1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mirtazapine Disintegrating Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

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)
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.
Mirtazapine Disintegrating Formulation

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</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; 25</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>

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.

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.
SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

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.

Notes to physician:
- Treat symptomatically and supportively.

5. FIREFIGHTING 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.

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.
SAFETY DATA SHEET

Mirtazapine Disintegrating Formulation

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.

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 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.

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-</td>
<td>85650-52-8</td>
<td>TWA</td>
<td>25 µg/m3</td>
<td>Internal</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Substance</th>
<th>Wipe limit</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>a]pyrido[2,3-c][2]benzazepine</td>
<td>250 µg/100 cm²</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>NAB</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Inhalable particulate matter)</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</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).
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.
**SAFETY DATA SHEET**

**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>
</tr>
</thead>
<tbody>
<tr>
<td>2.14</td>
<td>2021/04/09</td>
<td>50195-00017</td>
<td>2020/10/01</td>
<td>2015/01/23</td>
</tr>
</tbody>
</table>

- **Appearance**: powder
- **Colour**: No data available
- **Odour**: No data available
- **Odour 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
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
Mirtazapine Disintegrating Formulation

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.

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 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

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
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SDS Number: 50195-00017
Date of last issue: 2020/10/01
Date of first issue: 2015/01/23

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

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

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

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

Repeated dose toxicity

Components:
(+/-)-1,2,3,4,10,14b-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:
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<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>4,000 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>8,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>10 Days</td>
</tr>
</tbody>
</table>

**Cellulose:**

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

**Magnesium stearate:**

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

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

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

**Ecotoxicity**

**Components:**

(+/-)-1,2,3,4,10b-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
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Date of first issue: 2015/01/23

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:

(+/−)-1,2,3,4,10b-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:

(+/−)-1,2,3,4,10b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:
Distribution among environ- log Koc: 4.48
mental compartments

**Other adverse effects**
No data available

### 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.

### 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.

### 15. REGULATORY INFORMATION

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

- **Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**
- **Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**
  - Hazardous substances that must be registered: Not applicable
- **Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**
  - Hazardous substances approved for use: Not applicable
  - Prohibited substances: Not applicable
  - Restricted substances: Not applicable
- **Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**
  - Type of Hazardous Materials Restricted to Import: Not applicable
The components of this product are reported in the following inventories:

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**16. OTHER INFORMATION**

Further information
- Date format: yyyy/mm/dd

**Full text of other abbreviations**
- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ID OEL**: Indonesia. Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **ID OEL / NAB**: Long term exposure limit

**Abbreviations**
- AICL - Australian Inventory of Industrial Chemicals
- ANTT - National Agency for Transport by Land of Brazil
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DSL - Domestic Substances List (Canada)
- ECx - Concentration associated with x% response
- ELx - Loading rate associated with x% response
- EmS - Emergency Schedule
- ENCS - Existing and New Chemical Substances (Japan)
- ErCx - Concentration associated with x% growth rate response
- ERG - Emergency Response Guide
- GHS - Globally Harmonized System
- GLP - Good Laboratory Practice
- IARC - International Agency for Research on Cancer
- IATA - International Air Transport Association
- IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IC50 - Half maximal inhibitory concentration
- ICAO - International Civil Aviation Organization
- IECSC - Inventory of Existing Chemical Substances in China
- IMDG - International Maritime Dangerous Goods
- IMO - International Maritime Organization
- ISHL - Industrial Safety and Health Law (Japan)
- ISO - International Organization 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
- 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
- TCSI - Taiwan Chemical Substance Inventory
- TDG - Transportation of Dangerous Goods
- TSCA - Toxic Substances Control Act (United States)
- UN - Unit-

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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