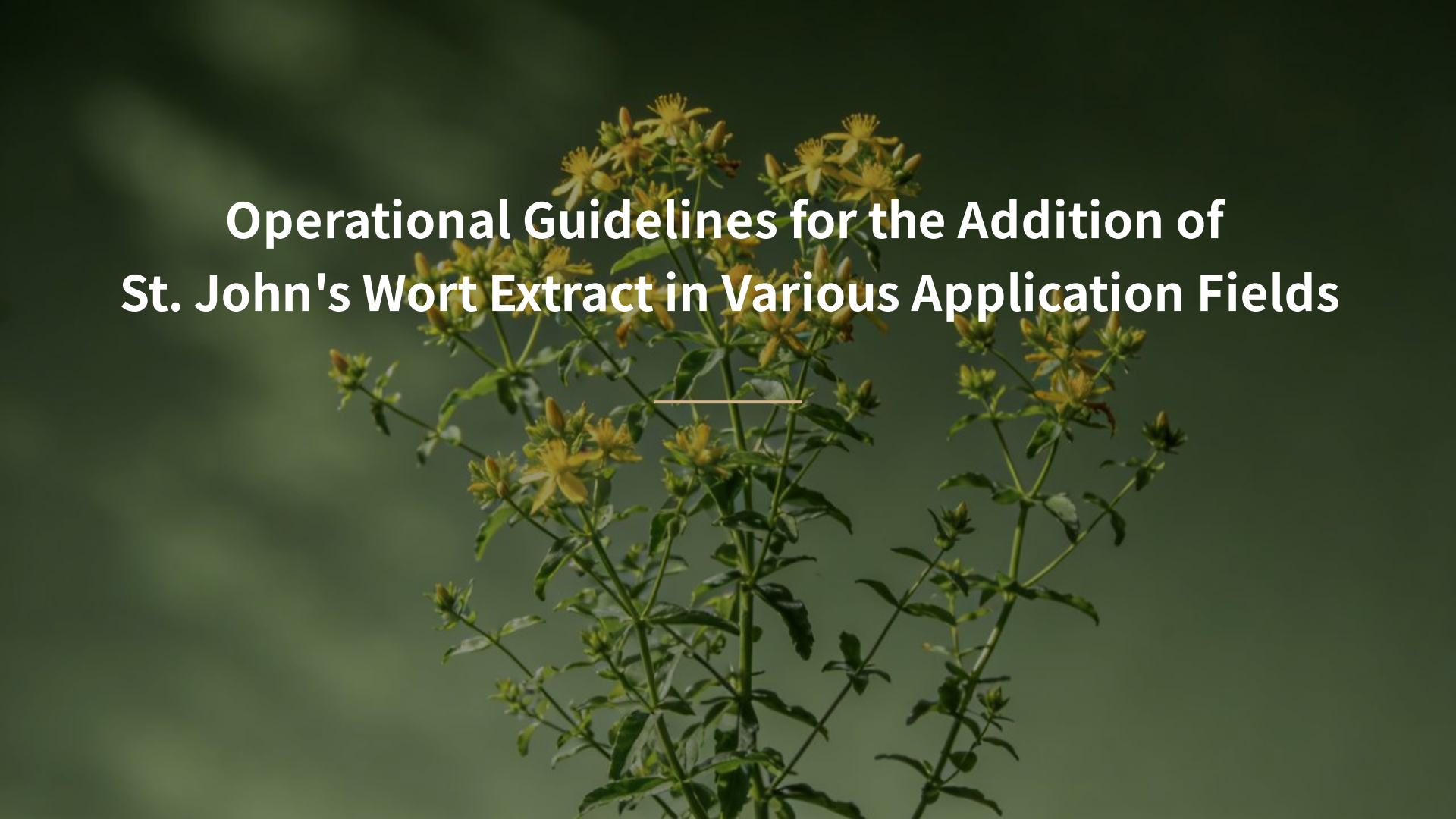


Operational Guidelines for the Addition of St. John's Wort Extract in Various Application Fields

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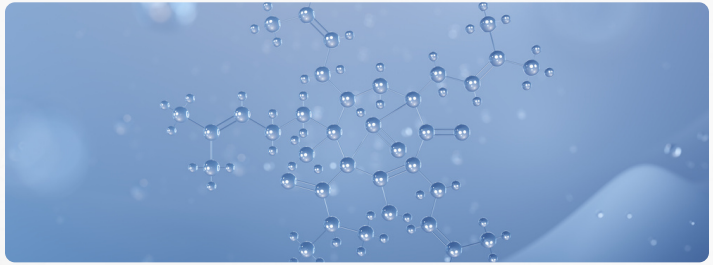
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Scope and Normative References

Scope of Application



This guideline specifies the technical requirements and operational procedures for the addition of St. John's Wort extract in food, health products, cosmetics, feed, and industrial applications.

Normative References

- Pharmacopoeia of the People's Republic of China (2020 Edition)
- GB 17405 National Food Safety Standard - Good Manufacturing Practice for Health Food
- GB 14881 National Food Safety Standard - General Hygiene Specification for Food Production
- Cosmetic Safety Technical Specification (2021 Edition)
- Catalogue of Feed Additives and Relevant Specifications

2. Terms and Definitions

St. John's Wort extract

The dried aerial parts of St. John's Wort are extracted, concentrated, and dried to obtain a powder or liquid, rich in active ingredients such as hypericin.

Hypericin

A naphthodianthrone compound, the main active component of Hypericum perforatum, with significant antiviral and antidepressant effects.



Addition Operation

The process of adding St. John's Wort extract to a product according to a predetermined formula and process to achieve the intended effect.

3. Raw Material Quality Requirements



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Sensory Requirements

The extract should be a fine powder with a characteristic odor, free from impurities and visible foreign matter.

Physical and Chemical Indicators

Hypericin content ⩾ 0.3%, Loss on drying ⩽ 5.0%, Ash ⩽ 5.0%.

Safety Indicators

Heavy metals (Pb, As, Cd, Hg) and microbial limits must comply with the corresponding national standards.

4. Addition Specifications in the Food Sector

Functional Beverages • Baked Foods • Dairy Products

4.1 Compliance Scope and Maximum Usage Levels

Food Category	Usage Level (g/kg)
Functional Beverages, Herbal Teas	0.03 – 0.1
Baked Foods	0.03 – 0.15
Confectionery, Preserves	0.08 – 0.2
Dairy Products	0.03 – 0.08
Alcoholic Beverages (Low Alcohol)	0.05 – 0.1



Illustration: Ingredient preparation process for functional beverages.

4.2 General Operational Procedures

01 Material Collection and Verification

Verify the name, batch number, quantity, and specifications of the St. John's Wort extract to ensure they match the production order.

02 Pre-treatment

Grind and sieve the raw materials to ensure uniform particle size for better dispersion.

03 Pre-dispersion

Dissolve the St. John's Wort extract in ethanol or propylene glycol to create a stock solution for easier incorporation.

04 Addition Process

Add the pre-dispersed St. John's Wort extract solution to the main product batch at the specified stage according to the formula.

05 Homogenization and Filtration

Homogenize the mixture to ensure uniformity and filter out any impurities.

06 Filling and Sterilization

Fill the final product into containers and perform sterilization according to food safety standards.

4.3 Key Process Control Points

Dissolution Temperature Control

Maintain temperature below 45°C to prevent degradation of active ingredients.

pH Value Compatibility Range

Maintain pH between 3.0 and 6.0 for optimal stability.

Incompatibility

Avoid mixing with strong oxidizing agents, which may cause chemical reactions.

Finished Product Storage Conditions

Store in a cool, dry place, protected from light, at a temperature below 25°C.

Dosage Control Standard

The daily intake per person should not exceed 900 mg.



5. Addition Specifications in the Food Sector (Supplement)

5.1 Compliance Scope and Maximum Usage Levels (Supplement)

Functional Beverages, Herbal Teas

Maximum usage: 0.03-0.1 g/kg (calculated as hypericin)

Baked Foods (Bread, Biscuits, Pastries)

Maximum usage: 0.03-0.2 g/kg

Confectionery, Preserves

Maximum usage: 0.08-0.2 g/kg

Dairy Products (Modified Milk, Fermented Milk)

Maximum usage: 0.03-0.08 g/kg

Alcoholic Beverages (Low Alcohol, Fruit Wine)

Maximum usage: 0.05-0.1 g/kg; Note: High alcohol content may cause active ingredient degradation

5.2 General Operational Procedures (Supplement)

01 Material Collection and Verification

Verify name, batch, quantity, and specifications; confirm compliance with requirements.

02 Pre-treatment

Grind to 80-100 mesh; store at 0-4°C before use; avoid high temperature and humidity.

03 Pre-dispersion

Dissolve in anhydrous ethanol or propylene glycol to make a 10-20% solution; avoid direct addition to prevent agglomeration.

04 Addition Process

Add during the cooling phase (≤45°C); control temperature and pH; ensure uniform dispersion.

05 Homogenization and Filtration

Homogenize at 20-30 MPa; filter through a 0.45μm membrane to ensure product clarity.

06 Filling and Sterilization

Use aseptic filling; sterilize at 85°C for 15-20 minutes; avoid excessive heat to prevent active ingredient loss.

5.3 Key Process Control Points (Supplement)

Dissolution Temperature Control

Standard: ⩽45°C

High temperature may cause degradation and discoloration.

pH Value Compatibility

Range: 3.5 – 6.0

Optimal stability for hypericin and flavonoids.

Incompatibility

Avoid: Strong oxidizing agents

Prevent contact with Fe/Cu ions to avoid oxidation.

Finished Product Storage

Condition: Dark, sealed, ⩽25°C

Avoid strong light within 48h after consumption.

Dosage Control Standard

Daily intake: ⩽900 mg

Excessive may cause dizziness or skin itching.



6. Addition Specifications in Health Products

6.1 Applicable Dosage Forms

Tablets, Hard Capsules, Softgels

The most common forms, convenient for carrying and taking, suitable for daily health care.

Granules, Oral Liquids

Easy to absorb, suitable for people with difficulty swallowing tablets or capsules.

Solid Drinks, Teabags

Serve as daily health drinks, convenient and fast, with rich taste, suitable for daily life.



6.2 Dosage and Daily Intake Control for St. John's Wort extract

Daily Intake Upper Limit Control

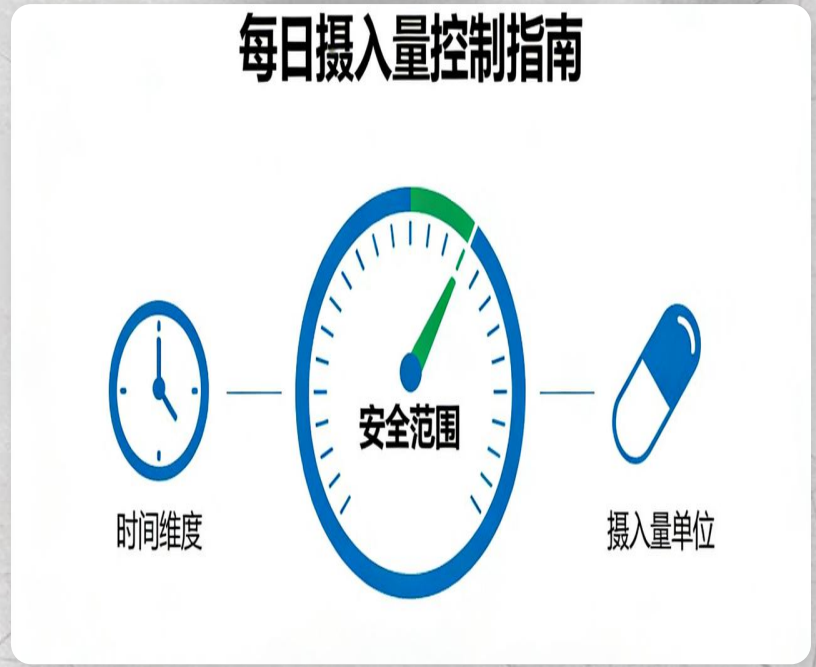
Based on safety standards (>0.3%), the daily intake per person should not exceed 900 mg.

Initial Dosage Recommendation

Start with 500 mg/day, allow the body to adapt gradually, and observe for any adverse reactions.

Formulation Warnings and Contraindications

Avoid use in pregnant or lactating women, children, and individuals with liver dysfunction.



6.3 Operational Requirements

Weighing Accuracy

Accuracy ⩽0.1%, use an analytical balance (0.1mg precision) for St. John's Wort extract.

Mixing Uniformity

Relative standard deviation (RSD) ⩽5%, use a double cone mixer for sufficient mixing of St. John's Wort extract.

Granulation and Tableting

Strictly control temperature and humidity to prevent moisture absorption and active ingredient degradation of St. John's Wort extract.

Label Specification

Clearly mark the St. John's Wort extract name, content, dosage, and warnings as required by regulations.



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7. Addition Specifications in the Cosmetics Sector

7.1 Applicable Product Categories

Toners/Essences

For sensitive skin care, utilizing its soothing and anti-inflammatory properties.

Lotions/Creams

Added to moisturizing and repairing products to enhance the skin barrier function.

Mask Products

Used as a key active ingredient for soothing and calming sun-damaged or irritated skin.

Sunscreen Products

To enhance sun protection and provide anti-inflammatory benefits.

Other Care Products

Such as cleansers and conditioners, utilizing its antibacterial and anti-inflammatory properties.

7.2 Addition Ratios

Daily Anti-allergy and Soothing

0.2% - 3%

Effectively relieves skin sensitivity and discomfort with St. John's Wort extract, suitable for daily use.

Efficacy-based Formulation

Verify before adjustment

After sufficient safety and efficacy verification of St. John's Wort extract, increase to pursue stronger effects.

Sunscreen Formulation

1% - 5%

Auxiliary to enhance overall protection and soothing capabilities with St. John's Wort extract.

7.3 Operational Procedures

Addition Timing Control

Add after the aqueous phase or emulsification is complete and the system temperature has cooled to 40-50°C to ensure the stability of active ingredients.

Dispersion Method Specification

Ensure complete and uniform dispersion of the extract in the system through sufficient stirring or ultrasonic dispersion to avoid localized high concentrations.

Strict pH Control

Maintain the system pH strictly between 4.5 and 6.5, as this range is most conducive to the stability of the St. John's Wort extract's active ingredients.

Incompatibility Avoidance

Avoid mixing with strong alkaline substances and strong reducing agents to prevent chemical reactions that could lead to ingredient failure or product deterioration.

7.4 Quality Control

Sample Retention and Observation

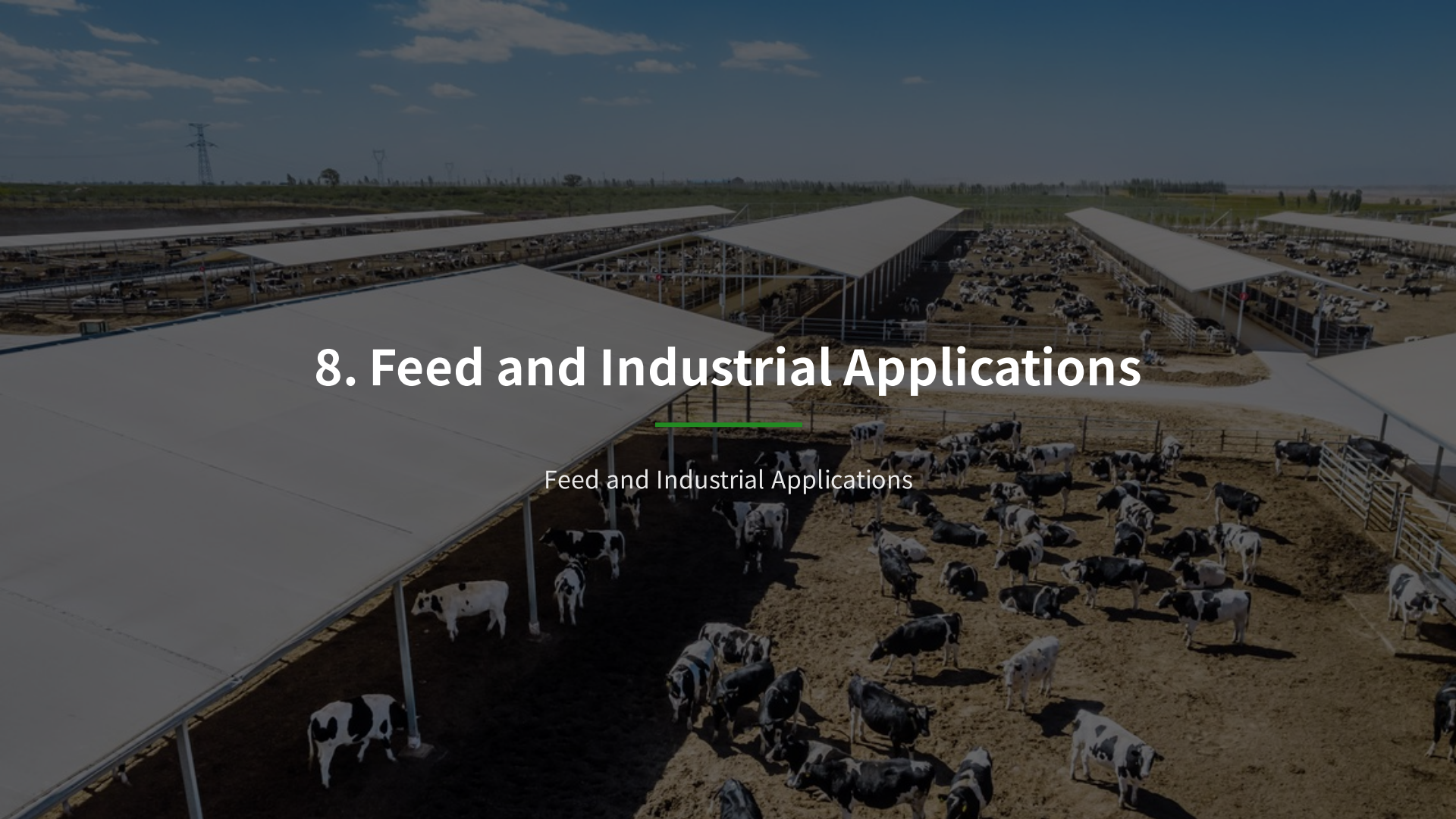
Retain samples of each batch for long-term observation, regularly check for changes in appearance and properties to ensure product stability during the shelf life. Include tests for St. John's Wort extract content.

Testing Requirements

Finished products must undergo stability testing, heavy metal testing, and microbial limit testing to ensure safety and efficacy.

Packaging Requirements

Use light-proof and airtight packaging materials to prevent the degradation of active ingredients and ensure product quality.



8. Feed and Industrial Applications

Feed and Industrial Applications

8.1 Feed Additive - Dosage

Poultry (Chickens, Pigeons)

Prevention
400 g/ton of feed, continuous use

Treatment
50-60 g/ton of feed
continuous use for 3-5 days

Swine

Prevention
100 g/ton of feed

Treatment
200 g/ton of feed
continuous use for 3-5 days

Other Livestock and Poultry

Addition ratio
0.01% - 0.1% of the total feed weight
adjust based on species and growth stage

8.1 Feed Additive - Functions



Immunity Enhancement

Enhances the body's cellular and humoral immunity, improving resistance to bacterial and viral infections.



Disease Prevention

Effectively prevents respiratory and digestive diseases in livestock and poultry, significantly reducing mortality rates.



Production Performance Improvement

Improves feed conversion rate and daily weight gain, enhancing the quality of meat, eggs, and milk products.

8.1 Feed Additive - Process

01. Premix Stage

- Mix the St. John's Wort extract with a small amount of carrier material at a ratio of**1:1000**
- Purpose: To pre-disperse the high-concentration St. John's Wort extract and ensure uniform distribution.

02. Scaling Up Mixing

- Add the pre-mixed St. John's Wort extract to larger batches of feed in stages for sufficient mixing.
- Advantage: Effectively prevents agglomeration and ensures uniform distribution of the St. John's Wort extract in the final product.

8.2 Industrial Applications - Dosage

Textile/Leather Industry

Used as a natural dye and finishing agent; addition level:

0.5% - 2%

Wood Processing Industry

Used for wood preservation and anti-corrosion; addition level:

1% - 5%

Other Industrial Applications

Can be used as a natural antioxidant, dye, or preservative in various industrial processes.

8.2 Industrial Applications - Functions



Textile/Leather Industry

Utilizes its natural color and antibacterial properties; not only for dyeing but also for enhancing the performance of textiles and leather.



Wood Processing Industry

Acts as a natural preservative, enhancing wood durability and significantly extending its service life.



Other Industrial Applications

Can be used as an excellent natural antioxidant or as a raw material for environmentally friendly products, contributing to sustainable development.

8.2 Industrial Applications - Operational Procedures

01. Dissolution and Preparation

Dissolve the St. John's Wort extract in water or organic solvents to prepare a solution of the required concentration for subsequent processing.

02. Impregnation/Spraying

Fully immerse or spray the substrate (e.g., textiles, wood) with the solution to ensure uniform coating.

03. Drying and Curing

Dry under appropriate temperature to evaporate the solvent and allow the active ingredients to adhere to the substrate, forming a stable functional layer.

9. General Operational Safety and Hygiene

Personnel Protection

Wear appropriate protective equipment, such as gloves, masks, and goggles, to prevent direct contact.

Environmental Requirements

Maintain a clean, well-ventilated, and dry operating environment; avoid high temperature and humidity.

Equipment Management

Regularly inspect and maintain equipment to ensure it is clean and in good working condition.

Area Management

Clearly mark production and storage areas; keep them clean and free of contamination.



10. Quality Inspection and Release

Batch Testing Items

Appearance, active ingredient content, loss on drying, ash, heavy metals, and microbial limits.

Sector-Specific Release Standards

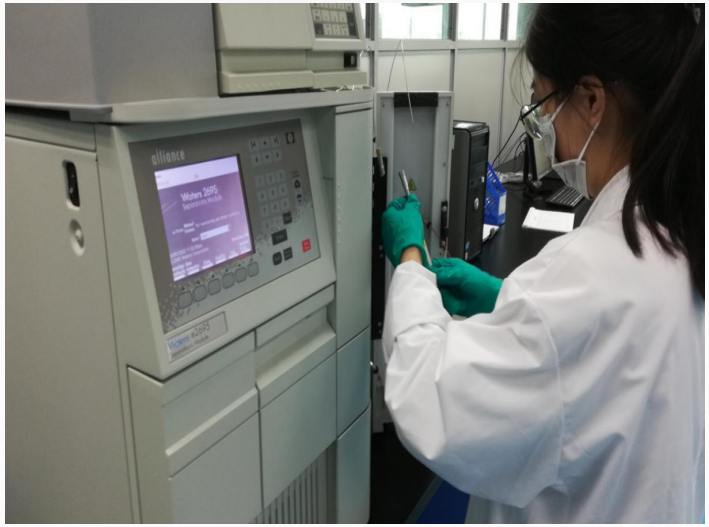
Food/Health Products: Comply with GB 2760, GB 17405, and relevant national food safety standards.

Cosmetics: Comply with the Cosmetic Safety Technical Specification.

Feed/Industry: Comply with relevant national and industry standards.

Non-conforming Product Handling Process

Isolate immediately, identify the cause, recall if necessary, and strictly prohibit from entering the market.



图：质量控制实验室HPLC检测场景

11. Storage and Transportation of St. John's Wort extract

Storage Conditions

Store in a sealed container, in a cool, dry, and well-ventilated place; temperature ⩽25℃, relative humidity ⩽60%; protect from light and moisture.

Storage Requirements

Store different batches separately, manage them by batch number, and strictly follow the first-in, first-out (FIFO) principle.

Transportation Requirements

Maintain transportation temperature between 10-30℃; strictly prohibit mixing with toxic or hazardous substances.



12. Labeling and Marking Requirements

Food/Health Products

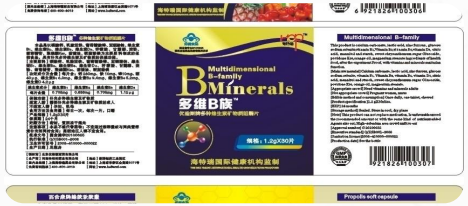
- Product name, ingredient list
- Net content, manufacturer information
- Shelf life, storage conditions
- Warnings and precautions

Cosmetics

- Product name, ingredient list (INCI)
- Manufacturer information
- Usage instructions, warnings
- Production/batch date

Feed/Industrial Products

- Product name, usage instructions
- Storage conditions
- Manufacturer information
- Batch number



13. Emergency and Abnormal Handling

St. John's Wort extract Degradation/Discoloration
Isolate the batch immediately, investigate the cause, and reject non-conforming products.

Uneven Distribution
Recheck the mixing process to ensure complete homogeneity.

Microbial Contamination Risk
Isolate the batch, confirm safety, and dispose of it properly.

Spillage/Contamination
Evacuate the area, clean and disinfect thoroughly, and recall affected products.

Adverse Reaction Handling
Stop using the product, collect feedback, and analyze the cause for optimization.



14. Supplementary Provisions

Application Principle
These guidelines are for reference only; specific products must comply with the latest national and industry standards.

Photosensitivity Warning
The product is photosensitive; avoid prolonged exposure to light during use and storage.

Unsuitable Populations
Not recommended for pregnant or lactating women, children, and individuals with liver dysfunction.

Traceability System
Establish a complete product traceability system to ensure product quality and safety.

Standard Updates
These guidelines will be updated in accordance with the latest national and industry standards.



避光储存


Thank You