Safety Assessment, Product Application and Recommended Dosage of Calcium Carbonate

Overview

Calcium Carbonate (CAS: 471-34-1) is an inorganic calcium nutritional fortifier refined from natural calcite, limestone, shell powder and other raw materials through mineral processing and purification, grinding and refining, purification and impurity removal, drying and classification. Its molecular formula is **$CaCO_3$**. It appears as white to off-white fine crystalline powder, odorless and tasteless. It features high calcium content, abundant raw material sources, superior cost performance, stable chemical properties and strong compatibility versatility, with the effective calcium content stably maintained at **39.0%~40.0%**.

It has been included in the national standard system of **GB 1903.14-2016** and **GB 14880-2012**, and has passed safety certifications from international authoritative institutions such as **US FDA GRAS**, **EU EFSA**, **JECFA** and **Codex**. It boasts complete toxicological data, mature compliance system and extremely wide formula adaptability. As a classic basic inorganic calcium source, it is widely applied in infant complementary foods, dairy products, grain baking products, solid beverages, health foods, conventional foods, feed and pet food. It is a benchmark raw material for basic calcium fortification with high calcium content, high cost performance and the strongest versatility, as well as the main basic compatible material for various organic calcium and compound calcium formulas.

I. Safety Assessment of Calcium Carbonate

(I) Conclusions of Toxicological Tests

1. Acute Toxicity

Oral acute toxicity tests on rats and mice were carried out in accordance with **GB 15193 Procedures and Methods for Food Safety Toxicological Evaluation**. The **LD_{50}** of calcium carbonate is **＞5000mg/kg·bw**, classified 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 experimental 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

A 90-day subchronic feeding test and a 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, bone development and organ coefficient of experimental animals, with no organic organ damage

or abnormal calcium accumulation in the body. 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 risk of liver and kidney metabolic burden, vascular calcification or calcium overload.

3. Genotoxicity and Carcinogenicity

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

4. Reproductive and Developmental Toxicity

Reproductive breeding and embryonic developmental toxicity tests show that calcium carbonate at compliant doses has no adverse effects on the reproductive function, embryo implantation, fetal bone calcification and offspring growth and development of experimental animals, with no stillbirth, malformation or growth retardation. Ordinary adults, middle-aged and elderly people, and adolescents can consume it safely within national standard doses. Excessive intake by infants and people with gastric acid deficiency may cause transient gastrointestinal reactions such as mild abdominal distension, constipation and belching, which can be avoided by controlling the compliant addition amount.

(II) Control of Risk Substances and Limits

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

- Calcium Content: **39.0%~40.0%**
- Calcium Carbonate Purity: **≥98.5%**
- Moisture: **≤1.0%**
- pH (100g/L Suspension): **9.0~10.5**
- Stability: Physicochemical properties remain stable below **600℃**; no decomposition, no moisture absorption and no easy reaction with neutral systems under normal temperature and pressure.

2. Limits of Heavy Metals and Harmful Elements

- Lead (Pb): **≤2.0mg/kg**
- Total Arsenic (As): **≤2.0mg/kg**

- Cadmium (Cd): **≤0.3mg/kg**
- Total Mercury (Hg): **≤0.05mg/kg**

3. Microbial Indicators

- Total Aerobic Bacteria: **≤3×10³ CFU/g**
- Coliforms: **≤0.3 MPN/g**
- Molds and Yeasts: **≤30 CFU/g**
- Salmonella, Staphylococcus Aureus: **0/25g Not Detected**

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

4. Allergenicity and Irritation

Calcium carbonate is a natural mineral-derived inorganic carbonate with no plant protein allergens or exogenous allergens. It can only be absorbed by the human body after dissociation by gastric acid. Excessive intake or consumption on an empty stomach tends to neutralize gastric acid, causing abdominal distension, constipation, acid regurgitation and belching. It has slightly higher gastrointestinal irritation compared with organic calcium. People with insufficient gastric acid, infants and sensitive constitutions need to control the addition ratio and consumption dosage.

(III) Safety Conclusions by Authoritative Institutions

- **China**: Listed in **GB 14880-2012 Standard for the Use of Food Nutritional Fortifiers**, implementing the special national standard **GB 1903.14-2016**. It is allowed to fortify various foods within specified limits and included in the raw material catalogue of health food nutrient supplements for routine declaration of blue-certified product formulas.
- **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 no strict **ADI** limit, allowing legal addition in all categories of conventional food.
- **FAO/WHO (JECFA/Codex)**: Approved by reviews of toxicological and nutritional absorption data, recognized for high safety and high calcium content, listed as a globally universal basic inorganic calcium fortifier.
- **Japan, South Korea, Australia and New Zealand**: Included in the positive list of food additives, approved for compliant application in conventional health food, processed food, export food and feed fields.

II. Product Application of Calcium Carbonate

This section systematically elaborates on the core advantages, functional mechanism, application scenarios, solutions and core market selling points of calcium carbonate. It conforms to the actual production of food, health products, conventional processed food, functional beverages, feed and pet industries, balancing professional theories and practical implementation, focusing on application pain points in various fields and providing implementable solutions.

(I) Core Value

As a mainstream inorganic calcium source, calcium carbonate has eight core values: it has the highest calcium content in the industry with extremely low unit calcium supplementation cost; sufficient supply of natural mineral raw materials with stable supply; strong inert physicochemical properties, not prone to side reactions with formula components; good powder fluidity for easy mixing and processing; compatible with high-temperature baking, extrusion puffing and other processes; full category coverage of food, health products and feed; global compliance with low export thresholds; compoundable with calcium citrate and calcium lactate to balance cost and absorption, making it the preferred basic calcium source for popular calcium supplementation formulas.

(II) Functional Mechanism

1. Basic Calcium Supplementation for Bone Strengthening

It releases calcium ions after dissociation by gastric acid, which are absorbed and utilized by the intestines to meet human calcium demand, promote calcification of bones and teeth, and prevent problems such as stunted bone development in adolescents, osteoporosis in middle-aged and elderly people, and lumbocrural pain caused by daily calcium deficiency. It is the most basic and universal source of dietary calcium supplementation.

2. Acid-Base Buffering and Regulation Mechanism

As a weakly alkaline inorganic mineral salt, it acts as a pH buffer and acidity regulator in food systems, neutralizing part of acidic components in the formula, stabilizing the acid-base balance of the system, and improving food taste and shelf life stability.

3. Filling and Flow-Assisting Carrier Mechanism

With uniform particle size and good fluidity, it can be used as a filler, glidant and anti-caking auxiliary for health food tablets and solid beverages, improving powder moldability, preventing agglomeration and optimizing tablet pressing effect.

4. Nutrient Compound Synergy Mechanism

Compounded with vitamin D3, magnesium, zinc and vitamin K2, it can make up for its own shortcoming of gastric acid-dependent absorption, improve calcium ion absorption rate and bone deposition efficiency, and realize low-cost compound nutritional fortification.

(III) Application Scenarios

1. Infant Formula and Complementary Food Field

Suitable for grain complementary foods, nutrition packs, infant snacks and multi-dimensional nutrients for infants over 36 months old. With high calcium content and cost performance, it is mostly used in calcium supplementation formulas for ordinary infant complementary foods. It needs to be matched with vitamin D3 to promote absorption, and the addition amount should be controlled to reduce gastrointestinal burden.

2. Dairy and Fermented Milk Field

Applied to formulated milk powder, normal temperature liquid milk, solid milk beverages and conventional yogurt. As a basic calcium fortification raw material, it has good powder dispersibility, compatible with the dry mixing process of dairy products, does not seriously damage the flavor system, and is suitable for calcium supplementation in popular dairy products.

3. Grain and Baked Food Field

Suitable for oatmeal, miscellaneous grain powder, nutritional rice powder, biscuits, cakes, bread, puffed grains and meal replacement grains. It has excellent high temperature resistance, tolerating the high-temperature processes of **180~220℃** baking and extrusion puffing, with stable calcium content and no loss during processing, making it the most commonly used calcium supplementation raw material for baked food.

4. Solid Beverage, Meal Replacement and Sports Nutrition Field

Used in multi-dimensional meal replacement powder, ordinary protein powder, nutrient solid granules and instant beverages. The powder is easy to mix with low cost, suitable for basic calcium supplementation of popular meal replacements and ordinary nutritional solid beverages.

5. Health Food Field

Applied to ordinary calcium supplementation tablets, compound multi-dimensional mineral capsules, basic calcium supplementation formulas for middle-aged and elderly people, and dietary supplements. The raw materials are compliant and easily available with good tablet moldability and controllable formula cost. It is the main raw material for affordable blue-certified calcium supplementation products, often compounded with organic calcium to optimize absorption.

6. Conventional Processed Food Field

Used in popular processed foods such as dried noodles, instant noodles, bean products, casual snacks and condiments. As a universal nutritional fortifier, it completes basic calcium nutrition upgrading of food at low cost without affecting the original taste and flavor of products.

7. Functional Beverage and Liquid Food Field

Applied to ordinary fruit-flavored beverages, plant protein beverages and daily nutritional oral liquids. Mostly used for basic calcium supplementation in mid-to-low-end liquid beverages; particle size and addition amount need to be controlled to avoid precipitation and stratification upon standing.

8. Feed and Pet Food Field

Covers livestock and poultry compound feed, aquaculture feed, dog and cat staple food and pet nutritional snacks. With extremely high cost performance and pure mineral elements, it meets the bone growth and daily nutritional needs of livestock, poultry and pets, being the most mainstream calcium source raw material in the feed industry.

(IV) Solutions

Targeting the core pain points in various application fields (gastric acid dependence of calcium absorption, easy precipitation in liquid systems, powder agglomeration, compatibility with baking processes, formula cost control, etc.), combined with the inorganic mineral characteristics of calcium carbonate, it provides accurate and implementable solutions balancing safety, functionality and production operability.

1. Infant Formula / Infant Complementary Food Field

● Pain Points: Weak gastric acid secretion in infants, poor absorption of calcium carbonate, easy abdominal distension and constipation, high hygienic standard requirements

● Solutions: Select food-grade ultra-fine light calcium carbonate to refine particle size and improve dispersibility; compound with vitamin D3 and magnesium to promote absorption; control the formula addition ratio and avoid single high-dose use; prioritize compounding with organic calcium to reduce gastrointestinal irritation and fit the digestive physiological characteristics of infants.

2. Dairy / Fermented Milk Field

● Pain Points: Easy sedimentation of calcium ions, affecting dairy transparency and astringent taste

● Solutions: Select fine-mesh calcium carbonate and adopt dry low-speed mixing process; control the system in neutral to weakly acidic environment to reduce precipitation of calcium ions; match with emulsifying stabilizers to improve dispersibility and avoid stratification and precipitation upon standing; control the addition amount of popular dairy products to balance calcium supplementation effect and sensory quality.

3. Grain and Baked Food Field

● Pain Points: Local agglomeration under high temperature, moisture absorption during storage, affecting baking fluffiness

● Solutions: Pre-mix and dilute calcium carbonate with grain powder in advance before feeding; tolerate conventional baking high temperature of **180~220℃** without worrying about thermal decomposition; match with a small amount of anti-caking agents and leavening agents to ensure stable calcium content without damaging the fluffy taste and appearance of baked food.

4. Solid Beverage / Meal Replacement Powder Field

● Pain Points: Large difference in powder density, uneven mixing, easy sedimentation during brewing

● Solutions: Adopt gradient pre-mixing process, first mix with trace vitamins and auxiliary materials, then blend with bulk grains and protein substrates; select light fine calcium carbonate to reduce density difference and improve brewing suspension; use calcium carbonate as the main raw material for popular formulas and compound with calcium citrate for high-end formulas to balance cost and drinking experience.

5. Health Food Field

● Pain Points: Low absorption rate when used alone, poor tablet fluidity, high compliance requirements for blue-certified products

● Solutions: Scientifically compound with vitamin D3, VK2 and magnesium to make up for gastric acid dependence and improve calcium utilization; utilize its own filling and flow-assisting characteristics to optimize tablet pressing molding and disintegration time limit; strictly follow the raw material catalogue of health food and national standard limits for feeding, suitable for declaration and mass production of affordable blue-certified calcium supplementation products.

6. Functional Liquid Beverage Field

● Pain Points: Insoluble in water, easy precipitation upon standing, affecting beverage appearance

● Solutions: Select ultra-fine food-grade calcium carbonate and match with food-grade emulsifying and thickening agents to stabilize the system; control low-dose addition only for basic nutritional fortification; adopt back-end low-temperature blending process with high-speed homogeneous stirring to reduce particle sedimentation and ensure uniform stability of beverages during shelf life.

(V) Market Selling Points

1. **Ceiling of Calcium Content**: As a natural inorganic calcium source, its calcium content is as high as **39%~40%**, with calcium supplementation efficiency far exceeding calcium lactate and calcium gluconate at the same addition amount.
2. **Extreme Cost Performance**: Abundant raw material reserves and low processing cost; the unit cost of calcium addition is much lower than various organic calcium, suitable for mass production formulas.
3. **Strong Process Compatibility**: High temperature resistance and stable physicochemical properties, compatible with full-category food processing technologies such as baking, puffing, spray drying and tableting.
4. **Wide Formula Compatibility**: Inert mineral properties, not prone to adverse reactions with protein, vitamins and dietary fiber, with no taboos in compounding application.
5. **Full Global Compliance**: Multiple authoritative certifications including national standard, FDA, EFSA and JECFA, simple domestic declaration and no global export barriers.
6. **Diversified Functional Reuse**: It has multiple functions including calcium supplementation, pH buffering and powder filling and flow assisting, realizing multi-purpose use and simplifying the formula raw material system.

III. Recommended Dosage by Application Field

Based on food-grade calcium carbonate complying with **GB 1903.14-2016** and **GB 14880-2012**, classified by application field, the compliant addition range and recommended process dosage calculated as elemental calcium are marked, strictly following national standard limits and balancing safety and calcium supplementation functionality.

1. Infant Formula and Complementary Food Field

- Grain complementary foods and nutrition packs for infants over 36 months old: **200~350 mg/100g (Calculated as Calcium)**
- Ordinary formula food for preschool children: Accurately matched with the recommended daily nutrient intake of **400~700mg/day**
- Infant casual snacks: **150~300 mg/100g (Calculated as Calcium)**

2. Dairy Product Field

- Formulated milk powder and adult milk powder: **2000~4500 mg/kg (Calculated as Calcium)**
- Flavored yogurt and fermented milk: **80~200 mg/100g (Calculated as Calcium)**
- Liquid sterilized milk and ordinary milk beverages: **150~350 mg/kg (Calculated as Calcium)**

3. Grain and Baked Food Field

- Wheat flour, rice flour and miscellaneous grain nutritional powder: **200~350 mg/kg (Calculated as Calcium)**
- Instant oatmeal and compound grain cereal: **120~280 mg/100g (Calculated as Calcium)**
- Biscuits, cakes, bread and puffed food: **80~180 mg/100g (Calculated as Calcium)**

4. Solid Beverage, Meal Replacement and Sports Nutrition Field

- Ordinary solid beverages and popular meal replacement powder: **180~350 mg/100g (Calculated as Calcium)**
- Ordinary protein powder and multi-dimensional nutritional granules: Added according to internal formula control, not exceeding the upper limit of national standards
- Ordinary plant beverages and grain functional beverages: **40~120 mg/100ml (Calculated as Calcium)**

5. Health Food Field

- Adult basic calcium supplementation preparations: Daily elemental calcium intake **600~1000 mg/day**
- Affordable calcium supplementation formulas for middle-aged and elderly people: Daily elemental calcium **700~1000 mg/day**
- Children's health food: Daily elemental calcium **300~500 mg/day**
- Single tablet / capsule feeding: Calcium carbonate feeding amount **300~500mg/tablet**, adjust the compound ratio with organic calcium as needed

6. Conventional Processed Food Field

- Dried noodles, instant noodles and flour products: **150~300 mg/kg (Calculated as Calcium)**
- Bean products and casual snacks: **100~250 mg/kg (Calculated as Calcium)**
- Condiments and meal replacement staple food: **120~280 mg/kg (Calculated as Calcium)**

7. Functional Beverage and Daily Fortification Field

- Ordinary bottled functional beverages and nutritional oral liquids: **50~150 mg/100ml (Calculated as Calcium)**
- Plant protein beverages and grain beverages: **40~130 mg/100ml (Calculated as Calcium)**

8. Feed and Pet Food Field

- Basic compound feed for livestock and poultry: **1500~3000 mg/kg**
- Compound feed for aquaculture: **1000~2500 mg/kg**
- Dog and cat staple food and ordinary pet snacks: **1200~3000 mg/kg**

IV. Application Precautions and Quality Control

1. Raw Material Quality Standards

- Appearance: White to off-white uniform fine powder, no agglomeration, no visible foreign impurities to the naked eye, no peculiar smell;
- Content: Calcium **39.0%~40.0%**, purity **≥98.5%**, stable and uniform physical and chemical indicators per batch;
- Safety: Heavy metals and microorganisms strictly comply with **GB 1903.14** national standard and food-grade internal control standards, no excessive heavy metals and no pathogenic microbial contamination;
- Properties: Good powder fluidity and moderate dispersibility; ultra-fine grade has excellent suspension, compatible with solid and liquid food systems.

2. Processing and Compatibility Taboos

- Temperature: Tolerates conventional baking and puffing high temperature of **180~220℃**, starts to decompose above **600℃**, no risk under conventional food processing temperature;
- pH Compatibility: Stable range **pH 7.0~11.0**, not suitable for long-term placement in strong acid systems, prone to reaction and dissolution of calcium ions causing precipitation;
- Compatibility Recommendation: Synergistically compound with vitamin D3, vitamin K2, magnesium and zinc to significantly improve calcium absorption and utilization;
- Compatibility Avoidance: Avoid high-proportion compounding with high-concentration oxalic acid, phytic acid and phosphate, which easily form insoluble calcium salt precipitation and reduce nutritional absorption rate.

3. Production and Usage Suggestions

- Powder products must adopt small proportion pre-mixing and dilution before large-scale feeding and stirring to avoid uneven mixing caused by density difference;
- For liquid beverages and milk beverages, ultra-fine mesh raw materials are preferred combined with homogenization process to reduce sedimentation upon standing;
- For infant and high-end gastrointestinal-friendly formulas, it is recommended to compound calcium carbonate with calcium citrate / calcium lactate to balance cost, absorption and gastrointestinal tolerance;
- Use strictly in accordance with the specified categories and limits of **GB 14880**, no addition beyond scope and limit.

4. Storage Conditions

Store in a sealed, cool, dry, ventilated and dark place with normal temperature storage environment **≤25℃**. Strictly prevent moisture, agglomeration due to moisture absorption and odor cross-contamination from acid and alkaline gas. The shelf life of unopened original packaging is **24 months**. Seal tightly immediately after opening for moisture and light protection, and it is recommended to use up within **4~6 months** to ensure stable powder fluidity and physicochemical indicators.

V. Summary

Calcium carbonate has complete and detailed toxicological research data and authoritative safety certifications from China, the United States, the European Union, JECFA and other countries and institutions. It is a classic inorganic calcium source with practically non-toxic grade, no teratogenic and mutagenic effects, and no reproductive and developmental toxicity. With extremely high calcium content, outstanding cost performance and stable physicochemical properties, ordinary adults, adolescents and middle-aged and elderly people can consume it safely for a long time within the recommended national standard doses. Only infants and people with gastric acid deficiency need to control the single use dosage or compound with organic calcium.

It has six core advantages: high calcium content, low cost, high temperature resistance and easy processing, wide formula compatibility, diversified functions and global compliance. It perfectly meets the basic calcium supplementation needs of popular food, baked grains, affordable health products, feed and pet industries, and is the preferred basic calcium source to replace calcium lactate and calcium gluconate for formula cost control.

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 food. The recommended dosage in various fields is strictly formulated in accordance with **GB 14880**, **GB 1903.14** and JECFA international general standards, with authoritative and reliable data directly applicable to formula production.

Under the industry trend of popular food nutritional fortification, formula cost optimization and feed industry rigid demand expansion, calcium carbonate is not only a rigid raw material for basic calcium supplementation, but also an ideal compound partner for organic calcium in high-end formulas. It balances functionality, economy and compliance, with long-term stable and prominent industrial application coverage and market rigid demand value.