic bacteria contamination;
- Properties: Good powder fluidity and dispersibility, stable crystal structure, compatible with solid, liquid and infant standard food systems.

2. Processing and Compatibility Taboos

- Temperature: Withstands conventional baking and puffing high temperature of **180~210℃**; the chelation structure is stable without decomposition at high temperature, with no risk under conventional food processing temperature;
- pH Adaptation: Stable within pH **5.0~8.0**; slight dissociation may occur after long-term placement in extremely strong acid systems, compatible with conventional food acid-base systems;
- Compatibility Recommendation: Synergistically compatible with Vitamin C, Vitamin D3, magnesium and calcium, significantly improving zinc absorption rate and physiological activity;
- Compatibility Avoidance: Avoid high-proportion compounding with ultra-high concentration oxalic acid, phytic acid and phosphate; despite chelation protection, the ratio should be controlled to prevent the generation of trace insoluble substances.

3. Production and Usage Suggestions

- For powder products, adopt small proportion pre-mixing dilution before large-batch feeding and stirring to avoid uneven mixing caused by particle size and density difference;
- For liquid beverages and milk beverages, prioritize fine-mesh crystalline raw materials combined with homogenization process to improve dispersibility and reduce precipitation and stratification;

- For infant and high-end functional formulas, use Zinc Citrate alone to replace inorganic zinc to maximize absorption and gastrointestinal tolerance; appropriately compound with zinc sulfate for mass formulas to balance quality and cost;
- Use strictly in accordance with the specified categories and limits of **GB 14880**, follow infant standard limits for infant food, no addition beyond scope and dosage.

4. Storage Conditions

Seal and store in a cool, dry, ventilated and dark place at normal temperature with ambient temperature **≤25℃**. Strictly prevent moisture, deliquescence and caking, as well as odor cross-contamination from acid and alkali gas. The shelf life of unopened original packaging is **24 months**. Seal immediately for moisture and light protection after opening, and it is recommended to use up within 4~6 months to ensure stable powder fluidity and chelated physical and chemical indicators.

V. Summary

Zinc Citrate has complete and detailed toxicological research data, with authoritative safety certifications from China national standards, US FDA, EU EFSA, JECFA and other countries and institutions. It is a high-end organic chelated zinc source with practical non-toxic grade, no teratogenic and mutagenic effect, and no reproductive and developmental toxicity. Featuring high zinc content, excellent bioavailability and extremely low gastrointestinal irritation, it can be safely consumed for a long time by ordinary adults, adolescents, middle-aged and elderly people and infants within the recommended national standard dosage, being the only high-quality zinc supplementation raw material suitable for all age groups.

It has six core advantages: high absorption, low irritation, anti-antagonism, high temperature resistance and easy processing, wide infant standard compliance and strong formula compatibility. It perfectly meets the upgrading zinc supplementation demand in infant complementary food, high-end dairy products, baked grains, health food, high-end processed food, pet feed and other fields, serving as the preferred organic zinc source for replacing zinc sulfate and zinc oxide to realize formula high-end upgrading.

Its application fully covers the entire industrial chain of infant complementary food, dairy products, grain baking, solid beverages, processed food, health food, functional beverages, feed and pet industry. The recommended dosage in various fields is strictly formulated in accordance with **GB 14880**, **GB 1903.23** and JECFA international general standards, with authoritative and reliable data directly applicable to formula production.

Under the industry trend of high-end food nutrition, infant standard quality upgrading and green and healthy pet food, Zinc Citrate is not only a core raw material in rigid demand for high-end zinc supplementation, but also an ideal alternative for iterative upgrading of inorganic zinc formulas. It balances functionality, safety and compliance, with long-term steady improvement in industrial application value and market rigid demand.