




TECHNICAL DATA PACKAGE

MELATONIN

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PRODUCT SPECIFICATION SHEET

IDENTIFICATION		
NAME	MELATONIN	
INCI Name	N-(2-(5-methoxyindol-3-y)-ethyl)acetamide	
SHELF LIFE	2 Years / 24 Months	
MOLECULAR FORMULA	C13H16N2O2	
MOLECULAR WEIGHT	232.28	
CAS NUMBER	73-31-4	
COUNTRY OF ORIGIN	China	
PHYSICAL & CHEMICAL ANALYSIS		
PARAMETER	SPECIFICATION	METHODS
1 APPEARANCE	White or off-white crystalline powder	USP 38
2 IDENTIFICATION	Complies Complies Complies	IR USP 38 UV USP 38 HPLC USP 38
3 LOSS ON DRYING	NMT 1.0%	USP 38
4 MELTING POINT	116°C – 118°C	USP 38
5 RESIDUE ON IGNITION	NMT 0,1%	USP 38
6 MESH OF THE PRODUCT	80	-
7 ASSAY (on dry basis)	NLT 98.5%- NMT 101.5%	HPLC
MICROBIOLOGICAL CONTROL		
PARAMETER	SPECIFICATION	METHODS
TOTAL AEROBIC MICROBIAL COUNT (TAMC)	NMT 1000 CFU/g	USP 38
TOTAL COMBINED YEASTS & MOULDS COUNT (TYMC)	NMT 100 CFU/g	USP 43/ EP 10
E. COLI	Absent/g	USP 43/ EP 10
SALMONELLA	Absent/25g	USP 43/ EP 10
CONTAMINANTS		
PARAMETER	SPECIFICATION	METHODS
HEAVY METALS		
LEAD (Pb)	NMT 0.5 ppm	USP 38
CADMIUM (Cd)	NMT 0.1 ppm	USP 38
MERCURY (Hg)	NMT 0,1 ppm	USP 38
ARSENIC (As)	NMT 0.5 ppm	USP 38
CHLORIDE AND SULFATE	NMT 0.02%	USP 38
INDIVIDUAL IMPURITY	NMT 0.1%	USP 38
TOTAL IMPURITY	NMT 1.0%	USP 38
SOLVENT RESIDUE	Negative	USP 43/ EP 10
ETO RESIDUE	Negative	EU Regular
<p><u>STORAGE CONDITIONS:</u> Dry and cold place.</p> <p><u>MANUFACTURING SITE:</u> THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT 904 FORTUNE PLAZA, CHANG'AN DISTRICT, HEBI, CHINA. TO MEET SUANFARMA SPECIFICACIONS.</p>		
<p>  José Manuel Crespo Quality Head - Nutra Division SUANFARMA </p>		

ALLERGEN STATEMENT

We, Suanfarma, hereby declare the absence or presence of each allergen or intolerance according to the major Food Allergens specified in the US Federal Law of Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and EU Directive 2003/89/CE amending EU Directive 2000/13/CE in the table below for **MELATONIN**:

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES as per Annex II of FIC regulation	Direct incorporation as a base raw material or in derivative form (including the carriers, the additives, and the processing aids)		Presence on the production line		Presence in the productions workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise nature)	No	Yes (precise nature)	No	Yes (precise nature)	No
Cereals containing gluten (1) and products thereof		X		X		X		X
Crustaceans and products thereof		X		X		X		X
Eggs and products thereof		X		X		X		X
Fish and products thereof		X		X		X		X
Peanuts and products thereof		X		X		X		X
Soybeans and products thereof		X		X		X		X
Milk and products thereof (including lactose)		X		X		X		X
Nuts (2) and products thereof		X		X		X		X
Celery and products thereof		X		X		X		X
Mustard and products thereof		X		X		X		X
Sesame seeds and product thereof		X		X		X		X
Suphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/l expressed as SO ₂		X		X		X		X
Lupin and products thereof		X		X		X		X
Mollusc and products thereof		X		X		X		X

NOTES TO THE TABLE:

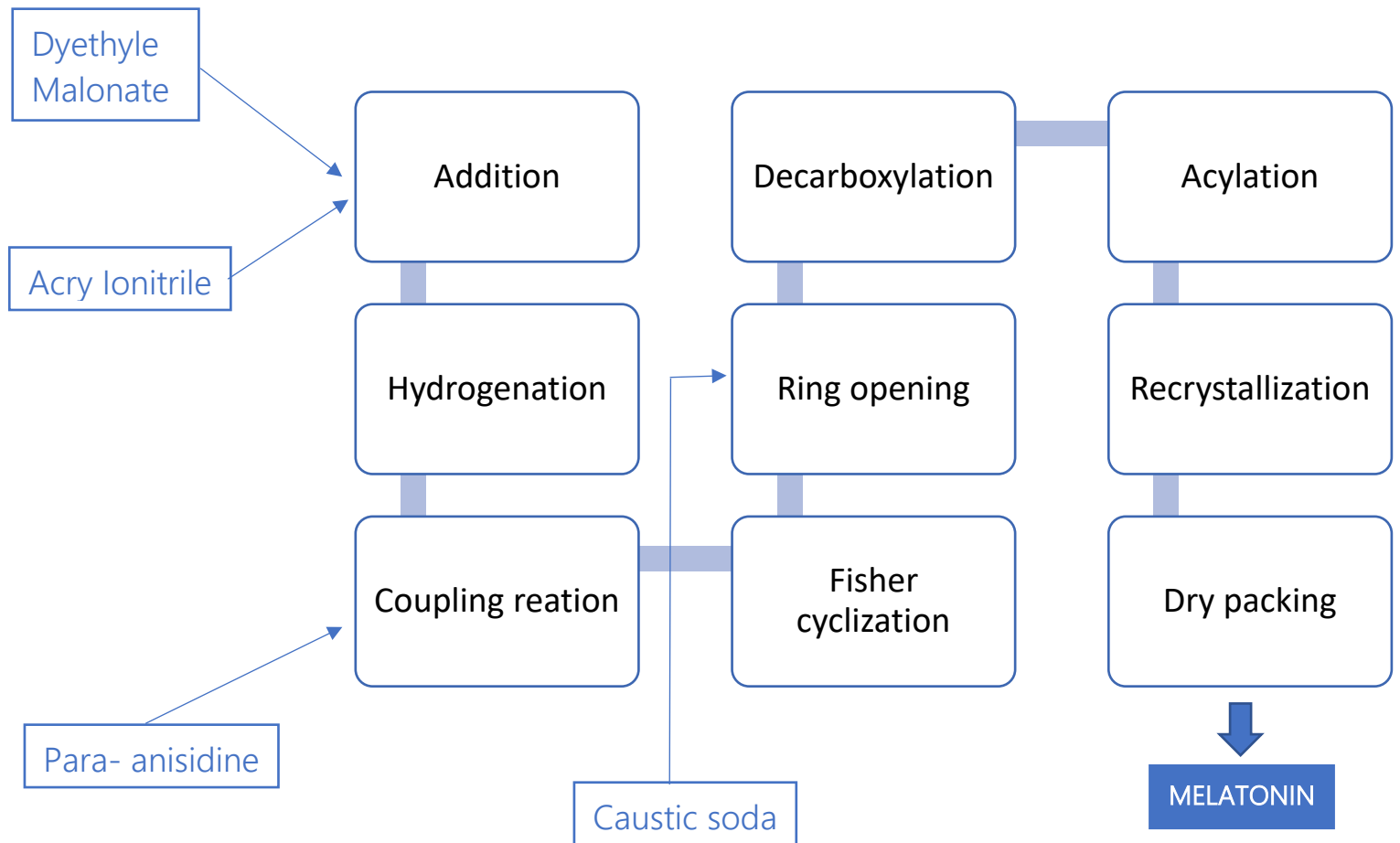
- (1) Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof, except:
- Wheat based glucose syrups including dextrose.
 - Wheat based maltodextrin.
 - Glucose syrups based on barley.
 - Cereals used for making alcoholic distillates including ethyl alcohol of agriculture origin.
- (2) Namely, almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Junglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin.



José Manuel Crespo
Quality Head – Nutra Division
SUANFARMA

MANUFACTURING PROCESS FLOW CHART

Product Name: MELATONIN



SAFETY DATA SHEET
(According to Regulation 453/2010)

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

1.1 Product Identifier:

Product Name: MELATONIN
 Synonym: N-Acetyl-5-methoxytryptamine
 CAS Number: 73-31-4
 Chemical Formula: C₁₃H₁₆N₂O₂

1.2 Supplier details:

Supplier Name: Suanfarma, Inc.
 17-09 Zink Place, Unit 7, Fair Lawn,
 NJ 07410, USA
 Phone: +1-201-343-1188
 Fax: +1-201-343-1102
 E-mail: adminus@suanfarma.com

1.3 Emergency number:

CHEMTREC (24hr Access) 800-424-9300
 International CHEMTREC, call: +1-703-527-3887

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification

The product is not classified hazardous according to the Regulation (EC) 1272/2008 and the Council Directives 67/548/EEC and 1999/45/EEC.

This substance is not classified as dangerous according to Directive 67/548/EEC.

Label elements: The product does not need to be labelled in accordance with EC directives or respective national laws.

Other hazards: None

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Component

Substance	Melatonin
CAS	73-31-4

SAFETY DATA SHEET
(According to Regulation 453/2010)**SECTION 4: PRECAUTIONS FOR SAFE HANDLING AND USE****General advice:**

Consult a physician. Show this safety data sheet to the doctor in attendance.

Eyes:

Flush eyes with water as a precaution.

Skin:

Wash off with soap and plenty of water. Consult a physician.

Serious skin contact:

Not available.

Inhalation:

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Serious inhalation:

Not available.

Ingestion:

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Most important symptoms and effects, both acute and delayed:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Indication of any immediate medical attention and special treatment needed:

No data available.

SECTION 5: FIRE AND EXPLOSION HAZARD DATA**Extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NOx)

Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

Further information

No data available

SAFETY DATA SHEET
(According to Regulation 453/2010)**SECTION 6: ACCIDENTAL RELEASE MEASURE****Personal precautions**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

Environmental precautions

Do not let product enter drains.

Small spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow evacuating through the sanitary system.

SECTION 7: HANDLING AND STORAGE**Precautions for safe handling**

Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Conditions for safe storage

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Light sensitive.

SECTION 8: EXPOSURE CONTROLS & 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:

Safety glasses. Lab coat. Dust respirator. Be sure to use an approved / certified respirator or equivalent. Gloves.

Personal Protection in case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.

Exposure limits:

Not available.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

SAFETY DATA SHEET
(According to Regulation 453/2010)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

Appearance	White or off-white crystalline powder
Boiling point	N.A.
Melting point	about 116-118 °C
Vapor pressure	N.A.
Vapor density	N.A.
Molecular weight	232.28 g/mol
Particle size	80 mesh
Bulk Density	about 0,45- 0.50 g/ml
Solubility	Insoluble in cold water

SECTION 10: STABILITY AND REACTIVITY DATA

Chemical stability

Stable under recommended storage conditions.

Conditions to avoid

No data available

Materials to avoid

Strong oxidizing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides (NOx)

Hazardous Polymerization:

Will not occur.

SAFETY DATA SHEET
(According to Regulation 453/2010)**SECTION 11: HEALTH HAZARDOUS****Routes of entry:**

Inhalation. Ingestion.

Toxicity to animals:

LD50: Not available. LC50: Not available.

Chronic effects on humans:

Not available.

Other toxic effects on humans:

Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special remarks on toxicity to animals:

Not available.

Special remarks on chronic effects on humans:

Not available.

Special remarks on other toxic effects on humans:

Acute potential health effects: May cause skin irritation. May cause eye irritation. Inhalation: This material may produce dust. Breathing in large amounts may be harmful. May cause respiratory tract irritation. Ingestion: May cause gastrointestinal tract disorders. Signs and symptoms of exposure through inhalation or ingestion may include: mouth and throat irritation (soreness, dry or scratchy feeling, cough), stomach or intestinal upset (nausea, vomiting, diarrhea). The toxicological property is this substance has not been fully investigated.

SECTION 12: ECOLOGICAL INFORMATION**Ecotoxicity:**

Not available.

BOD5 and COD:

Not available.

Products of biodegradation:

Possibly hazardous short term degradation products and not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation:

The product itself and its products of degradation are not toxic.

Special remarks on the products of biodegradation:

Not available.

SAFETY DATA SHEET
(According to Regulation 453/2010)**SECTION 13: DISPOSAL CONSIDERATIONS****Waste Disposal:**

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste.

US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

SECTION 14: TRANSPORT INFORMATION**ADR/RID**

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

DOT Classification

Not a DOT controlled material (United States)

Special Provisions for transport:

Not applicable.

SECTION 15: REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible FST usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

EC Classification:

Not assigned an overall EC classification.

WHMIS (Canada):

Not controlled under WHMIS (Canada).

SAFETY DATA SHEET
(According to Regulation 453/2010)**SECTION 16: OTHER INFORMATION**

This information is based upon the present state of our knowledge. This SDS had been compiled and is solely intended for this product.

Employers should use this information only as a supplement to other information gathered by them and should make independent judgement of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty and any use of the product not in conformance with this Safety Data Sheet or in combination with other product or process is the responsibility of the user.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use, users should make their own investigations to determine the suitability of the information for their purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

ADDITIONAL INFORMATION

We, SUANFARMA, hereby declare that the MELATONIN is manufactured in accordance with the following guidelines:

- Name: MELATONIN
- The above material is manufactured in China.
- No animal derived products have been used in the manufacture of the above material, making it free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform encephalopathy (TSE).
- The above material has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free.
- The above material complies with the pesticide limits set forth by Reg 396/2005/EC.
- The residual solvent of the above material complies with Directive 2009/32/EC and Directive 2010/59/EU.
- The above material is free of nanoparticle and/or substances stem from nanotechnologies.
- The above material complies with California Proposition 65 Compliance and is safe for human consumption.
- The above material is free from Melamine and PCB's.
- The above material is suitable for vegetarian and vegan consumption.
- The above material does not contain any ingredient specified in EU Directive 2003/89/CE amending EU Directive 2000/13/CE: wheat, rye, barley, oat, spelt, kamut, crustacean, egg, fish, peanut, soybean, milk, nuts (almonds, hazelnuts, walnuts, cashew, pecan nuts, Brazil nuts, pistachio nuts, macadamia), celery, mustard, sesame seeds, lupin, molluscs and products made thereof.
- The above material has not been irradiated per 7 CFR 205.105(1) requirements with understanding that "irradiation" shall be defined as outlined in 21 CFR 179.26.
- The above material does not contain nor come in contact with gelatine, gelatine derived material, collagen and/or collagen derived material.
- The above material has been affirmed as GRAS by FDA, when used within the limitations set forth in 21 CFR 172.510.
- The above material and its raw material have not been treated with ethylene oxide (ETO) or any other chemical sterilization agent.
- At no point in the process is the above material is manufactured, handled, or comes in contact with sewage sludge, as defined in 7 CFR 205.105(g).
- The above material neither contains nor comes in contact with banned substances listed by WADA.
- The above material is Kosher and Halal certified.

The MELATONIN is composed by the following:

- Min 99% Melatonin

Typical nutritional data for the above material are as follows:

PARAMETER	RESULT	UNITS
Energy	0	kCal/100g
Protein	0	g/100g
Fat	0	g/100g
Carbohydrates	0	g/100g



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