**SAFETY DATA SHEET**

**Mirtazapine Disintegrating Formulation**

**Version** 4.4  
**Revision Date:** 01.10.2020  
**SDS Number:** 51106-00016  
**Date of last issue:** 23.03.2020  
**Date of first issue:** 23.01.2015

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

**Product name:** Mirtazapine Disintegrating Formulation

**Manufacturer or supplier’s details**

**Company:** 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

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**SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification**

**Acute toxicity (Oral):** Category 4

**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:**

- 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.
- H412 Harmful to aquatic life with long lasting effects.
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.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
- 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:
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<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>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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, DO NOT induce vomiting. 
Get medical attention. 
Rinse mouth thoroughly with water. 
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 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</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>

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## SAFETY DATA SHEET

### Mirtazapine Disintegrating Formulation

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Concentration</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 TWA</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6 CMP</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0 CMP</td>
</tr>
</tbody>
</table>

**Further information:** Irritation

- **Irritation**
  - TWA: 10 mg/m³
  - ACGIH

- **TWA (Respirable particulate matter)**
  - 3 mg/m³
  - 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 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).

#### 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
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<tr>
<td>Odor</td>
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<tr>
<td>Odor Threshold</td>
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<tr>
<td>pH</td>
<td>No data available</td>
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<tr>
<td>Melting point/freezing point</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
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</tr>
<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
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<tr>
<td>Autoignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
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<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Mirtazapine Disintegrating Formulation

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : 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:

(+/-)-1,2,3,4,10b-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
   Method: OECD Test Guideline 405
   Result: Irritation to eyes, reversing within 21 days

**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:

(+/-)-1,2,3,4,10b-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)
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 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:
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
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:
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:
LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Magnesium stearate:
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.
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:

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

Distribution among environmental compartments: \(\text{log Koc: 4.48}\)

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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.

: Not applicable

Control of precursors and essential chemicals for the preparation of drugs.

: Sodium hydrogencarbonate

International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined
Further information

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

All abbreviations are explained herein. 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
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