St. John's Wort Extract: Safety Assessment, Product Application & Recommended Dosage

A Comprehensive Analysis Based on Scientific Data

CONTENTS

01 Safety Assessment

Conduct a comprehensive safety analysis from three dimensions: toxicology, irritation & sensitization, and risk substance control.

02 Product Application

Explore its extensive application scenarios and cases in pharmaceuticals, cosmetics, food, and industrial sectors.

03 Recommended Dosage

Provide standard recommended dosages for various application fields to ensure a balance between product efficacy and safety.

04 Supplementary Information

Supplement key technical specifications such as product purity, storage conditions, and testing methods.

I. Safety Assessment



Toxicology Evaluation

Comprehensive analysis of acute and chronic toxicity data to ensure the extract meets international safety thresholds.



Irritation & Sensitization

Rigorous testing for skin and eye irritation, as well as potential sensitization reactions.



Risk Substance Control

Stringent monitoring of heavy metals, pesticides, and other harmful residues to guarantee purity.

(I) Toxicological Assessment - Acute Toxicity



Oral Toxicity in Rats (LD_{50})

⩾5000 mg/kg (calculated as hypericin), practically non-toxic; pure monomer LD_{50}⩾7000 mg/kg.

Oral Toxicity in Mice (LD_{50})

⩾5000 mg/kg, consistent with rat results, no species difference.

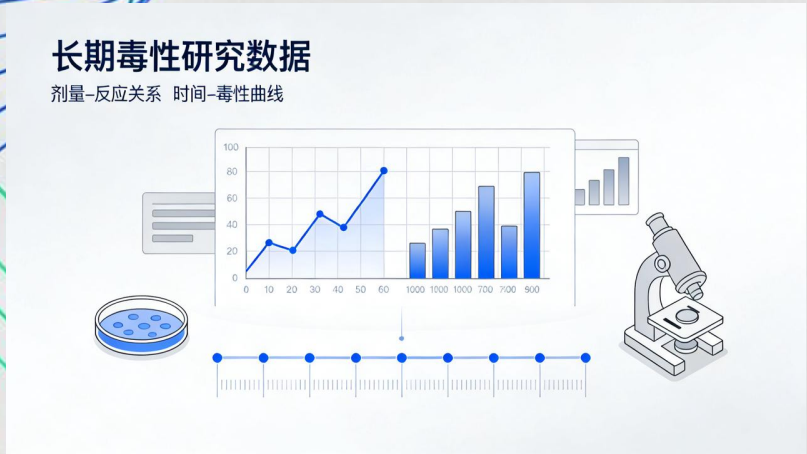
Dermal Toxicity in Rabbits (LD_{50})

⩾5000 mg/kg, no acute dermal toxicity reactions.

Acute Toxicity Manifestations

A few animals showed transient diarrhea at high doses, fully recovered within 48 hours, no deaths, very low risk.

(I) Toxicological Assessment - Subchronic & Chronic Toxicity



90-Day Oral Gavage Test in Rats

No abnormalities in low/medium dose groups; mild diarrhea in high dose group, recovered after withdrawal, no toxicity accumulation.

90-Day Oral Test in Dogs

No weight loss, appetite disorders, no subchronic toxicity accumulation.

2-Year Animal Carcinogenicity Test (NTP 2024)

No clear carcinogenicity, no relevant tumor risk found.

Comprehensive Conclusion

Daily oral exposure ⩽600 mg/kg・d, safe for long-term use, no cumulative toxicity.

(I) Toxicological Assessment - Genotoxicity



AMES Test

No mutagenic effect, no gene mutation risk.

Mouse Bone Marrow Micronucleus Test

No chromosome damage or breakage risk, does not affect cell division stability.

Chromosome Aberration Test

No obvious chromosome deletions, translocations, or other abnormalities, does not affect genetic material stability.

Conclusion

All three core tests are negative, no genotoxicity risk.

(II) Irritation & Sensitization Assessment - Skin Irritation



Rabbit Skin Irritation Test (OECD 404)

8% St. John's Wort extract (aqueous solution) was applied to the depilated back skin of rabbits for 24 consecutive hours. No irritation reactions such as erythema, edema, erosion, or desquamation were observed. The irritation index was 0, indicating no skin irritation.

Human Skin Patch Test

Thirty healthy volunteers were recruited. Three concentrations (3%, 5%, 8%) of St. John's Wort extract were used for a 48-hour patch test. No discomfort such as redness, itching, or stinging was reported. The positive reaction rate was 0, making it suitable for long-term external use in cosmetics and daily chemical products.

Precautions

High-concentration extracts (⩾10%) may cause mild stinging in individuals with fragile skin barriers (sensitive skin) due to the presence of small amounts of flavonoids. It is recommended to control the concentration in cosmetic formulations to ⩽8% (⩽5% for sensitive skin). A local skin test is advised before external use.

(II) Irritation & Sensitization Assessment - Mucosal Irritation



Oral Mucosal Irritation

Rats were treated with 5% extract for 7 consecutive days; no mucosal congestion or ulcers were observed. Suitable for oral care products like toothpaste and mouthwash.

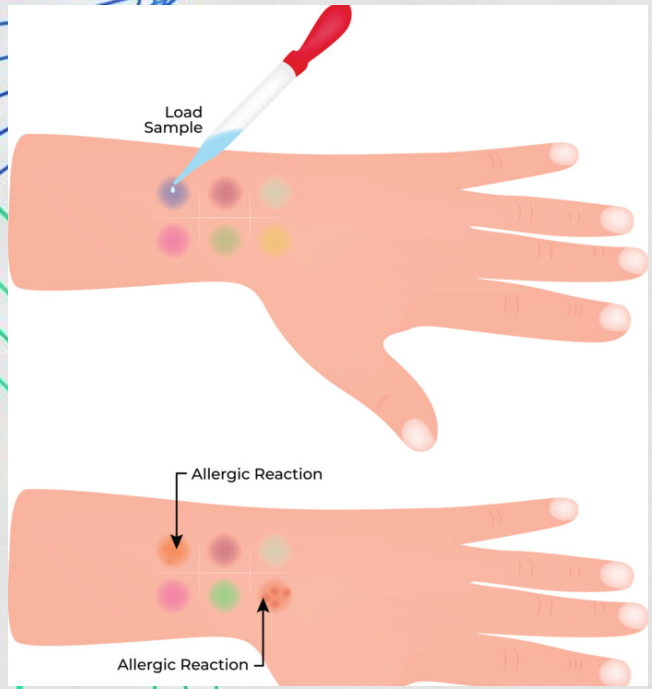
Ocular Irritation (OECD 405)

No abnormalities within 24 hours and complete recovery by 48 hours in rabbit eye irritation test. Classified as non-irritating, suitable for eye care products.

Gastrointestinal Mucosal Irritation

No mucosal damage observed in rats after 30 days of oral gavage, indicating good oral safety. Suitable for long-term consumption in food and health products.

(II) Irritation & Sensitization Assessment - Skin Sensitization



Guinea Pig Maximization Test (GPMT)

No skin sensitization reaction was observed; sensitization rate was 0, indicating good safety.

Human Repeat Insult Patch Test (HRIPT)

No sensitization reactions were reported by subjects, and no skin discomfort symptoms were observed.

Special Population Note

A very small number of individuals allergic to hypericin (incidence <0.003%) may experience mild skin itching; such individuals are advised to avoid contact.

(III) Risk Substance Control - Pesticide Residues



Control Core

Implement strict control over pesticide residues according to Chinese Pharmacopoeia standards, ensuring compliance with maximum residue limits (MRLs).

(III) Risk Substance Control - Heavy Metal Residues



Core Control Strategy

Control heavy metal contaminants (Pb, Cd, As, Hg, Cu) within acceptable limits to meet food and cosmetic safety standards.

Heavy Metal Limit Standards (mg/kg)

Lead (Pb): ⩽2 mg/kg (Food Grade), ⩽10 mg/kg (Cosmetic Grade)
Arsenic (As): ⩽1 mg/kg (Food Grade), ⩽2 mg/kg (Cosmetic Grade)
Mercury (Hg): ⩽0.1 mg/kg (Universal for both grades)
Cadmium (Cd): ⩽0.3 mg/kg (Food Grade), ⩽5 mg/kg (Cosmetic Grade)

(III) Risk Substance Control - Microbial Control

Core Control Principles

Classified control based on application scenarios to avoid microbial contamination and ensure compliance with food and cosmetic industry standards.

Specific Limit Standards

Food-grade St. John's Wort Extract: Total aerobic bacteria ⩽1000 CFU/g, Mold & Yeast ⩽100 CFU/g, Coliforms ⩽10 CFU/g, Pathogens: Not detected.

Cosmetic-grade St. John's Wort Extract: Total aerobic bacteria ⩽100 CFU/g, Mold & Yeast ⩽100 CFU/g, Pseudomonas aeruginosa & Staphylococcus aureus: Not detected.

Key Control Measures

- Environment & Packaging: Aseptic processing, vacuum-sealed packaging
- Preservation: Addition of compliant preservatives (e.g., parabens)
- Storage: Strict control of cool and dry conditions



(III) Risk Substance Control - Other Risks



Solvent Residue Control

Strictly control residues of ethanol, acetone, etc. (food grade ⩽500mg/kg), prioritize supercritical CO_2 solvent-free extraction process to ensure raw material purity.

St. John's Wort Extract Stability Management

For oxidation-prone characteristics, strictly control storage conditions (avoid light, sealed, low temperature ⩽25℃), shelf life ⩽24 months, use as soon as possible after opening.

Flavonoids Intake Recommendations

Pay attention to the impact of high-concentration oral administration on the gastrointestinal tract, recommend controlling daily intake, avoid taking on an empty stomach, children and pregnant women should use under professional guidance.

II. St. John's Wort Extract Application

Core Value & Solutions

Based on its unique active ingredients (e.g., Hypericin, Hyperforin) and excellent safety profile, we provide customized solutions for various industries.

Through precise extraction processes, we ensure high stability of active ingredients to meet diverse needs from health supplements to personal care products.

Multi-field Application Overview

Pharmaceutical Field

Utilizing its antidepressant and antibacterial properties to develop prescription and OTC formulations.

Cosmetics & Personal Care

Applied in sunscreen, soothing, and repair skincare products to provide natural protection.

Food & Industrial Applications

Used as a dietary supplement ingredient and a natural colorant.

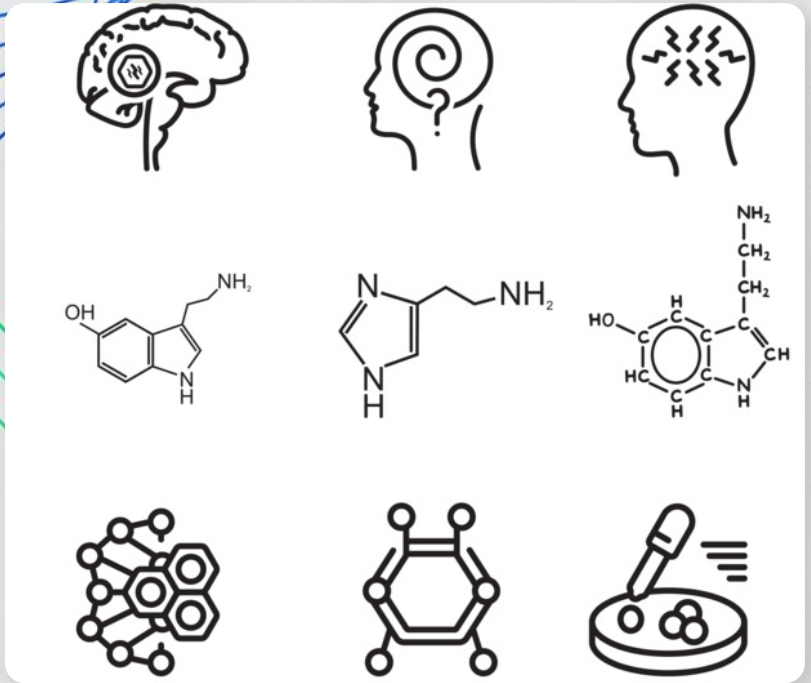
(I) Pharmaceutical Application - Core Value



Core Value

As a natural antidepressant, it has good safety and is suitable for mild to moderate depression and anxiety disorders.

(I) Pharmaceutical Application - Mechanism of Action



Mood regulation mechanism

- Inhibits the reuptake of neurotransmitters (serotonin, norepinephrine, dopamine).

Antiviral and antibacterial mechanism

- Inhibits viral DNA replication and bacterial protein synthesis.

(I) Pharmaceutical Application - Recommended Dosage Form



Oral Dosage Forms

- **Preferred Types:**Tablets, Capsules, Granules (Specifications: 150mg/300mg)
- **Quality Control:**Tablet disintegration ⩽30min; Capsule dissolution ⩾80%; Granule solubility ⩽10min

Topical Dosage Forms

- **Preferred Types:**Ointments, Lotions, Gels (Refreshing texture, strong penetration)
- **Base System:**Ointment: Vaseline-Lanolin (7:3); Lotion: Water-Ethanol (10-15%)

(I) Pharmaceutical Application - Application Solutions

Reference: Drug Compatibility Chart

上 素	异丙肾 上腺素	布地 奈德[a]	色甘酸[b]	异丙托 溴铵[c]	乙酰 胱氨
I	NI	C	C	C	N
	NI	NI	C	NI	N
I		NI	C	C	N
I	NI		C	C	C
	C	C		C	C
I	C	C	C		C
I	NI	C	C	C	
I	NI	NI	R	NI	N
I	NI	NI	NI	NI	N
	X	X	X		X

Core Application Scenarios

Suitable for emotional relief in mild to moderate depression, anxiety, and menopausal syndrome; can also assist in treating skin inflammation such as eczema and dermatitis, as well as postpartum lactation disorders.

Compatibility and Contraindication Suggestions

Synergistic effect can be achieved with Vitamin B6 and Dipotassium Glycyrrhizinate; strictly prohibited from combined use with antidepressant western medicine and anticoagulants, must follow doctor's advice.

Market Compliance Claims

Compliant claim: "Helps improve mild to moderate depressive mood". Mandatory labeling of warning: "Cannot replace prescription drugs" and core ingredient content.

(II) Cosmetic Application - Core Value



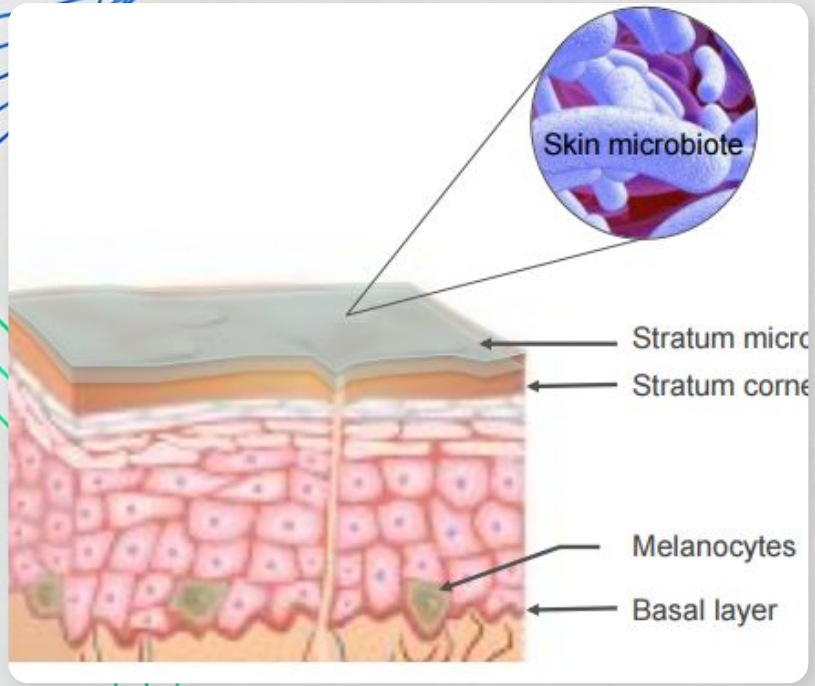
Core Value

Natural plant extract with anti-inflammatory, antioxidant, and moisturizing effects, suitable for sensitive skin care.

Core Advantage

Derived from natural plants, mild in composition, with multiple functions, meeting consumers' needs for safe and effective skincare, in line with the natural and functional development trend of cosmetics.

(II) Cosmetic Application - Mechanism of Action



Anti-inflammatory mechanism

Inhibits inflammatory mediators (PGE2).

Antioxidant mechanism

Scavenges free radicals.

Moisturizing mechanism

Enhances skin barrier function.

(II) Cosmetic Application - Recommended Dosage Form



Liquid Formulations

Suitable for toners and serums. Recommended pH 4.5-6.5, addition temperature ⩽40°C, solubility ⩾95%.

Emulsion Systems

Suitable for lotions and creams. Recommended O/W system, lightweight texture, stability ⩾6 months, with emulsifiers.

Other Formulations

Suitable for masks and sunscreens. Added to serums, compatible with sunscreen agents, meets leave-on product requirements.

(II) Cosmetic Application - Application Solutions



白芨(Bletilla striata)根提取物	0	美白祛斑
白鲜(DICTAMNUS DASYCARPUS)根皮提取物		舒缓抗敏

Core Application Scenarios

Suitable for daily care of sensitive skin, anti-aging care of mature skin, auxiliary repair of problem skin, and daily sun protection assistance, fully covering various skincare needs.

Scientific Formulation Suggestions

Synergistic effect: Recommended to be compounded with licorice extract, hyaluronic acid, and vitamin C.
Contraindications: Avoid combination with high-concentration acids, strong oxidants, and irritating preservatives.

Compliance Market Claims

Compliant claims: "Soothe redness and improve skin sensitivity";
Mandatory labeling of "For sensitive skin use with caution" warning, and strictly comply with heavy metal and microbial limit standards.

(III) Food Application - Core Value



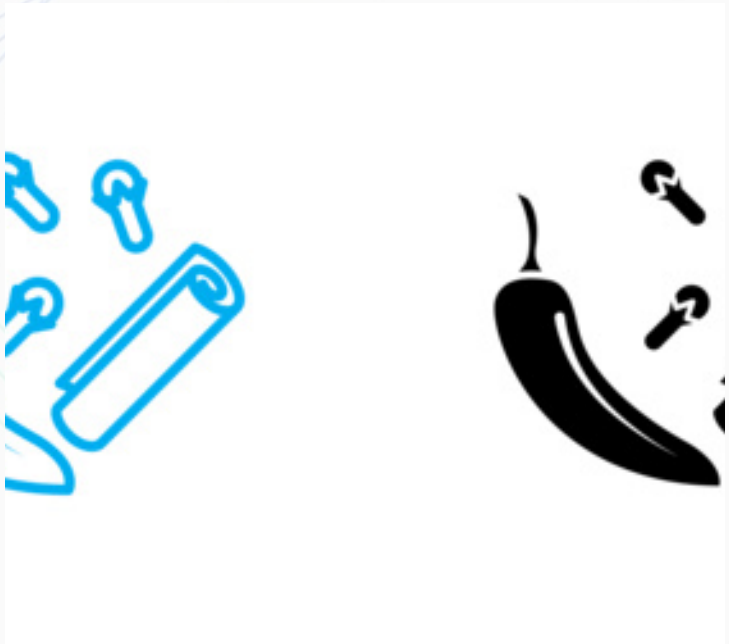
Natural Substitution & Health Trends

Possessing dual functions of natural antioxidant and flavor enhancement, it can replace**30%-50%**of chemical antioxidants (such as BHA, BHT), perfectly aligning with the health and naturalization trends in the food industry.

Potent Antioxidant & Quality Improvement

At a concentration of 0.1g/L, the lipid peroxidation inhibition rate is**⩾65%**, effectively extending the shelf life of food. It also imparts a unique natural herbal flavor to the product, enriching the taste layers.

(III) Food Application - Mechanism of Action



Antioxidant mechanism

Inhibits lipid peroxidation.

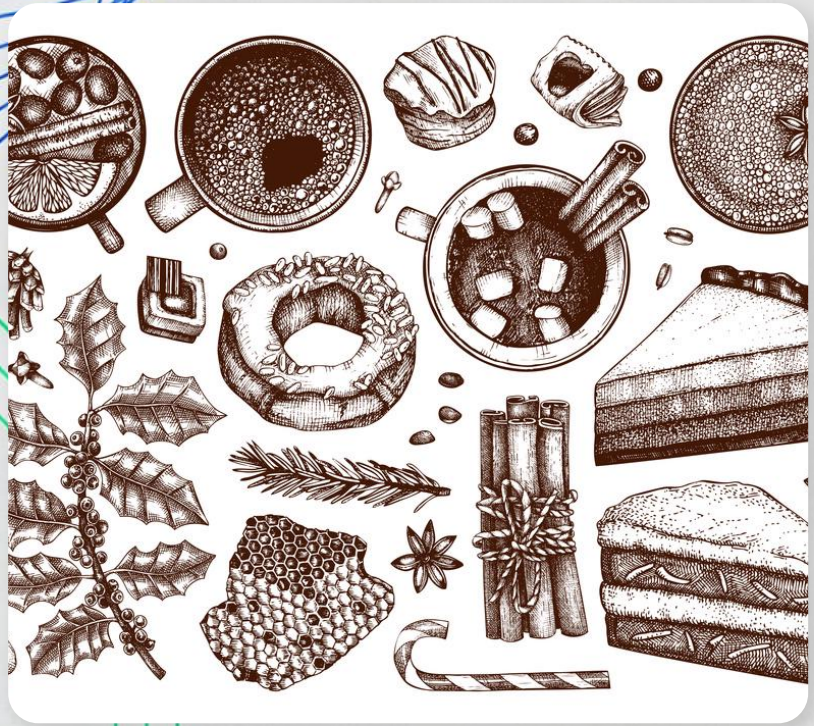
Flavor enhancement mechanism

Enhances sweet and umami tastes.

Functional mechanism

Regulates intestinal flora.

(III) Food Application - Recommended Dosage Form



Liquid Formulations

Suitable for fruit juices, teas, oral liquids. Add during batching, control temperature ⩽60°C. Stevia glycosides can be added to oral liquids to improve taste.

Solid Formulations

Suitable for baked goods, nuts, health food tablets. Can be made into microencapsulated dosage forms. Control temperature ⩽180°C when adding to baked goods.

Oil-based Foods

Suitable for edible oils, nuts, etc. Directly add extract powder and mix evenly to exert antioxidant effect.

(III) Food Application - Application Solutions



Core Application Scenarios

Suitable for anti-corrosion and preservation of oils, anti-oxidation and flavor enhancement of baked goods; can improve the flavor of tea drinks and juices; used as raw material for dietary supplements for calming the nerves and aiding sleep.

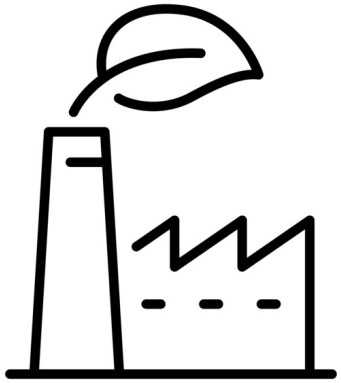
Scientific Formulation Suggestions

Synergistic effect can be compounded with vitamin E and tea polyphenols; flavor enhancement can be compounded with mint and dried orange peel. Avoid compatibility with high-concentration acidic and strong-flavor additives.

Compliance Market Claims

Regular food can be legally claimed as "natural antioxidant"; health food can claim "assist in improving mood", which must strictly comply with regulations and mandatory labeling of warning signs.

(IV) Industrial & Other Applications - Core Value



Core Value: Green Environmental Protection & Functional Enhancement

Effectively replaces some chemical additives, aligning with the trend of industrial greening to achieve dual improvement in environmental protection and efficiency.

Wood Preservation Application

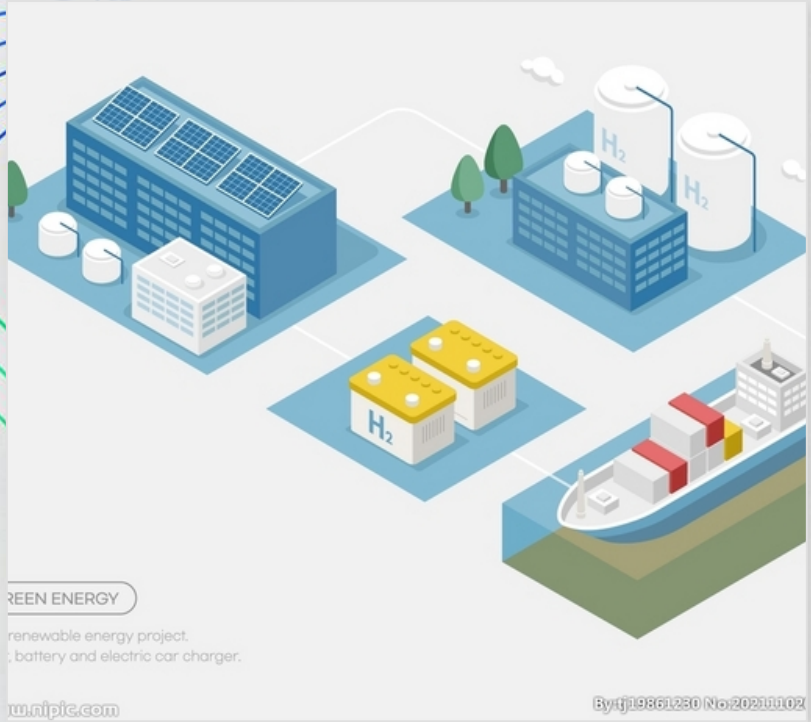
A concentration of 1%-5% can achieve ⩾90% mortality rate of wood decay fungi, significantly enhancing wood durability.

Natural Surfactant

A concentration of 0.5% can reduce the surface tension of the system to 32mN/m, possessing excellent surface activity.

Green Feed Additive

(IV) Industrial & Other Applications - Mechanism of Action



Antibacterial mechanism

Disrupts bacterial cell membranes.

Preservative mechanism

Inhibits microbial growth.

Adsorption mechanism

Adsorbs harmful substances.

Aquaculture mechanism

Enhances immune function and promotes growth.

(IV) Industrial & Other Applications - Recommended Dosage Form



Solution: Wood Preservation & Wastewater

Recommended water-ethanol solvent (8:2), 1%-5% concentration for soaking or spraying.

Suspension: Leather & Textile Processing

1%-5% suspension with dispersant (Tween-80) to prevent sedimentation.

Premix: Feed Additive

10%-20% premix for precise and uniform mixing with animal feed.

Powder: Chemical Adsorbents & Dyes

Direct use of extract powder for adsorption and dyeing processes.

(IV) Industrial & Other Applications - Application Solutions



Core application scenarios

Wood preservation, leather processing, water treatment.

Scientific formulation suggestions

Combine with other industrial additives.

Compliant market claims

Strictly follow industry standards, support "green corrosion protection", "natural and environmentally friendly", "long service life" and "natural surfactant" claims.

III. Recommended Dosage

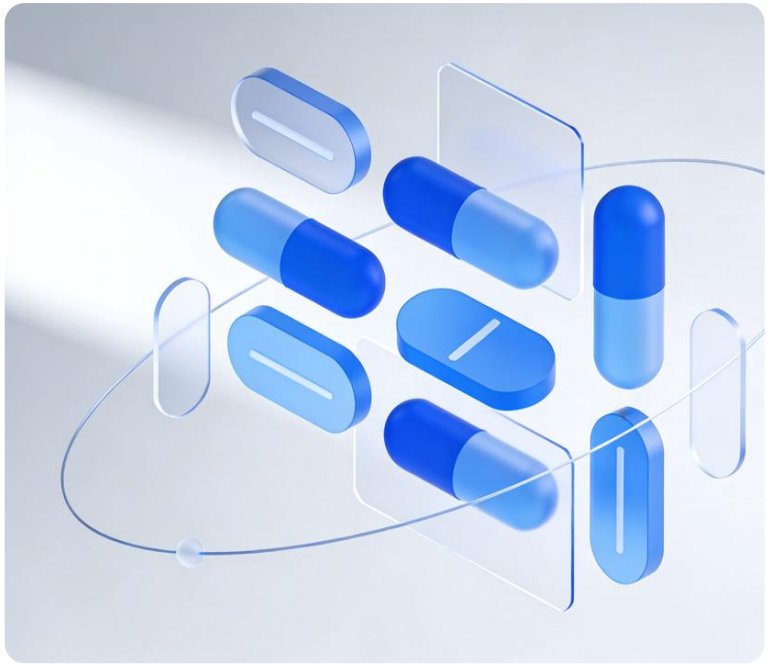
Core Dosage Guidelines

Based on standardized practical experience, we have defined core dosage ranges for each application field to ensure a balance between efficacy and safety in real-world scenarios.

Impact of Purity and Manufacturing Process

We analyzed the influence of raw material purity and production processes on the final effective dosage, providing adjustment basis for optimizing results.

Core Dosage Summary - Pharmaceutical Field



Oral Formulation Recommended Dosage

Single dose: 150-300mg per tablet/capsule
Daily recommended dose: 300-900mg

Topical Formulation Recommended Dosage

Recommended concentration: 2.0% - 5.0%

Usage Instructions & Precautions

Note: Data based on standard purity (St. John's Wort Extract 0.3%-0.5%, Total Flavonoids 5.0%-8.0%). Adjust dosage according to actual raw material purity and optimize through process testing.

Core Dosage Summary - Cosmetic Field



Leave-on products (Serum/Cream/Mask)

Regular: 0.01% - 0.5%
Sensitive skin: 0.01% - 0.1%

Rinse-off products (Cleanser/Body wash)

Regular: 0.1% - 2.0%
Max limit: Not exceed 4.0%

Sunscreen products

Recommended: 0.5% - 1.0%

Core Dosage Summary - Food Field



Antioxidant (0.01% - 0.1%)

Oil & fat: 0.05%-0.1%; Beverages: 0.01%-0.05%.

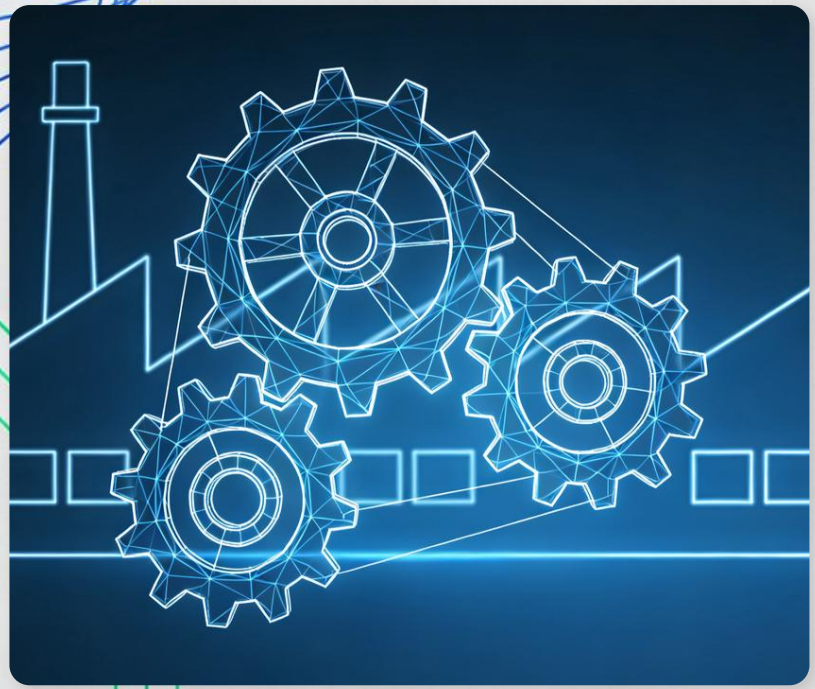
Flavor Enhancer (0.05% - 0.5%)

Adjust dosage based on specific product characteristics.

Functional Food (0.5% - 2.0%)

Daily intake should be strictly controlled ⩽ 500mg.

Core Dosage Summary - Industrial & Other Fields



Wood Preservation
Solution Concentration: 1% - 5%

Leather Industry
Based on leather weight: 0.5% - 2.0%

Chemical Industry
Surfactant 0.1%-1.0% / Adsorbent 1%-10%

Textile Field
Dye 1%-5% / Auxiliary 0.1%-0.5%

Feed Field
Dosage: 0.1% - 0.5%

Supplementary Information: Purity, Storage & Testing



Purity

≥95%. Higher purity allows for lower addition levels. Recommended to use products meeting pharmacopoeia or international standards.

Storage

Cool, dry place, avoid light. Sealed storage required. Shelf life: 24 months.

Testing

HPLC, UV-Vis, microbiological tests, heavy metals, pesticide residues.

THANK YOU!