SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

Section 1: Identification

Product name : Mirtazapine Disintegrating Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

Section 2: Hazard identification

GHS Classification
Acute toxicity (Oral) : Acute Tox.4
Reproductive toxicity : Repr.2
Specific target organ toxicity - repeated exposure (Oral) : STOT RE2 (Nervous system)

GHS label elements
Hazard pictograms :

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Nervous system) through prolonged or repeated exposure if swallowed.

Precautionary statements :
Prevention: P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
Section 3: Composition/information on ingredients

**Substance / Mixture:** Mixture

### Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine</td>
<td>85650-52-8</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

Section 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.

**If swallowed:** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. P308 + P313 IF exposed or concerned: Get medical advice/attention.

**Disposal:** P501 Dispose of contents/container to an approved waste disposal plant.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:

- Harmful if swallowed.
- Suspected of damaging fertility. Suspected of damaging the unborn child.
- May cause damage to organs through prolonged or repeated exposure if swallowed.
- Contact with dust can cause mechanical irritation or drying of the skin.
- 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.

Section 5: Fire-fighting measures

- Suitable extinguishing media: Water spray
  Alcohol-resistant foam
  Carbon dioxide (CO2)
  Dry chemical

- Unsuitable extinguishing media: None known.

Specific hazards during firefighting:

- 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.
- Exposure to combustion products may be a hazard to health.

- Hazardous combustion products: Carbon oxides
  Nitrogen oxides (NOx)
  Metal oxides

Specific extinguishing methods:

- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for firefighters:

- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
  Follow safe handling advice and personal protective equipment recommendations.

- Environmental precautions: Discharge into the environment must be avoided.
  Prevent further leakage or spillage if safe to do so.
  Retain and dispose of contaminated wash water.
  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.
  Avoid dispersal of dust in the air (i.e., clearing dust surfaces...
with compressed air).
Dust deposits should not be allowed to accumulate on surfac-
es, as these may form an explosive mixture if they are re-
leased into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items
employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
certain local or national requirements.

Section 7: Handling and storage

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 as-
essment
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.

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.

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine</td>
<td>85650-52-8</td>
<td>TWA</td>
<td>25 µg/m3</td>
<td>Internal</td>
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</table>
SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

<table>
<thead>
<tr>
<th></th>
<th>Wipe limit</th>
<th>250 µg/100 cm²</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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.).

Section 9: Physical and chemical properties

Appearance:
powder

Colour:
No data available

Odour:
No data available

Odour Threshold:
No data available

pH:
No data available
## Section 10: Stability and reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
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<tbody>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
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<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
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<tr>
<td>Flammability (liquids)</td>
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<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<tr>
<td>Vapour pressure</td>
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<tr>
<td>Relative vapour density</td>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
<td>Water solubility No data available</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
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<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
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<tr>
<td>Viscosity</td>
<td>Viscosity, dynamic No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
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<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reac-...
Section 11: Toxicological information

Exposure routes: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,588 mg/kg
Method: Calculation method

Components:
(+/-)-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

Citric acid:
Acute oral toxicity: LD50 (Mouse): 5,400 mg/kg
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Magnesium stearate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Skin corrosion/irritation
Not classified based on available information.

Components:

Citric acid:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Citric acid:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials
Chronic toxicity

Germ cell mutagenicity
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:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  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
  Species: Rat
  Cell type: Bone marrow
  Application Route: Oral
  Result: negative

Citric acid:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: in vitro micronucleus test
  Result: positive
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

Genotoxicity in vivo:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Rat
  Application Route: Ingestion
  Result: negative

Cellulose:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Mirtazapine Disintegrating Formulation

Species: Mouse
Application Route: Ingestion
Result: negative

Magnesium stearate:
Genotoxicity in vitro
Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

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
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

Cellulose:
Species: Rat
Application Route: Ingestion
Exposure time: 72 weeks
Result: negative

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

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.

Citric acid:
- Effects on foetal development:
  - Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

Cellulose:
- Effects on fertility:
  - Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
- Effects on foetal development:
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

Magnesium stearate:
- Effects on fertility:
  - Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 422
  - Result: negative
  - Remarks: Based on data from similar materials
- Effects on foetal development:
  - Test Type: Embryo-foetal development
  - Species: Rat
SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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.

Components:

(±)-1,2,3,4,10b-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:

(±)-1,2,3,4,10b-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

Citric acid:
Species : Rat
NOAEL : 4,000 mg/kg
LOAEL : 8,000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

Cellulose:
Species : Rat
SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

Version 3.10
Revision Date: 09/13/2019
SDS Number: 50203-00014
Date of last issue: 24.04.2019
Date of first issue: 23.01.2015

NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Magnesium stearate:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

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

Section 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
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 19.5 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 5.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 3.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 3.6 mg/l
Exposure time: 31 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.32 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Toxicity to microorganisms:  
EC50 (Natural microorganism): > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  

NOEC (Natural microorganism): < 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Citric acid:  
Toxicity to microorganisms:  
EC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h

Toxicity to fish:  
LC50: > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:  
EC50 (Daphnia magna (Water flea)): 1,535 mg/l  
Exposure time: 24 h

Cellulose:  
Toxicity to fish:  
LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Magnesium stearate:  
Toxicity to fish:  
LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:  
EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:  
EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility  
NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms:  
EC10 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction
SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

Version 3.10  Revision Date: 09/13/2019  SDS Number: 50203-00014  Date of last issue: 24.04.2019  Date of first issue: 23.01.2015

Remarks: Based on data from similar materials

Persistence and degradability

Components:

Citric acid:
Biodegradability : Result: Readily biodegradable.
  Biodegradation: 97 %
  Exposure time: 28 d
  Method: OECD Test Guideline 301B

Cellulose:
Biodegradability : Result: Readily biodegradable.

Magnesium stearate:
Biodegradability : Result: Not biodegradable
  Remarks: Based on data from similar materials

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)
  Bioconcentration factor (BCF): 334
  Method: OECD Test Guideline 305
  Partition coefficient: n-octanol/water : log Pow: 2.78

Citric acid:
Partition coefficient: n-octanol/water : log Pow: -1.72

Magnesium stearate:
Partition coefficient: n-octanol/water : log Pow: > 4

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

Other adverse effects
No data available

Section 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.

Section 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

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS: not determined

DSL: not determined

IECSC: not determined

Section 16: Other information

Further information
Mirtazapine Disintegrating Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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</thead>
</table>

**Date format**: dd.mm.yyyy

**Full text of other abbreviations**

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average

Abbreviations and Acronyms:

- AIICS - 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
- IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IC50 - Lethal Concentration to 50 % of a test population
- ID50 - Lethal Dose to 50% of a test population (Median Lethal Dose)
- IEC - International Electrotechnical Commission
- IECSC - Inventory of Existing Chemicals and Other Chemicals
- IECSC - Inventory of Existing Chemicals and Other Chemicals (Japan)
- IECSC - Inventory of Existing Chemicals and Other Chemicals (Mexico)
- IEOCL - Inventory of Existing Chemicals and Other Chemicals (United States)
- ILDI - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- ILO - International Labour Organization
- ILE - Inherently Low Explosive
- ILS - Inherently Low Sensitivity
- INCLP - Inventory of Existing Chemicals and Other Chemicals (Pesticides)
- INESC - Inventory of Existing Chemicals and Other Chemicals (South Africa)
- INESC - Inventory of Existing Chemicals and Other Chemicals (Taiwan)
- IOA - Inherently Oxidising
- IOCL - Inventory of Existing Chemicals and Other Chemicals (Brazil)
- IOCS - International Orchestration of Chemicals and Other Chemicals
- IOTC - International Union of Pure and Applied Chemistry
- IPCS - International Programme on Chemical Safety
- IRE - Inherently Reactive
- IRT - Inherently Toxic
- ISCL - Inventory of Existing Chemicals and Other Chemicals (Latin America)
- ISCL - Inventory of Existing Chemicals and Other Chemicals (South America)
- ISTRM - Inventory of Existing Chemicals and Other Chemicals (Moldova)
- ISWM - Inventory of Existing Chemicals and Other Chemicals (South Africa)
- ITU - International Telecommunication Union
- JIS - Japanese Industrial Standard
- KECI - Korean Existing Chemicals Inventory
- LC50 - Lethal Concentration to 50 % of a test population
- LD50 - Lethal Dose to 50% of a test population (Median 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
- SADT - Self-Accelerating Decomposition Temperature
- SDS - Safety Data Sheet
- TDG - Transport of Dangerous Goods
- TSCA - Toxic Substances Control Act
- UN - United Nations
- UPNTDG - 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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