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

1.1 PRODUCT IDENTIFIER

Product name:	EN:	Papaverine hydrochloride
	LAT:	Papaverini hydrochloridum
	NL:	Papaverine hydrochloride
	FR:	Papavérine (chlorhydrate de)
	DE:	Papaverinhydrochlorid
N° CAS:		61-25-6
N° EC:		200-502-1

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, oral 4 H302

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Warning

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

P102 Keep out of reach of children.

P101 If medical advice is needed, have product container or label at hand.

P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P501	Dispose of contents/container to an appropriate recycling or disposal facility
Additional applicable label elements:	

2.3 OTHER HAZARDS

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name:	Papaverine hydrochloride
IUPAC name:	1-(3,4-Dimethoxybenzyl)-6,7-dimethoxyisoquinoline hydrochloride
Synonyms:	Cardoverina Artegodan Delapav
N° CAS:	61-25-6
N° EC:	200-502-1
Molecular Formula:	$C_{20}H_{22}ClNO_4$
Content:	99.0 per cent to 101.0 per cent (dried substance)

3.2 MIXTURES

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

After inhalation:	If inhaled remove to well-ventilated area. Administer artificial respiration, if necessary and call physician.
After skin contact:	Wash with soap and large amounts of running water. If symptoms develop, call physician.
After eye contact:	Wash with running water for 15 minutes. Call physician, if required.
After ingestion:	Contact physician immediately. If physician unavailable, induce vomiting.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

General discomfort, nausea, abdominal discomfort, anorexia, constipation, diarrhoea, skin rash, headache, flushing of the face increase in the depth of respiration, increase in heart rate, a slight rise in blood pressure and excessive sedation.

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:	Water, carbon dioxide, dry chemical, foam extinguisher.
Unsuitable extinguishing media:	Not available.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

As a finely divide material, may explode if suspended in air in heavy concentration and subjected to a source of ignition.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires:	Fire fighting procedure: None specified by manufacturer.
Protection against fire:	Wear self-contained breathing apparatus & protective clothing.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

FOR NON-EMERGENCY PERSONNEL

Wear respirator, safety goggles, rubber boots and gloves.

FOR EMERGENCY RESPONDERS

Wear respirator, safety goggles, rubber boots and gloves.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid raising dust.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Sweep up into clean, dry containers and dispose of in accordance with local authority regulations.

6.4 REFERENCE TO OTHER SECTIONS

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling:	Not available.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	No special requirements.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

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

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

Ventilation: Good general (mechanical) room ventilation is recommended.
Work hygienic practices: Wash thoroughly after handling.

INDIVIDUAL PROTECTION MEASURES

Eye/face protection:	Safety glasses.
Skin protection:	Not available.
Hand protection:	Gloves.
Respiratory protection:	NIOSH approved dust / mist respirator or a laboratory fume hood mask may be needed if excess aerosols are generated.
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, or white or almost white crystals.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	3.0 to 4.0
Melting/freezing point:	146 to 149°C
Initial boiling point:	Not available.
Boiling range:	Not applicable.
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:	Slightly soluble in ethanol (96 per cent).
Solubility in water:	Sparingly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Thermal decomposition: Breaks down at high temperatures to yield NO_x, CO, CO_2, HCL.
Viscosity:	Not available.
Explosive properties:	Not available.

Oxidising properties:	Not available.

9.2 OTHER INFORMATION

Molecular weight:	375.85
Bulk density:	Tapped about 0.562 g/ml Untapped about 0.421 g/ml

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Hazardous Polymerization: Will not occur.

10.2 CHEMICAL STABILITY

Stable under normal temperatures and pressures. May discolour on exposure to light.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Not available.

10.4 CONDITIONS TO AVOID

Incompatible materials, light, dust generation, excess heat.

10.5 INCOMPATIBLE MATERIALS

Direct light, strong oxidizing agents.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity:	Oral LD_{50} (rat): 360 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Irritating to mucous tract, membrane and upper respiratory tract.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible of confirmed human carcinogen by IARC.
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:	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

Not available.

12.6 OTHER ADVERSE EFFECTS

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Sweep up into clean, dry containers and dispose of in accordance with local authority 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 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) :	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

This substance is considered non-hazardous for transport. Transport in accordance with local, state, and federal regulations.

SECTION 15: REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE/MIXTURE

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

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 Bioaccumalative

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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