SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mirtazapine Disintegrating Formulation

Manufacturer or supplier's details
Company: Organon & Co.
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  B-2220
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 ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
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.
- P260 Do not breathe dust.
- 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:**
- P308 + P313 IF exposed or concerned: Get medical advice/attention.

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**

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</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>Acute toxicity (Oral), Category 4, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated exposure (Oral) (Nervous system), Category 2, Short-term (acute) aquatic hazard, Category 2, Long-term (chronic) aquatic hazard, Category 2</td>
<td>&gt;= 20 - &lt; 25</td>
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<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>Eye irritation, Category 2A</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td></td>
<td>&gt;= 1 - &lt; 5</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.
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: Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

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.

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.

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 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>
</tr>
<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>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<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).

**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

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).

**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**
- **Autoignition 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.
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:
(+/-)-1,2,3,4,10,14b-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
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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:
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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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
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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.
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

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.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : 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
Sources of key data used to compile the Material Safety Data Sheet:

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

All abbreviations are mentioned, and the information is provided as a guideline 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.
<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<td>01.10.2020</td>
<td>50188-00016</td>
<td>23.03.2020</td>
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