

## Mirtazapine Solid Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2019/09/13  |
| 5.0     | 2020/03/23     | 50162-00015 | Date of first issue: 2015/01/23 |

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name : Mirtazapine Solid Formulation

**Supplier's company name, address and phone number**

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999


**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

**2. HAZARDS IDENTIFICATION****GHS classification of chemical product**

|   |   |                             |
|---|---|-----------------------------|
| Reproductive toxicity                                     | : | Category 2                  |
| Specific target organ toxicity - repeated exposure (Oral) | : | Category 2 (Nervous system) |
| Short-term (acute) aquatic hazard                         | : | Category 3                  |
| Long-term (chronic) aquatic hazard                        | : | Category 3                  |

**GHS label elements**

|                          |   |   |
|--------------------------|---|---|
| Hazard pictograms        | : |    |
| Signal word              | : | Warning   |
| Hazard statements        | : | H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.<br>H373 May cause damage to organs (Nervous system) through prolonged or repeated exposure if swallowed.<br>H412 Harmful to aquatic life with long lasting effects. |
| Precautionary statements | : | <b>Prevention:</b><br>P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read  |

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and understood.  
P260 Do not breathe dust.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.  
lines of the emergency as- : Contact with dust can cause mechanical irritation or drying of  
sumed : the skin.  
May form explosive dust-air mixture during processing, handling or other means.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name   | CAS-No.    | Concentration (% w/w) | ENCS No. |
|---|------------|-----------------------|----------|
| Starch  | 9005-25-8  | >= 10 - < 20          | 8-98     |
| (+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine | 85650-52-8 | >= 10 - < 20          |          |

**4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

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|   |   |  |
|---|---|--|
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : | Suspected of damaging fertility. Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated exposure if swallowed.<br>Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation. |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).  |
| Notes to physician  | : | Treat symptomatically and supportively.  |

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**5. FIREFIGHTING MEASURES**

|   |   |   |
|---|---|---|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                | : | None known.   |
| Specific hazards during fire-fighting         | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                 | : | Carbon oxides<br>Silicon oxides   |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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**6. ACCIDENTAL RELEASE MEASURES**

|   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations.  |
| Environmental precautions   | : | Discharge into the environment must be avoided.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces  |

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with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**7. HANDLING AND STORAGE****Handling**

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

**Storage**

- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Threshold limit value and permissible exposure limits for each component in the work environment**

| Components | CAS-No. | Value type | Control parame- | Basis |
|------------|---------|------------|-----------------|-------|
|------------|---------|------------|-----------------|-------|

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|   |            | (Form of exposure) | ters / Permissible concentration |          |
|---|------------|--------------------|----------------------------------|----------|
| (+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine | 85650-52-8 | TWA                | 25 µg/m <sup>3</sup>             | Internal |
|   |            | Wipe limit         | 250 µg/100 cm <sup>2</sup>       | Internal |
| Starch  | 9005-25-8  | TWA                | 10 mg/m <sup>3</sup>             | ACGIH    |

**Engineering measures** : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

### Personal protective equipment

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

**Hand protection**

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

**Eye protection** : Wear the following personal protective equipment:  
Safety goggles

**Skin and body protection** : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling : No data available

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point and boiling range

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

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**10. STABILITY AND REACTIVITY**

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | Not classified as a reactivity hazard.   |
| Chemical stability                 | : | Stable under normal conditions.  |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : | Oxidizing agents   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.   |

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**11. TOXICOLOGICAL INFORMATION**

|  |   |  |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|--|---|--|

**Acute toxicity**

Not classified based on available information.

**Product:**

|                     |   |  |
|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |
|---------------------|---|--|

**Components:****Starch:**

|                       |   |                              |
|-----------------------|---|------------------------------|
| Acute oral toxicity   | : | LD50 (Rat): > 5,000 mg/kg    |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

**(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

|                     |   |                             |
|---------------------|---|-----------------------------|
| Acute oral toxicity | : | LD50 (Rat): 320 - 490 mg/kg |
|---------------------|---|-----------------------------|

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Starch:**

|         |   |                   |
|---------|---|-------------------|
| Species | : | Rabbit            |
| Result  | : | No eye irritation |

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**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Starch:**

|                 |   |                   |
|-----------------|---|-------------------|
| Test Type       | : | Maximisation Test |
| Exposure routes | : | Skin contact      |
| Species         | : | Guinea pig        |
| Result          | : | negative          |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Starch:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|---|--|

**(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|---|--|

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster lung cells  
Result: negative

Test Type: unscheduled DNA synthesis assay  
Test system: mammalian cells  
Result: negative

Test Type: sister chromatid exchange assay  
Test system: mammalian cells  
Result: negative

|                      |   |   |
|----------------------|---|---|
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Rat<br>Cell type: Bone marrow<br>Application Route: Oral<br>Result: negative |
|----------------------|---|---|

**Carcinogenicity**

Not classified based on available information.

**Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

|         |   |       |
|---------|---|-------|
| Species | : | Mouse |
|---------|---|-------|



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Application Route : Oral  
 Exposure time : 18 month(s)  
 LOAEL : 200 mg/kg body weight  
 Result : equivocal  
 Target Organs : Liver

Species : Rat  
 Application Route : Oral  
 Exposure time : 2 Years  
 LOAEL : 20 mg/kg body weight  
 Result : equivocal  
 Target Organs : Liver, Thyroid

**Reproductive toxicity**

Suspected of damaging fertility. Suspected of damaging the unborn child.

**Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Oral  
 Fertility: LOAEL: 15 mg/kg body weight  
 Symptoms: Effect on estrous cycle, Increase of early resorptions  
 Result: Animal testing did not show any effects on fertility., Embryotoxic effects and adverse effects on the offspring were detected.

Effects on foetal development : Test Type: Development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 100 mg/kg body weight  
 Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 40 mg/kg body weight  
 Result: No adverse effects, No teratogenic effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

May cause damage to organs (Nervous system) through prolonged or repeated exposure if swallowed.

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**Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

Exposure routes : Ingestion  
 Target Organs : Nervous system  
 Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Starch:**

Species : Rat  
 NOAEL : >= 2,000 mg/kg  
 Application Route : Skin contact  
 Exposure time : 28 Days  
 Method : OECD Test Guideline 410

**(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

Species : Rat  
 LOAEL : 120 mg/kg  
 Application Route : Oral  
 Exposure time : 13 Weeks  
 Target Organs : Nervous system

Species : Dog  
 LOAEL : 15 mg/kg  
 Application Route : Oral  
 Exposure time : 52 Weeks  
 Target Organs : Nervous system  
 Symptoms : Tremors

Species : Dog  
 LOAEL : 20 mg/kg  
 Application Route : Oral  
 Exposure time : 13 Weeks  
 Target Organs : Nervous system, Testis  
 Symptoms : Tremors

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

Ingestion : Symptoms: Drowsiness, constipation, dry mouth, asthenia, Dizziness, Disorientation

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**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

|  |  |
|--|--|
| Toxicity to fish   | : LC50 (Pimephales promelas (fathead minnow)): 6.92 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11  |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 19.5 mg/l<br>Exposure time: 48 h  |
| Toxicity to algae/aquatic plants                                       | : EC50 (Pseudokirchneriella subcapitata (green algae)): 5.7 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201                 |
|  | NOEC (Pseudokirchneriella subcapitata (green algae)): 3.2 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201                   |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC (Pimephales promelas (fathead minnow)): 3.6 mg/l<br>Exposure time: 31 d<br>Method: OECD Test Guideline 210                          |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 0.32 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211                                   |
| Toxicity to microorganisms   | : EC50 (Natural microorganism): > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |
|  | NOEC (Natural microorganism): < 100 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209     |

**Persistence and degradability**

No data available

**Bioaccumulative potential****Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

|                 |   |
|-----------------|---|
| Bioaccumulation | : Species: Oncorhynchus mykiss (rainbow trout)<br>Bioconcentration factor (BCF): 334<br>Method: OECD Test Guideline 305 |
|-----------------|---|

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Partition coefficient: n-octanol/water : log Pow: 2.78

### Mobility in soil

#### Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:

Distribution among environmental compartments : log Koc: 4.48

### Hazardous to the ozone layer

Not applicable

### Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

Refer to section 15 for specific national regulation.

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## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

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### **Industrial Safety and Health Law**

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

#### **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

#### **Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

#### **Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

#### **Substances Subject to be Notified Names**

Not applicable

#### **Substances Subject to be Indicated Names**

Not applicable

#### **Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

#### **Ordinance on Prevention of Lead Poisoning**

Not applicable

#### **Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

#### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

#### **Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

#### **Poisonous and Deleterious Substances Control Law**

Not applicable

#### **Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

#### **High Pressure Gas Safety Act**

Not applicable

#### **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

Not regulated as a dangerous good

#### **Aviation Law**

Not regulated as a dangerous good

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**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicableSpecific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable**Waste Disposal and Public Cleansing Law**

Industrial waste

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION****Further information**Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median

# SAFETY DATA SHEET



## Mirtazapine Solid Formulation



|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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