

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## MELATONINUM

EN

FORM-06-14-01 (V00)

Page 1/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name:	Melatonin Melatoninum Melatonine Mélatonine Melatonin
N° CAS:	73-31-4
N° EC:	200-797-7

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
------------------	--

#### 1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreatipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

#### 2.3 Other hazards

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



## MELATONINUM

This substance/mixture does not contain any components that can be considered persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Product name:	Melatonin
IUPAC name:	<i>N</i> -[2-(5-methoxy-1 <i>H</i> -indol-3-yl)ethyl]acetamide
Synonyms:	Circadin <i>N</i> -(2-(5-methoxyindol-3-yl)ethyl)acetamide
N° CAS:	73-31-4
N° EC:	200-797-7
Molecular Formula:	C <sub>13</sub> H <sub>16</sub> N <sub>2</sub> O <sub>2</sub>
Content:	It contains not less than 98.0 per cent and not more than 102.0 per cent, calculated with reference to the anhydrous substance.

#### 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	Consult a physician. Show this safety data sheet to the doctor in charge.
After inhalation:	In case of inhalation, move the victim to fresh air. If breathing has stopped, give artificial respiration. Consult a physician.
After skin contact:	Wash up with soap and plenty of water. Consult a physician.
After eye contact:	Flush eyes with water as a precaution.
After ingestion:	Never let an unconscious person drink (or eat). Rinse mouth with water. Consult a physician.

#### 4.2 Most important symptoms and effects, both acute and delayed

The main known symptoms and effects are described on the label (see section 2.2) and/or section 1.1

#### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Use water spray, alcohol-resistant foam, dry chemical powder, or carbon dioxide.
Unsuitable extinguishing media:	Not available.

#### 5.2 Special hazards arising from the substance/mixture

Not available.

#### 5.3 Advice for firefighters

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 3/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



## MELATONINUM

Surrounding fires:	Not available.
Protection against fire:	If necessary, wear a compressed air mask when fighting a fire.
Hazardous combustion products:	Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### For non-emergency personnel

Use personal protective equipment. Avoid dust formation. Avoid inhaling fumes/mist/gas. Avoid breathing dust. For personal protection, see section 8.

##### For emergency responders

Use personal protective equipment. Avoid dust formation. Avoid inhaling fumes/mist/gas. Avoid breathing dust. For personal protection, see section 8.

#### 6.2 Environmental precautions

Do not allow product to reach sewage system.

#### 6.3 Methods and material for containment and cleaning up

Pick up and remove without creating dust. Sweep up and scoop out. Store in suitable and closed containers for disposal.

#### 6.4 Reference to other sections

For waste disposal, see section 13.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Avoid formation of dust and aerosols. For precautionary measures, see section 2.2
Personal protection:	Not available.
Technical protective measures:	Provide suitable exhaust ventilation in places where dust is generated.
Handling:	Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a dry and well-ventilated place. Store in a cool place. Recommended storage temperature: 2 - 8 °C.
Storage – away from:	Protected from light.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

The product does not contain any components for which exposure values have been established.

#### 8.2 Exposure controls

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 4/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



## MELATONINUM

### Appropriate engineering control

Use according to established rules and practices regarding industrial hygiene and safety. Wash hands before breaks and at the end of the working day.

### Individual protection measures

Eye/face protection:	Use face and/or eye protection tested and approved by official bodies such as NIOSH (US) or EN166 (EU).
Skin protection:	Select protective clothing according to the type, amount and concentration of hazardous substances, and the specific workplace. The type of protective equipment depends on the concentration and amount of hazardous substances at the workplace in question.
Hand protection:	Handle with gloves. Check gloves thoroughly before use. Take off gloves neatly without touching the outside with the bare hand. Immediately dispose of used gloves in accordance with applicable laboratory regulations. Wash and dry hands. The selected protective gloves must comply with the specifications of EU Directive 89/686 / EEC and the standard EN 374 derived from it.
Respiratory protection:	Face mask is not required. Wear protection and a dust mask type N95 (US) or type P1 (EN 143), if a certain nuisance/value is observed and/or dust particles do not fully comply. Use respiratory masks tested and approved by official government agencies such as NIOSH (US) or CEN (EU).
Thermal hazards:	Not determined.

### Environmental exposure control

Do not allow product to reach sewage system.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White to off-white crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	About 117 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



## MELATONINUM

Relative density:	Not available.
Solubility:	Soluble in acetone, ethyl acetate and methanol.
Solubility in water:	Slightly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Molecular weight: 232,28 g/mol

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Avoid dust formation. Avoid light.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Other decomposition products - No data available.

In case of fire, hazardous decomposition products are formed. - Carbon oxides, nitrogen oxides (NO<sub>x</sub>).

In case of fire, see section 5.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (rat): > 3 200 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



## MELATONINUM

Carcinogenicity:	IARC: No component of this product, when present in a concentration greater than or equal to 0.1%, has been identified as a probable, possible or confirmed carcinogen by IARC.
Reproductive toxicity:	Overexposure may cause reproductive disorder(s), based on animal testing.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	RTECS: AC5955000 To our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

This substance/mixture does not contain any components that can be considered persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Product: Take residues and non-reusable solutions to a licensed disposal company. Dissolve or mix with a combustible solvent and incinerate in a chemical incinerator equipped with afterburner and scrubber.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## MELATONINUM

EN

FORM-06-14-01 (V00)

Page 7/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



Contaminated packaging: Dispose of as unused product.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not dangerous goods.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : ADR/RID: No.  
IMDG Marine pollutant: No.  
IATA: No.

##### 14.6 Special precautions for user

Not available.

##### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

##### 14.8 Additional transport information

Not available.

### SECTION 15: REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol: Not applicable.  
Risk phrases: Not applicable.  
Safety phrases: Not applicable.

#### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## MELATONINUM

EN

FORM-06-14-01 (V00)

Page 8/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.  
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### 16.8 Department issuing MSDS

Quality Department  
FAC SECUNDUM ARTEM NV



# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## MELATONINUM

EN

FORM-06-14-01 (V00)

Page 9/8

Publication: 12/04/2022

Revision: 12/04/2022

Version: 00



info@magis-pharma.be