

Safety Data Sheet

acc. to OSHA HCS

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Printing date 02/23/2024

Reviewed on 02/23/2024

1 Identification

- **Product identifier**
- **Trade name:** Clozapine
- **Article number:** 100330
- **CAS Number:**
5786-21-0
- **Application of the substance / the mixture** Pharma Active ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
Acute Toxicity - Oral 3 H301 Toxic if swallowed.
Germ Cell Mutagenicity 2 H341 Suspected of causing genetic defects.
Toxic to Reproduction 2 H361 Suspected of damaging fertility or the unborn child.
- **Label elements**
- **GHS label elements**
The substance is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS06 GHS08
- **Signal word** Danger
- **Hazard statements**
Toxic if swallowed.
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
- **Precautionary statements**
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective gloves/protective clothing/eye protection/face protection.
If swallowed: Immediately call a poison center/doctor.

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Specific treatment (see on this label).

Rinse mouth.

IF exposed or concerned: Get medical advice/attention.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

• **Classification system:**

• **NFPA ratings (scale 0 - 4)**



Health = 2
Fire = 1
Reactivity = 0

• **HMIS-ratings (scale 0 - 4)**



Health = 2
Fire = 1
Reactivity = 0

• **Other hazards**

• **Results of PBT and vPvB assessment**

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

3 Composition/information on ingredients

• **Chemical characterization: Substances**

• **CAS No. Description**

CAS: 5786-21-0 Clozapine

4 First-aid measures

• **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; immediately call for medical help.

• **Information for doctor:**

• **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

• **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Use fire fighting measures that suit the environment.
Alcohol resistant foam
Carbon dioxide
Water spray
Fire-extinguishing powder
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** Carbon monoxide (CO)
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Keep away from ignition sources
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
- **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.
- **Protective Action Criteria for Chemicals**
- **PAC-1:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

7 Handling and storage

- **Handling:**
- **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 protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
- **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.
- **Specific end use(s)** No further relevant information available.

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8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **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.
- **Breathing equipment:**
Filter P2
Suitable respiratory protective device recommended.
- **Protection of hands:**



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 protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid material
Color:	Light yellow
Odor:	Characteristic

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· Odor threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition Melting point/Melting range:	183–184°C (361.4–363.2°F)
Boiling point/Boiling range:	489°C (912.2°F)
· Flash point:	250°C (482°F)
· Flammability (solid, gaseous):	Product is not flammable.
· Decomposition temperature:	Not determined.
· Ignition temperature:	Not determined.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits: Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density at 20°C (68°F):	1.1327 g/cm ³ (9.45238 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Soluble. Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Other information	No further relevant information available.

10 Stability and reactivity

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

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

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

Oral	LD50	251 mg/kg (rat)
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- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)** Substance is not listed.

- **NTP (National Toxicology Program)** Substance is not listed.

- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

Water hazard class 2 (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.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**

- **Recommendation:**

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

- **Uncleaned packagings:**

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

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

14 Transport information

- **UN-Number**

- **DOT, IMDG, IATA**

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· **UN proper shipping name**
· **DOT**
· **IMDG**
· **IATA**

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

· **Transport hazard class(es)**

· **DOT**



· **Class**
· **Label**

6.1 Toxic substances
6.1

· **IMDG, IATA**



· **Class**
· **Label**

6.1 Toxic substances
6.1

· **Packing group**
· **DOT, IMDG, IATA**

III

· **Environmental hazards:** Not applicable.

· **Special precautions for user**
· **Hazard identification number (Kemler code):**
· **EMS Number:**
· **Stowage Category**

Warning: Toxic substances
60
F-A,S-A
A

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Transport/Additional information:**

· **DOT**
· **Quantity limitations**

On passenger aircraft/rail: 100 kg
On cargo aircraft only: 200 kg

· **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

· **UN "Model Regulation":** UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (CLOZAPINE), 6.1, III

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15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**
- **Section 355 (extremely hazardous substances):** Substance is not listed.
- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is not listed.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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 US
Quality Assurance
- **Contact:** QA@fagron.us
- **Date of preparation / last revision** 02/23/2024
- **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
DOT: US Department of Transportation
IATA: International Air Transport Association
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Acute Toxicity - Oral 3: Acute toxicity – Category 3
Germ Cell Mutagenicity 2: Germ cell mutagenicity – Category 2
Toxic to Reproduction 2: Reproductive toxicity – Category 2

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