

PRIMIDONUM

Publication: 22/08/2024
Revision: 07/10/2024
Version: 01

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

1.1 Product identifier

Product name: Primidone
Primidonum
Primidon
Primidone
Primidon

N° CAS: 125-33-7

N° EC: 204-737-0

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

Identified uses: Active Pharmaceutical Ingredient.

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 toxicity (category 4) H302

Carcinogenicity (category 2) H351

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302 Harmful if swallowed.

H351 Suspected of causing cancer

Precautionary statements:

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P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P203	Obtain, read and follow all safety instructions before use.
P264	Wash hands [and ...] thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P281	Use personal protective equipment as required.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P301+P317	If swallowed: Get medical help.
P308+P313	IF EXPOSED OR CONCERNED: Get medical advice/attention.
P318	If exposed or concerned, get medical advice.
P330	Rinse mouth.
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:	Primidone
IUPAC name:	5-ethyl-5-phenyl-1,3-diazinane-4,6-dione
Synonyms:	Primaclone Mysoline Lepimidin Neurosyn Misodine
N° CAS:	125-33-7
N° EC:	204-737-0
Molecular Formula:	C ₁₂ H ₁₄ N ₂ O ₂
Content:	98.0 % to 102.0 % (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Not applicable.

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After inhalation:	Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.
After skin contact:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist.
After ingestion:	Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.
Self-protection of the first aider:	Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation: Cause burns. Delayed adverse effects possible.
Symptoms/effects after skin contact: Insufficient data available.
Symptoms/effects after eye contact: Insufficient data available.
Symptoms/effects after ingestion: burns to the gastric/intestinal mucosa. Symptoms may include dizziness, headache, nausea and loss of coordination.

4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray. Carbon dioxide. Dry powder.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Fire hazard: See Heading 2.2.

5.3 Advice for firefighters

Surrounding fires:	Use extinguishing media appropriate for surrounding fire.
Protection against fire:	Not available.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

General precautions: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.
Personal precautions: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

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For emergency responders

General precautions: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

Personal precautions: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Ensure waste is collected and contained. Clean thoroughly.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Material should be handled with caution. Avoid any direct contact with the product.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Handle in accordance with good industrial hygiene and safety procedures.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in well closed container. Protected from light.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter.

Individual protection measures

Eye/face protection:	Chemical goggles or safety glasses.
Skin protection:	Wear suitable protective clothing.
Hand protection:	Wear suitable gloves resistant to chemical penetration.

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Respiratory protection:	Wear approved mask. In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards:	Not determined.
Environmental exposure control	
Not available.	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	279-284 °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:	Very slightly soluble in water, slightly soluble in ethanol (96 %). It dissolves in alkaline solutions.
Solubility in water:	Insoluble.
Partition coefficient (n-octanol/water):	0.91
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

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Stable under normal condition.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

None under normal use. See Heading 7.

10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Rat oral LD ₅₀ [mg/kg]	1500
Rabbit dermal LD [mg/kg]	Not available.
Rat inhalation LC [mg/L/4h]	Not available.
Acute toxicity:	Nervous system disorders. Damage to central nervous system. Gastrointestinal disorders. Symptoms may include dizziness, headache, nausea and loss of co-ordination. Drowsiness.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Category 3: Substance which may concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment.
Reproductive toxicity:	Unborn child: Category 2: Substance which should be regard as if they cause developmental toxicity to human.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

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

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Inhalation: Not available.
Ingestion: Not available.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology-general: Hazardous waste. Use suitable disposal containers.

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

Regional legislation (waste): Dispose in a safe manner in accordance with local/national 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 classified.

14.4 Packing group

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

14.5 Environmental hazards

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ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) :

Not classified.

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

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

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

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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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