

**PIPAMPERONI DIHYDROCHLORIDUM**

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

**1.1 Product identifier**

Product name: Pipamperone dihydrochloride  
Pipamperoni dihydrochloridum  
Pipamperon dihydrochloride  
Pipampérone (dichlorhydrate de)  
Pipamperondihydrochlorid

N° CAS: 2448-68-2

N° EC: 219-507-5

**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 toxicity (category 4)	H302
Acute toxicity (category 4)	H312
Eye irritation (category 2A)	H319
Acute toxicity (category 4)	H332
Aquatic chronic (category 3)	H412

**2.2 Label elements**

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

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

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H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H412	Harmful to aquatic life with long lasting effects.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash 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.
P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of water.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P317	Not applicable.
P330	Rinse mouth.
P404	Store in a closed container.
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:	Pipamperone dihydrochloride
IUPAC name:	1-[4-(4-fluorophenyl)-4-oxobutyl]-4-piperidin-1-ylpiperidine-4-carboxamide;dihydrochloride
Synonyms:	Not applicable.
N° CAS:	2448-68-2
N° EC:	219-507-5
Molecular Formula:	C <sub>21</sub> H <sub>32</sub> Cl <sub>2</sub> FN <sub>3</sub> O <sub>2</sub>
Content:	99.0 % to 101.0 % (anhydrous and solvent free substance).

### 3.2 Mixtures

Not applicable.

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**SECTION 4: FIRST AID MEASURES**

**4.1 Description of first aid measures**

General notes:	Not applicable.
After inhalation:	Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention.
After skin contact:	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.
After eye contact:	Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
After ingestion:	Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.
Self-protection of the first aider:	Not applicable.

**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:	In case of fire use water, chemical type foam, carbon dioxide, dry chemical. Prevent run off of water from entering drains.
Unsuitable extinguishing media:	Not available.

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

The substance evolves toxic fumes due to the presence of CO, CO<sub>2</sub>, NO<sub>x</sub>, HCl, HF.

**5.3 Advice for firefighters**

Surrounding fires:	Not available.
Protection against fire:	Wear: - Gas masks scuba - Complete protective equipment composed by: helmet whit face shield and neck protection, fireproof jacket and trousers with straps

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Hazardous combustion products:

around arms, legs and waist. As not expected at this point, refer to the personal protective equipment recommended in Section 8 of this sheet.

Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

##### For non-emergency personnel

Keep away any ignition source. Wear protective equipment. Keep unprotected persons away. Use respiratory protective device against the effects of fumes. Ensure adequate ventilation.

##### For emergency responders

Keep away any ignition source. Wear protective equipment. Keep unprotected persons away. Use respiratory protective device against the effects of fumes. Ensure adequate ventilation.

#### 6.2 Environmental precautions

Do not allow to penetrate the ground/soil. Prevent seepage into sewage system, workpits and cellars. Inform respective authorities in case of seepage into water course or sewage system.

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

Absorb spillage in earth or sand. Sweep or shovel-up spillage and remove to a safe place. Damp down to avoid dust generation.

#### 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:

This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this sheet. It should always be handled in an efficient fume hood or equivalent system and, if necessary, wear protective equipment.

Care should be taken to prevent the chemical from coming into contact with the skin or eyes and from contaminating personal clothing.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Not available.

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

Storage:

Not available.

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Conditions for safe storage, including any incompatibilities:

Avoid contact with oxidising substances.

For safety purposes, the substance does not require any special storage conditions. As an indication, the information provided by official monographs are:

**USP: Preserve in the original packaging tightly closed.**

**EP: Preserve in the original packaging tightly closed.**

For storage of the substance for pharmaceutical use, or for registration purposes please refer to the stability data conducted in-house and reported in the document regulatory "Active Substance Master File" (ASMF or DMF).

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**

**Components with workplace control parameters**

Contains no substances with occupational exposure limit value.

**8.2 Exposure controls**

**Appropriate engineering control**

Not available.

**Individual protection measures**

Eye/face protection: Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection: The type of protective equipment (es. Tyvek suit) must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Complete suit protecting against chemicals, flame retardant antistatic protective clothing.

Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a fullface particle respirator type N99 (US) or type P2 (EN 143) with cartridges P1 (inert substances) P2 (harmful substances) P3 (toxic substances). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

**Environmental exposure control**

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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:	Odourless
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	124-126 °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 water, soluble in methanol, sparingly soluble in chloroform.
Solubility in water:	Freely soluble
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**

Not available.

**SECTION 10: STABILITY AND REACTIVITY**

**10.1 Reactivity**

See 10.3

**10.2 Chemical stability**

The product is stable in usual working conditions.

**10.3 Possibility of hazardous reactions**

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Not available.

**10.4 Conditions to avoid**

Heat, flames and sparks.

**10.5 Incompatible materials**

Strong oxidising agents. Alkali metals, bases, strong acids, halogens.

**10.6 Hazardous decomposition products**

The substance evolves toxic fumes due to the presence of CO, CO<sub>2</sub>, NO<sub>x</sub>, HCl, HF.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

Acute toxicity:	Acute Oral LD 50, rat: 1120 mg/kg Acute Oral LD 50, mouse: 910 mg/kg Acute sub. cut. LD 50, rat: 400 mg/kg Acute sub. cut. LD 50, mouse: 312 mg/kg Acute I.V. LD 50, mouse: 71 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Causes serious eye irritation.
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:	Not available.

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

Eye contact:	Not available.
Skin contact:	May cause skin irritation.
Inhalation:	May be harmful if inhaled.
Ingestion:	May be harmful if swallowed.
Aspiration:	Not available.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity**

Not available.

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### 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

#### Product

Do not empty into drains. Use appropriate containment to avoid environmental contamination. Disposal should be in accordance with local, state or national regulation.

#### Wasted containers / drums

The containers and packing materials contaminated with dangerous substances or preparations, have the same treatment products.

## SECTION 14: TRANSPORT INFORMATION

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

#### 14.1 UN Number

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

#### 14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

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

#### 14.5 Environmental hazards

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

#### 14.6 Special precautions for user

Not available.



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### 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

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.

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**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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