

CLOZAPINUM

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

1.1 Product identifier

Product name:	Clozapine Clozapinum Clozapine Clozapine Clozapin
N° CAS:	5786-21-0
N° EC:	227-313-7

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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. 3	H301
Muta. 2	H341
Repr. 2	H361

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

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Hazard statements:

H301	Toxic if swallowed.
H341	Suspected of causing genetic defects.
H361	Suspected of damaging fertility or the unborn child.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P281	Use personal protective equipment as required.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P405	Store locked up.
P501	Dispose of contents/container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

Additional applicable label elements:	Not applicable.
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2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Clozapine
IUPAC name:	3-chloro-6-(4-methylpiperazin-1-yl)-11H-benzo[b][1,4]benzodiazepine
Synonyms:	Leponex Fazaclo Clorazil Iprox
N° CAS:	5786-21-0
N° EC:	227-313-7
Molecular Formula:	C ₁₈ H ₁₉ ClN ₄
Content:	99.0 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

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4.1 Description of first aid measures

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.

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

In case of reactions described in hazards identification or other severe, immediate or persisting symptoms, seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray. Carbon dioxide. Dry powder.
Unsuitable extinguishing media:	Do not use a heavy water stream.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	Use water spray or fog for cooling exposed containers. Avoid (reject) fire-fighting water to enter the environment. Prevent entry to sewers and public water.
Protection against fire:	Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous combustion products:	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove ignition sources. Evacuate area. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

For emergency responders

Remove ignition sources. Evacuate area. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2 Environmental precautions

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Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

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:	Avoid all unnecessary exposure. Ensure prompt removal from eyes, skin and clothing.
Technical protective measures:	Material should be handled in a laboratory hood whenever possible.
Handling:	Handle in accordance with good industrial hygiene and safety procedures.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	CLOZAPINE CRS is not intended for long-term storage. Keep container tightly closed in a cool, well-ventilated place.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a cool, well-ventilated place.
Storage – away from:	All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials, see section 10

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

Provide local exhaust or general room ventilation. Material should be handled in a laboratory hood whenever possible.

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. (P3) 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:	Yellow, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	182 °C to 186 °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 methylene chloride. Soluble in ethanol (96 per cent). It dissolves in dilute acetic acid.
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

Molecular weight: 326.8

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

None under normal conditions.

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Moisture. Light.

10.5 Incompatible materials

Strong oxidisers.

10.6 Hazardous decomposition products

Carbon monoxide.

Chlorides.

Nitrogen oxides.

Carbon dioxide.

When heated to decomposition, emits dangerous fumes.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (rat): 172 mg/kg Weakness. Nervous system disorders. Can affect blood cell formation. Changes in blood pressure. May produce irregular heartbeat and nervous symptoms. Sleepiness. Causes depressions of the respiratory system. Weight gain.
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:	Category 3: Substances which cause concern for humans owing possible developmental toxic effects.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.

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Aspiration Hazard: Not available.
Other: RTECS: HP1750000

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

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

LC₅₀ – 96h – Fish 0.71 mg/l
EC₅₀ – 48 h – *Daphnia magna* 2 mg/l
IC₅₀ – 72 h – Algae 2.38 mg/l

12.2 Persistence and degradability

Biodegradation: 5%. Minimally biodegradable.

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

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

General: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.
Special precautions: This product contains hazardous components for the environment. Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), TOXIC SOLIC, ORGANIC, N.O.S. (Clozapine)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IMDG – Marine pollution: Yes.
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:

R25 Toxic if swallowed.
R62 Possible risk of impaired fertility.
R63 Possible risk of harm to the unborn child.

Safety phrases:

S1 Keep locked up.
S20/21 When using do not eat, drink or smoke.
S46 If swallowed, seek medical advice immediately and show this container or label.
S53 Avoid exposure - obtain special instructions before use.
S56 Dispose of this material and its container at hazardous or special waste collection point.
S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.
S64 If swallowed, rinse mouth with water (only if the person is conscious).

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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.

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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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

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