



Certificate of Analysis

Product Name	Royal Jelly Extract	Batch Number	4362603
Specification	5%	Expiry Date	June 2021
Plant Part Used	Royal jelly	Active Ingredient Markers	10-HAD

Analysis Items	Specifications	Results	Test Methods
Organoleptic			
Appearance & Color	Fine off-white or light yellow powder	Conforms	Visual
Odor & Taste	Characteristic	Conforms	Organoleptic
Solubility	Partially soluble in water	Conforms	Visual
Marker Compounds			
Assay	NLT 5% 10-HDA	5.02%	HPLC
Physical Characteristics			
Mesh Size	NLT 95% through 100 mesh	Conforms	100 Mesh Screen
Bulk Density	0.45-0.65g/ml	Conforms	CP2015
Other			
Chloramphenicol	NMT 0.3ppb	Conforms	USP
5-Nitofuran	NMT 0.5ppb	Conforms	USP
Heavy metals			
Total Heavy Metals	NMT 10ppm	Conforms	CP2015
Microbiological Tests			
Total Plate Count	NMT 10,000cfu/g	Conforms	GB.4789.2
Total Yeast & Mold	NMT 1000cfu/g	Conforms	GB.4789.15
E. Coli	Negative	Conforms	GB.4789.38
Salmonella	Negative	Conforms	GB.4789.4
Staphylococcus	Negative	Conforms	GB.4789.10
GMO	Non-GMO		
Vegan Suitability	Yes		
Storage	Store in a well-closed container away from moisture.		



Allergen Statement

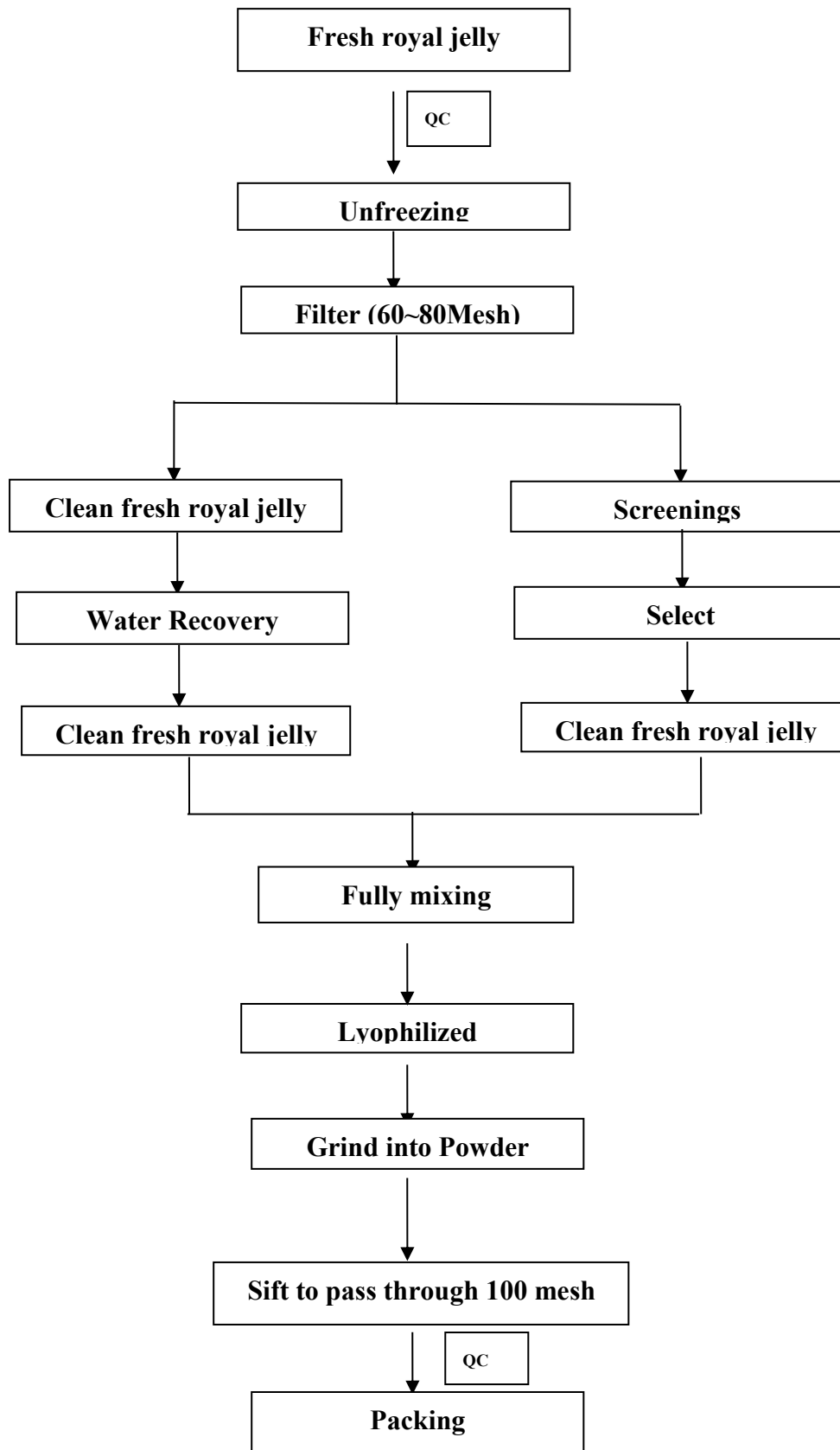
Product: Royal Jelly Extract 5%

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Reference:

Category of food allergen	Presence (Yes / No)	Comment
Celery (deleriac) and derivatives	No	
Egg's and derivatives	No	
Milk and derivates	No	
Peanut and derivates	No	
Soybean / Soya bean and derivatives	No	
Sulfites (concentration > 10 mg/kg)	No	
Wheat (gluten)	No	
Dairy(lactose) and derivatives	No	
Seafood and derivatives	No	
Sesame and derivatives	No	
Treenuts and derivatives	No	
Crustaceans and derivatives	No	
fish and derivatives	No	
Molluscs and derivatives	No	
Lupin and derivatives	No	
Mango and derivatives	No	
Mustard and derivatives	No	
Kiwi and derivatives	No	

Manufacturing Process Sketch Of Royal Jelly Powder



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NON-GMO & VEGAN STATEMENT

WE, MADAR CORPORATION, CERTIFY THAT THE
PRODUCT:

ROYAL JELLY EXTRACT 5% 10-HDA

- IS 100% NATURAL EXTRACT POWDER AND GMO FREE PRODUCTS.
- IS NOT SUITABLE FOR VEGANS.

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Material Safety Data Sheet

1. PRODUCT NAME AND COMPANY IDENTIFICATION

Product Name: Royal Jelly Powder 5% 10-HDA
Product Use: Food addition, etc.
Company Name: MADAR Corporation Limited
Company Address: 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire,
SP6 1PA
Date Issued: 2/06/2020
Emergency Telephone Number: +44 1425 655555 (during office hours)

2. COMPOSITION/INGREDIENT INFORMATION

Chemical Identity: Royal Jelly Powder
Hazardous Components: None
Exposure Limits: N/A
CAS #: 8031-67-2

3. HAZARDS IDENTIFICATION

Routes of Entry:

- Eyes
- Inhalation
- Ingestion

Eye Contact: Slight Irritant
Skin Contact: Not hazardous
Ingestion: Not hazardous
Inhalation: Slight Irritant

4. FIRST AID MEASURES

Eyes: Flush with plenty of water or eye wash solution for 15 minutes. Get medical attention if irritation persists.
Skin: Wash with soap and water - get medical attention if irritation occurs.
Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Medical Conditions Generally Aggravated by Exposure: None

5. FIRE FIGHTING MEASURES

Flash Point (Method Used):	Not Established
Flammable Limits	LEL: Not Established UEL: Not Established
Auto Ignition Temperature:	Not Available
Hazardous Combustion Products:	None
Conditions Under Which Flammability Could Occur:	May be combustible at high temperatures. <ul style="list-style-type: none"> • Dry Chemical • Carbon Dioxide
Extinguishing Media:	
Special Firefighting Procedures:	Note: Do not use water except to cool containers. <ul style="list-style-type: none"> • Combustible material. Limit the spread of oil. • Use air supplied equipment for fighting interior fires. • Cool fire exposed containers with water spray.
Unusual Fire & Explosion Hazards:	Organic dusts can form explosive mixtures in air.

6. ACCIDENTAL RELEASE MEASURES (STEPS FOR SPILLS)

Personal Protection:	Use appropriate respiratory protection to avoid breathing casual vapors.
Environmental Protection:	Notify authorities if large amounts of product enters sewer. <ul style="list-style-type: none"> • Absorb onto an inert, absorbent substrate and sweep up.
Methods for Cleaning Up:	<ul style="list-style-type: none"> • Wash area with soap and water. Area may be slippery; take precautions.

7. HANDLING AND STORAGE

Handling	
Safe Handling:	<ul style="list-style-type: none"> • Wear safety glasses. • Keep away from oxidizing agents, excessive heat and sources of ignition.
Storage	
Requirements for Storage Areas and Containers:	Store in a cool, dry location, in a sealed container in a well ventilated area.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls:	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
Personal Protection	
Eye:	Safety glasses should be worn.
Skin/Body:	Lab coats and gloves may be worn.
Respiratory:	Not needed under normal conditions of use. Use adequate ventilation or NIOSH-approved respiratory devices if required for application.
Ventilation:	Handle in well ventilated areas.

Other:

Evaluate need based on application. Slip proof shoes may be worn where spills may occur.

Work/Hygiene Practice:

Normal work and hygiene practices for handling non-hazardous liquid material.

9. PHYSICAL AND CHEMICAL PROPERTIES Physical

State:	Powder
Color:	Off-white or light yellow
Odor:	Characteristic
Specific Gravity (H ₂ O = 1):	Not Available
Acid Value: (% oleic)	Not Available
Vapor Pressure (mm Hg.):	Not Available
Vapor Density (AIR = 1):	Not Available
Flash Point:	Not Available
Boiling Point:	Not Available
Melting Point:	N/A
Evaporation Rate:	N/A
Solubility in Water:	N/A

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	Avoid excessive heat
Incompatibility (Materials to Avoid):	Avoid strong oxidizers
Hazardous Decomposition or Byproducts:	None (Thermal decomposition products are H ₂ O and CO ₂)
Hazardous Polymerization:	Will Not Occur

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Exposure:	Not Available
Toxicity Data:	Not Available
Medical Conditions Generally Aggravated by Exposure:	None
Irritancy:	Skin: Not expected to be an irritant Eyes: Slight irritant
Carcinogenicity:	Not Available
Reproductive Toxicity:	Not Available
Teratogenicity:	Not Available
Mutagenicity:	Not Available
Name of toxicologically synergistic products:	N/A

12. ECOLOGICAL INFORMATION

Ecological Information:	No ecological hazards are associated with this product.
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13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods:	Do not put into sewer lines. Dispose of according to local, state and federal regulations.
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14. TRANSPORT INFORMATION

DOT Classification:	Not regulated
IATA:	Not regulated
IMDG:	Not regulated

15. REGULATORY INFORMATION

HMIS Classification: Health: 1 Fire: 1 Reactivity: 0 Personal Protection: a

16. ADDITIONAL INFORMATION

This information is provided for documentation purposes only.
This product is not considered hazardous.

The complete range of conditions or methods of use are beyond our control therefore we do not assume any responsibility and expressly disclaim any liability for any use of this product. Information contained herein is believed to be true and accurate however, all statements or suggestions are made without warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local laws and local regulations remains the responsibility of the user.

This safety sheet cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined to determine if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers.



Specification Sheet

Product Name	Royal Jelly Extract	Plant Part Used	Royal Jelly
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Analysis Items	Specifications	Test Methods
Organoleptic		
Appearance & Color	Fine off-white or light yellow powder	Visual
Odor & Taste	Characteristic	Organoleptic
Solubility	Partially soluble in water	Visual
Marker Compounds		
Assay	NLT 5% 10-HDA	HPLC
Physical Characteristics		
Mesh Size	NLT 95% through 100 mesh	100 Mesh Screen
Bulk Density	0.45-0.65g/ml	CP2015
Heavy metals		
Total Heavy Metals	NMT 10ppm	CP2015
Microbiological Tests		
Total Plate Count	NMT 10,000cfu/g	GB.4789.2
Total Yeast & Mold	NMT 1000cfu/g	GB.4789.15
E. Coli	Negative	GB.4789.38
Salmonella	Negative	GB.4789.4
Staphylococcus	Negative	GB.4789.10
Packing and Storage	Packed in sealed aluminum foil bags lined with plastic seal or sealed double plastic bags. Store in a well-closed container away from moisture.	
Shelf Life	2 years if sealed and store away from direct sun light.	

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TECHNICAL DATA SHEET OF ROYAL JELLY EXTRACT 5% (TDS)

TDS Format for Herbal Active	Documentation required
3.2.S.1. General Information 3.2.S.1.1. Nomenclature	Royal Jelly Extract
Royal Jelly Extract	Source of leaves Royal Jelly Extract from Royal jelly
3.2.S.1.2. Structure Physical form	Powder
Description of the constituents with known therapeutic activity or markers	C ₁₀ H ₁₈ O ₃ 10-HDA
3.2.S.1.3. General properties	<p>Substance: [source] from royal Jelly [Chemical composition] 10-HDA. Herbal preparations properties: 1、 Physical Properties</p> <p>Boiling Point / Igniting point / Flash Point / Explosion Point / Bulk Density 0.3-0.8g/ml Solubility Partially soluble in water</p> <p>2、 Chemical Properties: Typical properties of royal Jelly Extract Form :Fine Powder Color : off white or light yellow powder Odor : Characteristic</p>

3.2.S.2. Manufacturer (s) 3.2.S.2.1. Manufacturer of raw material	CONFIDENTIAL
3.2. S.2.2. Description of critical steps and Intermediates	OPEN PART: Only flow chart and schematic Information: See appendix 1 Detailed information included in restricted part of the EDMF
3.2.S.2.3. Control of materials	Detailed information included in restricted part of the EDMF
3.2.S.2.4. Control of critical steps and Intermediates	OPEN PART: Only flow chart and schematic Detailed information included in restricted part of the EDMF
3.2.S.2.5. Process validation and/or Evaluation	Detailed information included in restricted part of the EDMF
3.2.S.2.6. Manufacturing process Development	Detailed information included in restricted part of the EDMF

3.2.S.3. Characterization 3.2.S.3.1. Elucidation of structure and other characteristics	<p>The royal jelly is a kind of special milk - like substance secreted by the head nutrition gland (tongue gland and jaw) of 5 - 15 days old worker bee used for feeding queen bee and larva , also known as bee milk , royal jelly and the like .[1]</p> <p>royal jelly contains rich nucleic acid .If the content of nucleic acid in the human body is insufficient, it will affect the division of cells, cause cell defects, slow protein synthesis, and lead to body damage, pathological changes, aging.Taking royal jelly is one of the best ways to get ribonucleic acid. It can make the nucleic acid in the human body be replenished, thus delaying the aging process and prolonging the life span of human beings. The theory of free radical senescence holds that human aging is due to the excessive production and accumulation of free radicals in human body. Only by eliminating these excessive free radicals can health be guaranteed.[2]</p>
3.2.S.3.2. Impurities	<p>Potential impurities arising during the production and purification</p> <p>Analytical test procedures and their limits if detection</p> <p>Conclusions</p>
3.2.S.4. Control of drug substance	Specification for extraction substance and according the specification
3.2.S.4.1. Specification	
3.2.S.4.2. Analytical procedure	Description of the methods used to obtain the specification (when possible according to European Pharmacopoeia) HPLC
3.2.S.4.3. Batch analysis	Three COA for Herbal drug, for the production intermediates and for the herbal preparations taking into account the traceability between them.
3.2.S.4.4. Justification of specification	5% 10-HDA
3.2.S.5. Reference standards of material	Certificates for the standards used in the analytical determinations CHP2015
3.2.S.6. Container closure system	Certificate of analysis for the material used as Container pharmaceutical grade
3.2.S.7. Stability	

3.2.S.7.1. Stability summary and conclusion	Stability conditions and parameters (ICH) Normal Evaluation of the result and proposed period of validity. Parameters measured: –Physical appearance Fine off white or light yellow powder -Assay HPLC NLT 5% 10-HDA –Microbiology Total Plate Count NMT 10,000cfu/g Total Yeast & Mold NMT 1000cfu/g E. Coli Negative Salmonella Negative Staphylococcus Negative
3.2.S.7.2. Post-approval stability protocol and stability commitment	Do you have a test program on-going for a longer period? At least for one batch Stability data of one batch See appendix

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Appendix

Stability data of one batch(Feb 07, 2015~Feb 06,2017)

Analysis Items/ Test Date	Feb 07, 2015	May 07, 2015	Aug 05, 2015	Nov 04, 2015	Feb 05, 2016	Aug 06, 2016	Feb 05, 2017
Appearance & Color	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder
Odor & Taste (Characteristic)	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Heavy Metals (NMT 100ppm)	NMT10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm
Assay (NLT 5% 10-HDA)	5.03%	5.02%	5.01%	5.01%	5.02%	5.02%	5.01%
Total Plate Count (NMT 10,000cfu/g)	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g
Total Yeast & Mold (NMT 1000cfu/g)	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g
E. Coli (Negative)	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Salmonella (Negative)	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Staphylococcus (Negative)	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Packing and Storage	Packed in sealed aluminum foil bags lined with plastic seal or sealed double plastic bags. Store in a well-closed container away from moisture						
Shelf Life	2 years if sealed and store away from direct sun light.						

References:

- (1) 方国桢. 蜂王浆成分及其分析方法研究进展. 中国乳品工业, 1994,6:2-4.
- (2) 蔡柳, 林亲录,蜂王浆的研究进展, 中国食物与营养. 2007, 8: 20-22.