



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 UK Ltd
4B Coquet St
Newcastle upon Tyne
England NE1 2QB
Tel. 0845 6522525
- **Further information obtainable from:**
Emergency response telephone number:
+44 (0) 845 652 2525
- **1.4 Emergency telephone number:**
Emergency response telephone number:
+44 (0) 845 652 2525

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 GB 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.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

(Contd. on page 2)

Trade name: Clozapine

(Contd. of page 1)

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
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** Carbon monoxide (CO)

(Contd. on page 3)

GB

Trade name: Clozapine

(Contd. of page 2)

- **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.
- **Maximum storage temperature:** 40° C
- **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
Suitable respiratory protective device recommended.

(Contd. on page 4)

Trade name: Clozapine

(Contd. of page 3)

· **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.

(Contd. on page 5)

GB

Trade name: Clozapine

(Contd. of page 4)

<ul style="list-style-type: none"> · Solubility · water: · Partition coefficient n-octanol/water (log value) · Vapour pressure: · Density and/or relative density · Density at 20°C: · Relative density · Vapour density 	<ul style="list-style-type: none"> Soluble. Fully miscible. Not determined. Not applicable. 1.1327 g/cm³ Not determined. Not applicable.
<ul style="list-style-type: none"> · 9.2 Other information · Appearance: · Form: · Important information on protection of health and environment, and on safety. · Ignition temperature: · Explosive properties: · Molecular weight · Change in condition · Evaporation rate 	<ul style="list-style-type: none"> Solid material Not determined. Product does not present an explosion hazard. 326.83 g/mol Not applicable.
<ul style="list-style-type: none"> · Information with regard to physical hazard classes · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures · Pyrophoric liquids · Pyrophoric solids · Self-heating substances and mixtures · Substances and mixtures, which emit flammable gases in contact with water · Oxidising liquids · Oxidising solids · Organic peroxides · Corrosive to metals · Desensitised explosives 	<ul style="list-style-type: none"> Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void

SECTION 10: Stability and reactivity

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

(Contd. on page 6)

Trade name: Clozapine

(Contd. of page 5)

- **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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- **Germ cell mutagenicity** Suspected of causing genetic defects.
- **Reproductive toxicity** Suspected of damaging fertility or the unborn child.
- **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.

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.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

(Contd. on page 7)


GB

Trade name: Clozapine

(Contd. of page 6)

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

SECTION 14: Transport information

<ul style="list-style-type: none"> · 14.1 UN number or ID number · ADR, IMDG, IATA 	UN2811
<ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, IMDG · IATA 	TOXIC SOLID, ORGANIC, N.O.S. (Clozapine) Toxic solid, organic, n.o.s. (Clozapine)
<ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, IMDG, IATA 	6.1 Toxic substances. 6.1
<ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA 	III
<ul style="list-style-type: none"> · 14.5 Environmental hazards: 	Not applicable.
<ul style="list-style-type: none"> · 14.6 Special precautions for user · Hazard identification number (Kemler code): · EmS Number: · Stowage Category 	Warning: Toxic substances. 60 F-A,S-A A
<ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments 	Not applicable.
<ul style="list-style-type: none"> · Transport/Additional information: 	
<ul style="list-style-type: none"> · ADR · Limited quantities (LQ) · Excepted quantities (EQ) · Transport category · Tunnel restriction code 	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g 2 E
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
<ul style="list-style-type: none"> · UN "Model Regulation": 	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (CLOZAPINE), 6.1, III

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(Contd. on page 8)

Trade name: Clozapine

(Contd. of page 7)

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
- **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 UK
Quality Assurance
- **Contact:** quality@fagron.co.uk
- **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)
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
- *** Data compared to the previous version altered.**

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