SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

SECTION 1. IDENTIFICATION

Product name : Mirtazapine Disintegrating Formulation

Manufacturer or supplier's details
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
          Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Acute toxicity (Oral) : Category 4
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Nervous system)

GHS label elements
Hazard pictograms : ⚠️ ⚠️
Signal Word : Warning
Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection
and face protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine</td>
</tr>
<tr>
<td></td>
<td>Citric acid</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms: Harmful if swallowed.
and effects, both acute and delayed

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 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. 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 fire-fighters:

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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:

Avoid release to the environment. 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
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.

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.
- Wash skin thoroughly after handling.
- 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.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled 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

Ingredients 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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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
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<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
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</table>
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Mirtazapine Disintegrating Formulation

<table>
<thead>
<tr>
<th></th>
<th>TWA (total dust)</th>
<th>15 mg/m³</th>
<th>OSHA Z-1</th>
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<tbody>
<tr>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
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<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable particulate matter)</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).
Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

**Personal protective equipment**

**Respiratory protection**

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

Material: Chemical-resistant gloves
Remarks: Choose gloves to protect hands against chemicals depending on the concentration 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:
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<td>50205-00016</td>
<td>03/23/2020</td>
<td>01/23/2015</td>
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</table>

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).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: No data available
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
SECTION 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. Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
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 402
Assessment: The substance or mixture has no acute dermal 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
Remarks: Based on data from similar materials

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 sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:
Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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:
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)
  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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 fetal 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.
Citric acid:
Effects on fetal 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 fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Rat
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:
(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:
Routes of exposure: Ingestion
Target Organs: Nervous system
Assessment: May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

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

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>120 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Nervous system</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>15 mg/kg</td>
<td>Oral</td>
<td>52 Weeks</td>
<td>Nervous system</td>
<td>Tremors</td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>20 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Nervous system, Testis</td>
<td>Tremors</td>
</tr>
</tbody>
</table>

Citric acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>4,000 mg/kg</td>
<td>Ingestion</td>
<td>10 Days</td>
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<tr>
<td>Species</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>8,000 mg/kg</td>
<td>Ingestion</td>
<td></td>
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</table>

Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; = 9,000 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

Magnesium stearate:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:
**SAFETY DATA SHEET**

**Mirtazapine Disintegrating Formulation**

Version 7.3  
Revision Date: 10/01/2020  
SDS Number: 50205-00016  
Date of last issue: 03/23/2020  
Date of first issue: 01/23/2015

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms: Drowsiness, constipation, dry mouth, asthenia, Dizziness, Disorientation</th>
</tr>
</thead>
</table>

### 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 fish | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h |
|------------------|-------------------------------------------------------|
| 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
   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.
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.
SAFETY DATA SHEET

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Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards :
- Combustible dust
- Acute toxicity (any route of exposure)
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313 :
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
D-mannitol 69-65-8
(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine 85650-52-8
Polyvinyl pyrrolidone 9003-39-8
Cellulose 9004-34-6

California List of Hazardous Substances
Polyvinyl pyrrolidone 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6
Magnesium stearate 557-04-0

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
**SAFETY DATA SHEET**

**Mirtazapine Disintegrating Formulation**

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**NFPA 704:**

- Flammability: 1  
- Health: 1  
- Special hazard: 0  
- Instability: 0

**HMIS® IV:**

- HEALTH: 2  
- FLAMMABILITY: 3  
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

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**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)  
- **NIOSH REL**: USA. NIOSH Recommended Exposure Limits  
- **OSHA Z-1**: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
- **ACGIH / TWA**: 8-hour, time-weighted average  
- **NIOSH REL / TWA**: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
- **OSHA Z-1 / TWA**: 8-hour time weighted average

- **AIIC**: Australian Inventory of Industrial Chemicals  
- **ASTM**: American Society for the Testing of Materials  
- **bw**: Body weight  
- **CERCLA**: Comprehensive Environmental Response, Compensation, and Liability Act  
- **CMR**: Carcinogen, Mutagen or Reproductive Toxicant  
- **DIN**: Standard of the German Institute for Standardisation  
- **DOT**: Department of Transportation  
- **DSL**: Domestic Substances List (Canada)  
- **ECx**: Concentration associated with x% response  
- **EHS**: Extremely Hazardous Substance  
- **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  
- **HMIS**: Hazardous Materials Identification System  
- **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 Lethal Dose)  
- **MARPOL**: International Convention for the Prevention of Pollution from Ships  
- **MSHA**: Mine Safety and Health Administration  
- **n.o.s.**: Not Otherwise Specified  
- **NFPA**: National Fire Protection Association  
- **NO(A)EC**: No Observed (Adverse) Effect Concentration  
- **NO(A)EL**: No Observed (Adverse) Effect Level  
- **NOELR**: No Observable Effect Loading Rate  
- **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)
SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 10/01/2020

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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