



SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Clozapine
- **Article number:** 100330
- **CAS Number:**
5786-21-0
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
FAGRON a.s.
Holická 1098/31m
779 00 Olomouc
Česká republika
- **Further information obtainable from:**
Tel.: +420 585 222 590
info@fagron.cz
- **1.4 Emergency telephone number:**
Toxikologické informační středisko,
Na Bojišti 1,
128 08 Praha 2
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),
e-mail:tis.cuni@cesnet.cz

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 3 H301 Toxic if swallowed.
Muta. 2 H341 Suspected of causing genetic defects.
Repr. 2 H361 Suspected of damaging fertility or the unborn child.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**

GHS06 GHS08
- **Signal word** Danger
- **Hazard statements**
H301 Toxic if swallowed.
H341 Suspected of causing genetic defects.
H361 Suspected of damaging fertility or the unborn child.

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· **Precautionary statements**

- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321 Specific treatment (see on this label).
P330 Rinse mouth.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.1 Substances**

· **CAS No. Description**

CAS: 5786-21-0 Clozapine

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.
Do not induce vomiting; call for medical help immediately.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

Use fire extinguishing methods suitable to surrounding conditions.
Alcohol resistant foam
Carbon dioxide
Water spray
Fire-extinguishing powder

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- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** Carbon monoxide (CO)
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Keep away from ignition sources.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
- **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**
Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
Open and handle receptacle with care.
- **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Filter P2

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Suitable respiratory protective device recommended.

• **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

• **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

• **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• **Eye/face protection**



Tightly sealed goggles

• **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

• **9.1 Information on basic physical and chemical properties**

• **General Information**

• **Physical state**

Solid

• **Colour:**

Light yellow

• **Odour:**

Characteristic

• **Odour threshold:**

Not determined.

• **Melting point/freezing point:**

183–184°C

• **Boiling point or initial boiling point and boiling range**

489°C

• **Flammability**

Product is not flammable.

• **Lower and upper explosion limit**

• **Lower:**

Not determined.

• **Upper:**

Not determined.

• **Flash point:**

250°C

• **Decomposition temperature:**

Not determined.

• **pH**

Not applicable.

• **Viscosity:**

• **Kinematic viscosity**

Not applicable.

• **Dynamic:**

Not applicable.

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<ul style="list-style-type: none"> · Solubility · water: Soluble. Fully miscible. · Partition coefficient n-octanol/water (log value) Not determined. · Vapour pressure: Not applicable. · Density and/or relative density · Density at 20°C: 1,1327 g/cm³ · Relative density Not determined. · Vapour density Not applicable. · Particle characteristics See section 3. 	
<ul style="list-style-type: none"> · 9.2 Other information · Appearance: · Form: Solid material · Important information on protection of health and environment, and on safety. · Ignition temperature: Not determined. · Explosive properties: Product does not present an explosion hazard. · Molecular weight 326,83 g/mol · Change in condition · Evaporation rate Not applicable. 	
<ul style="list-style-type: none"> · Information with regard to physical hazard classes · Explosives Void · Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void · Oxidising liquids Void · Oxidising solids Void · Organic peroxides Void · Corrosive to metals Void · Desensitised explosives Void 	

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.

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- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
Carbon monoxide and carbon dioxide
Nitrogen oxides (NO_x)
Hydrogen chloride (HCl)

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Toxic if swallowed.

- **LD/LC50 values relevant for classification:**

Oral	LD50	251 mg/kg (rat)
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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Suspected of causing genetic defects.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Suspected of damaging fertility or the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

HP6	Acute Toxicity
HP10	Toxic for reproduction
HP11	Mutagenic

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

14.1 UN number or ID number

ADR, IMDG, IATA UN2811

14.2 UN proper shipping name

ADR, IMDG TOXIC SOLID, ORGANIC, N.O.S. (Clozapine)
IATA Toxic solid, organic, n.o.s. (Clozapine)

14.3 Transport hazard class(es)

ADR, IMDG, IATA



Class 6.1 Toxic substances.
Label 6.1

14.4 Packing group

ADR, IMDG, IATA III

14.5 Environmental hazards: Not applicable.

14.6 Special precautions for user

Warning: Toxic substances.
Hazard identification number (Kemler code): 60
EmS Number: F-A,S-A
Stowage Category A

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

Transport/Additional information:

ADR
Limited quantities (LQ) 5 kg

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· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· Transport category	2
· Tunnel restriction code	E

· IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (CLOZAPINE), 6.1, III

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **Seveso category H2 ACUTE TOXIC**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
Substance is not listed.
- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
Substance is not listed.
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
- **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Fagron Česká republika
- **Contact:** msds@fagron.cz
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)

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Safety data sheet

according to 1907/2006/EC, Article 31

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Trade name: Clozapine

LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 3: Acute toxicity – Category 3
Muta. 2: Germ cell mutagenicity – Category 2
Repr. 2: Reproductive toxicity – Category 2

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