

Clozapine

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 25/10/2011 Revision date 25/06/2019

Supersedes 21/08/2017

711780

Version: 4.0

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

1.1. Product identifier

Product form : Substance
Substance name : Clozapine
IUPAC name : 8-Chloro-11-(4-methylpiperazin-1-yl)-5H-dibenzo[b,e][1,4]-diazepine
EC-No. : 227-313-7
CAS-No. : 5786-21-0
Product code : 711780
Formula : C₁₈H₁₉CIN₄
Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 3 H301
Germ cell mutagenicity, Category 2 H341
Reproductive toxicity, Category 2 H361

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

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

Precautionary statements (CLP)

: P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P330 - Rinse mouth.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Clozapine	(CAS-No.) 5786-21-0 (EC-No.) 227-313-7	≈ 100	Acute Tox. 3 (Oral), H301 Muta. 2, H341 Repr. 2, H361

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Assure fresh air breathing. Seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Rinse mouth. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide. Dry powder. Foam. Water spray.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides. Chlorine.

Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid raising dust.

6.1.1. For non-emergency personnel

Protective equipment : Use the personal protective equipment as indicated in chapter 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak if safe to do so.

Methods for cleaning up : Sweep up dry powder and dispose properly.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Safety glasses. Dustproof clothing. Dust/aerosol mask with filter type P3. Gloves.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Approved dust respirator. Dustmask with filtertype P3

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 326.8 g/mol
Colour	: Yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 183 - 184 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available

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Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in ethanol. Soluble in dichloromethane. Water: 11.8 mg/l
Log Pow	: 3.23
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

High temperature.

10.5. Incompatible materials

Strong oxidizing agents. Strong acids.

10.6. Hazardous decomposition products

In case of fire hazardous gases / vapors may form: flue gas.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Toxic if swallowed.

Clozapine (5786-21-0)	
LD50 oral rat	260 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Suspected of causing genetic defects.
Carcinogenicity	: Not classified

Reproductive toxicity : Suspected of damaging fertility or the unborn child.

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STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Clozapine (5786-21-0)	
LC50 fish 1	0.71 mg/l
EC50 Daphnia 1	2 mg/l 48 h

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Clozapine (5786-21-0)	
Log Pow	3.23
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

Clozapine (5786-21-0)	
Ecology - soil	There are no available data for a classification.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations



13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Product/Packaging disposal recommendations : Dispose of this material and its container at hazardous or special waste collection point.


SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
14.3. Transport hazard class(es)	
6.1	6.1
	
14.4. Packing group	
III	III
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Classification code (ADR)	: T2
Special provisions (ADR)	: 274, 614
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAH, L4BH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Bulk (ADR)	: VC1, VC2, AP7
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9
Hazard identification number (Kemler No.)	: 60
Orange plates	: 
Tunnel restriction code (ADR)	: E
EAC code	: 2X

- Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y645
PCA limited quantity max net quantity (IATA)	: 10kg
PCA packing instructions (IATA)	: 670
PCA max net quantity (IATA)	: 100kg
CAO packing instructions (IATA)	: 677
CAO max net quantity (IATA)	: 200kg
Special provisions (IATA)	: A3, A5
ERG code (IATA)	: 6L

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Clozapine is not on the REACH Candidate List

Clozapine is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.2	Use of the substance/mixture	Added	
1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Removed	
2.2	Hazard pictograms (CLP)	Modified	
2.2	Precautionary statements (CLP)	Removed	P273
7.2	Storage temperature	Added	storage conditions
7.2	Maximum storage period	Removed	
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
9.1	Log Pow	Added	
10.5	Incompatible materials	Added	strong acids
10.6	Hazardous decomposition products	Added	
12.2	Persistence and degradability		
14.1	UN-No. (ADR)	Modified	
14.1	UN-No. (ADR)	Modified	UN3077 altered to UN2811

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level

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NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

Data sources : EP. Supplier.

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Muta. 2	Germ cell mutagenicity, Category 2
Repr. 2	Reproductive toxicity, Category 2
H301	Toxic if swallowed.
H341	Suspected of causing genetic defects.
H361	Suspected of damaging fertility or the unborn child.

SDS EU (REACH Annex II) Version 2018

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product