



MATERIAL SAFETY DATA SHEET

EN

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

PAGE 1 OF 9

Publication: 21/08/2024

Revision: XX/XX/XXXX

Version: 00

MIRTAZAPINUM

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

1.1 Product identifier

Product name: Mirtazapine
Mirtazapinum
Mirtazapine
Mirtazapine
Mirtazapin

N° CAS: 61337-67-5

N° EC: 641-354-1

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: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
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.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
STOT SE 3	H336
Reproductive toxicity	H361fd
Warning Specific target organ toxicity, repeated exposure	H373
Hazardous to the aquatic environment, long-term hazard	H411

2.2 Label elements

Labelling according to (EC) n° 1272/2008

MIRTAZAPINUM

Hazard pictogram(s):



Signal word(s):

Warning, hazard, environmental hazard

Hazard statements:

H302

Harmful if swallowed.

H336

May cause drowsiness or dizziness.

H361fd

Reproductive toxicity.

H373

Warning Specific target organ toxicity, repeated exposure.

H411

Hazardous to the aquatic environment, long-term hazard.

Precautionary statements:

P203

Obtain, read and follow all safety instructions before use.

P260

Do not breathe dust/fume/gas/mist/vapors/spray.

P264

Wash hands [and ...] thoroughly after handling.

P270

Do not eat, drink or smoke when using this product.

P271

Use only outdoors or in a well-ventilated area.

P273

Avoid release to the environment.

P280

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P301+P317

IF SWALLOWED: Get emergency medical help.

P304+P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P318

If exposed or concerned, get medical advice.

P319

Get medical help if you feel unwell.

P391

Collect spillage.

P403+P233

Store in a well-ventilated place. Keep container tightly closed.

P405

Store locked up.

P501

Dispose of contents/container to local/regional/national/international regulations.

Additional applicable label elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:

Mirtazapine

IUPAC name:

(7S)-5-methyl-2,5,19- triazatetracyclo[13.4.0.0^{2,7}.0^{8,13}]nonadeca-1(19),8,10,12,15,17-hexaene

Synonyms:

Remeron

Remergil

N° CAS:

61337-67-5

MIRTAZAPINUM

N° EC: 641-354-1
Molecular Formula: $C_{17}H_{19}N_3$
Content: 100%

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

After skin contact: Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

After eye contact: Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

After ingestion: If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

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, dry chemical power (DCP), carbon dioxide (CO₂), etc.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Unusual fire and explosion hazards: Emits toxic fumes under fire conditions.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Use personal protective equipment and clothing. If necessary, use self-contained breathing apparatus.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

MIRTAZAPINUM

Wear respirator, approved masks, safety goggles, rubber boots and heavy rubber gloves.

For emergency responders

Wear respirator, approved masks, safety goggles, rubber boots and heavy rubber gloves.

6.2 Environmental precautions

Do not let the product enter into drains.

6.3 Methods and material for containment and cleaning up

Occupational spill: Use appropriate spill control kit and put the spilled solid in suitable waste disposal container.

Clean up – large spill: Vacuum or sweep up material and place into a suitable disposal container. Clean up spills immediately. Avoid generating dusty conditions. Provide adequate ventilation. Use appropriate personal protective equipment.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Keep container tightly closed. Avoid ingestion and inhalation. Avoid contact with eyes, skin and clothing.
Personal protection:	Use appropriate personal protective equipment while handling the material.
Technical protective measures:	Minimize dust generation and accumulation. Use with adequate ventilation.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store in a well-closed container between 15 °C and 30 °C.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Use adequate ventilation to keep airborne concentration low.

Individual protection measures

MIRTAZAPINUM

Eye/face protection:	Wear appropriate protective eyeglasses or chemical safety goggles.
Skin protection:	Wear appropriate protective gloves to prevent skin exposure.
Hand protection:	Wear appropriate protective gloves to prevent skin exposure.
Respiratory protection:	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator when necessary.
Thermal hazards:	Not determined.
Environmental exposure control	
Do not let the product enter into drains.	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White to creamy-white crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	117 – 122 °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.
Relative density:	Not available.
Solubility:	Freely soluble in methanol and in toluene, soluble in ethyl ether.
Solubility in water:	Practically insoluble 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

MIRTAZAPINUM

Molecular weight: 265.4
MIE: 1.4 mJ

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

Incompatible materials.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Toxic fumes of carbon monoxide, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral (Category 4)
Skin corrosion/irritation: Not available.
Serious eye damage/irritation: Not available.
Respiratory/skin sensitisation: Not available.
Germ cell mutagenicity: Not available.
Carcinogenicity: Not available.
Reproductive toxicity: Not available.
Summary of evaluation of the CMR properties: Not available.
STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.
Other: Information on likely routes of exposure: Eyes, skin, inhalation, ingestion.

11.2 Additional information on potential adverse human health effects and symptoms

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



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PAGE 7 OF 9

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MIRTAZAPINUM

Ingestion: Harmful if swallowed.
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

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations.

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 classified.

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

MIRTAZAPINUM

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

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:



Risk phrases:

R22 Harmful if swallowed.

R67 Vapours may cause drowsiness and dizziness.

Safety phrases:

S64 If swallowed, rinse mouth with water (only if the person is conscious).

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

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

MIRTAZAPINUM

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.

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16.8 Department issuing MSDS

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