

MIRTAZAPINE CRS

Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

Date of issue: 27/06/2013

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Supersedes: 04/02/2010

Version: 4.0

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

1.1. Product identifier

Product form : Substance
Trade name : MIRTAZAPINE CRS
EC no : 288-060-6
CAS No : 85650-52-8
Product code : Y0000705
Other means of identification : RTECS No : UQ4410250

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

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
F-67081 Strasbourg
T +33(0)388412035 - F +33(0)388412771

1.4. Emergency telephone number

Emergency number : +44(0)1235239670

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute Tox. 4 (Dermal) H312
Acute Tox. 4 (Inhalation) H332
Acute Tox. 4 (Oral) H302
Aquatic Chronic 2 H411

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xn; R20/21/22

N; R51/53

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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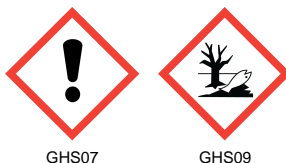
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2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS09

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed
H312 - Harmful in contact with skin
H332 - Harmful if inhaled
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P264 - Wash hands and other exposed areas thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER/doctor/physician if you feel unwell
P330 - Rinse mouth
P391 - Collect spillage
P501 - Dispose of contents/container to : Hazardous waste. Comply with applicable regulations

2.3. Other hazards

Other hazards not contributing to the classification

: Exposure may produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
MIRTAZAPINE (Main constituent)	(CAS No)85650-52-8 (EC no)288-060-6	≤ 100	Xn; R20/21/22 N; R51/53

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
MIRTAZAPINE (Main constituent)	(CAS No)85650-52-8 (EC no)288-060-6	≤ 100	Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302 Aquatic Chronic 2, H411

Full text of R-, H- and EUH-phrases: see section 16

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Move to fresh air in case of accidental inhalation. Assure fresh air breathing.
First-aid measures after skin contact : Rinse skin with water/shower.
First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Contact lenses should be removed.
First-aid measures after ingestion : Rinse mouth out with water.

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

Symptoms/injuries : See Heading 2.

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

In all cases of doubt, or when symptoms persist, seek medical attention.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Small amounts: Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder. Large amounts: Not applicable.
- Unsuitable extinguishing media : Water may be ineffective in firefighting due to low solubility.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Precautionary measures fire : Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Large amounts: Not applicable.

6.1.1. For non-emergency personnel

- Protective equipment : See Headings 7 and 8.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- Precautions for safe handling : Handle and open container with care. See Heading 8.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Comply with applicable regulations.
- Storage conditions : To guarantee the quality and properties of the product, keep : dry, Keep in a cool, well-ventilated place away from heat. Store in original container.
- Incompatible products : Strong oxidizing agents.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

- Hand protection : Gloves.
- Skin and body protection : Lab coat.
- Respiratory protection : Quarter mask (DIN EN 140).

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: white. Powder.
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: 7 (0.03%)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Self ignition temperature	: No data available
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	: Ethanol. Methylene chloride. Water: < 1 mg/l
Log Pow	: 3,09 at 20°C
Log Kow	: No data available
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

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful in contact with skin. Harmful if inhaled. Harmful if swallowed.

MIRTAZAPINE CRS(85650-52-8)	
LD50 oral rat	320 - 490 mg/kg
ATE (oral)	500,000 mg/kg
ATE (dermal)	1100,000 mg/kg

Skin corrosion/irritation : Not classified
pH: 7 (0.03%)

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Serious eye damage/irritation	: Not classified pH: 7 (0.03%)
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Small amounts: See Heading 2. Poorly soluble in water. No data available on ecotoxicity. Large amounts: Not applicable.

MIRTAZAPINE CRS(85650-52-8)	
LC50 fishes 1	6,96 mg/l LC50-96 Hour - fish
EC50 Daphnia 1	19,9 mg/l EC50 - 48 Hour - Daphnia magna

12.2. Persistence and degradability

MIRTAZAPINE CRS(85650-52-8)	
Biodegradation	0

12.3. Bioaccumulative potential

MIRTAZAPINE CRS(85650-52-8)	
Log Pow	3,09 at 20°C

12.4. Mobility in soil

No additional information available

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

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.
Waste disposal recommendations : Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: Transport information

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN number

UN-No : 3077
UN-No.(IATA) : 3077
UN-No. (IMDG) : 3077

14.2. UN proper shipping name

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Transport document description : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (E)

14.3. Transport hazard class(es)

Class (UN) : 9
Class (IATA) : 9
Class (IMDG) : 9

14.4. Packing group

Packing group (UN) : III
Packing group (IMDG) : III

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14.5. Environmental hazards

Dangerous for the environment :



Other information : No supplementary information available.

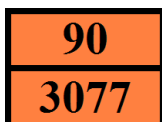
14.6. Special precautions for user

14.6.1. Overland transport

Hazard identification number (Kemler No.) : 90

Classification code (UN) : M7

Orange plates :



Tunnel restriction code : E

LQ : LQ27

Excepted quantities (ADR) : E1

14.6.2. Transport by sea

Ship Safety Act : Miscellaneous dangerous substances & articles

MFAG-No : 171

14.6.3. Air transport

Civil Aeronautics Law : Miscellaneous dangerous substances & articles

14.7. Transport in bulk according to Annex II of MARPOL 73/78 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

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of R-, H- and EUH-phrases::

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
H302	Harmful if swallowed
H312	Harmful in contact with skin
H332	Harmful if inhaled
H411	Toxic to aquatic life with long lasting effects
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
N	Dangerous for the environment
Xn	Harmful

SDS EU (REACH Annex II)

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