SAFETY DATA SHEET

Rizatriptan Orally Disintegrating Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Rizatriptan Orally 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

Skin irritation : Category 3
Skin sensitization : Category 1
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Cardio-vascular system)

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms : 

Signal Word : Warning
Hazard Statements : H316 Causes mild skin irritation.
                   H317 May cause an allergic skin reaction.
                   H373 May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.
Precautionary Statements : Prevention:
                          P260 Do not breathe dust.
                          P272 Contaminated work clothing should not be allowed out of the workplace.
                          P280 Wear protective gloves.
                          Response:
                          P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture**: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td></td>
<td></td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Peppermint oil</td>
<td>8006-90-4</td>
<td></td>
<td>Flammable liquids, Acute toxicity (Oral), Category 4</td>
<td>&gt;= 2.5 -&lt; 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin irritation, Category 5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye irritation, Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin sensitization, Category 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Short-term (acute) aquatic hazard, Category 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Long-term (chronic) aquatic hazard, Category 3</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td></td>
<td></td>
<td>&gt;= 1 -&lt; 5</td>
</tr>
<tr>
<td>Rizatriptan</td>
<td>145202-66-0</td>
<td></td>
<td>Acute toxicity (Oral), Category 4</td>
<td>&gt;= 1 -&lt; 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye irritation, Category 2B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Specific target organ toxicity - single exposure, Category 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Specific target organ toxicity - repeated exposure (Oral) (Cardio-vascular system), Category 1</td>
<td></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 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.

Most important symptoms and effects, both acute and delayed :
Causes mild skin irritation.
May cause an allergic skin reaction.
May cause damage to organs through prolonged or repeated exposure if swallowed.
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)

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 emer- : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal
Emergency procedures: 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 get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- 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.
- Contaminated work clothing should not be allowed out of the workplace.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures.
industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

Materials to avoid
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

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>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Rizatriptan</td>
<td>145202-66-0</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
- Minimize open handling.

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: Consider double gloving.

Eye protection
- Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection
- Work uniform or laboratory coat.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.
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: Not applicable
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
Relative density: No data available
Density: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  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

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not classified as a reactivity hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conditions to avoid</th>
<th>Heat, flames and sparks. Avoid dust formation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure
- Inhalation
- Skin contact
- Ingestion
- Eye contact

#### Acute toxicity
- Not classified based on available information.

#### Product:
- Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
  - Method: Calculation method

#### Components:

##### 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

##### Peppermint oil:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
- Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

##### Starch:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2.000 mg/kg

**Rizatriptan:**
Acute oral toxicity: LD50 (Rat): 2.227 mg/kg
LD50 (Mouse): 700 - 1.631 mg/kg

**Skin corrosion/irritation**
Causes mild skin irritation.

**Components:**
**Peppermint oil:**
Species: Rabbit
Result: Skin irritation
Remarks: Based on data from similar materials

**Rizatriptan:**
Species: Rabbit
Result: No skin irritation

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

**Components:**
**Peppermint oil:**
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

**Starch:**
Species: Rabbit
Result: No eye irritation

**Rizatriptan:**
Species: Bovine cornea
Remarks: Moderate eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**
May cause an allergic skin reaction.

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

**Components:**
**Peppermint oil:**
Test Type: Local lymph node assay (LLNA)
### Routes of exposure
- **Species**: Mouse
- **Method**: OECD Test Guideline 429
- **Result**: positive
- **Remarks**: Based on data from similar materials
- **Assessment**: Probability or evidence of skin sensitization in humans

### Starch:
- **Test Type**: Maximization Test
- **Routes of exposure**: Skin contact
- **Species**: Guinea pig
- **Result**: negative

### Rizatriptan:
- **Test Type**: Maximization Test
- **Routes of exposure**: Dermal
- **Species**: Guinea pig
- **Assessment**: Does not cause skin sensitization.
- **Result**: negative

### Germ cell mutagenicity
Not classified based on available information.

### Components:

#### Cellulose:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Genotoxicity in vivo**: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

#### Starch:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

#### Rizatriptan:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Alkaline elution assay
  - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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

Rizatriptan:
Species: Mouse
Application Route: Oral
Exposure time: 100 weeks
NOAEL: 125 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 106 weeks
NOAEL: 106 mg/kg body weight
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

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

Rizatriptan:
Effects on fertility:
Test Type: Fertility/early embryonic development
Species: Rat, female
SAFETY DATA SHEET
Rizatriptan Orally 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>3.1</td>
<td>10.10.2020</td>
<td>809059-00010</td>
<td>23.03.2020</td>
<td>22.07.2016</td>
</tr>
</tbody>
</table>

| Application Route: Oral | Fertility: LOAEL: 100 mg/kg body weight | Symptoms: altered estrus cycles | Result: No effects on fertility and early embryonic development were detected. |

| Test Type: Fertility/early embryonic development | Species: Rat, male | Application Route: Oral | Fertility: NOAEL: 250 mg/kg body weight | Result: No effects on fertility and early embryonic development were detected. |

| Effects on fetal development | Test Type: Embryo-fetal development | Species: Rat | Application Route: Oral | Developmental Toxicity: LOAEL: 10 mg/kg body weight | Result: No teratogenic effects, Embryo-fetal toxicity. |

| Test Type: Embryo-fetal development | Species: Rabbit | Application Route: Oral | Developmental Toxicity: LOAEL: 100 mg/kg body weight | Result: No teratogenic effects, Embryo-fetal toxicity. | Remarks: The effects were seen only at maternally toxic doses. |

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**STOT-single exposure**
Not classified based on available information.

**Components:**

**Rizatriptan:**
Assessment : May cause drowsiness or dizziness.

**STOT-repeated exposure**
May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

**Components:**

**Rizatriptan:**
Target Organs : Cardio-vascular system
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Cellulose:**
<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>&gt;= 9.000 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Ingestion</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>90 Days</td>
</tr>
</tbody>
</table>

**Starch:**

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>&gt;= 2.000 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Skin contact</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>28 Days</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>OECD Test Guideline 410</td>
</tr>
</tbody>
</table>

**Rizatriptan:**

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOAEL</strong></td>
<td>1 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>14 Weeks</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Dilatation of the pupil, Increased pulse rate, Redness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOAEL</strong></td>
<td>0,05 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Intravenous</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>2 Weeks</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Dilatation of the pupil, Increased pulse rate, Redness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOAEL</strong></td>
<td>0,2 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>1 y</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Dilatation of the pupil</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Rizatriptan:**

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Target Organs: Cardio-vascular system</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Symptoms: asthenia, Fatigue, Pain, Dizziness, Weakness, Drowsiness</td>
</tr>
</tbody>
</table>

**Ecotoxicity**

**Components:**

**Cellulose:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Rizatriptan Orally Disintegrating Formulation

Version 3.1  Revision Date: 10.10.2020  SDS Number: 809059-00010  Date of last issue: 23.03.2020  Date of first issue: 22.07.2016

Peppermint oil:
Toxicity to fish:  LL50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:  EL50 (Daphnia magna (Water flea)): > 10 - 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:  EL50 (Desmodesmus subspicatus (green algae)): > 10 - 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to microorganisms:  EC10: 51 mg/l
Exposure time: 3 h
Remarks: Based on data from similar materials

Rizatriptan:
Toxicity to fish:  LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:  EC50 (Daphnia magna (Water flea)): 1.000 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:  EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 48 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):  NOEC (Pimephales promelas (fathead minnow)): 9,6 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  NOEC (Daphnia magna (Water flea)): 110 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms:  EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Persistence and degradability

Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

Peppermint oil:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

Rizatriptan:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 13 d
Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Peppermint oil:
Partition coefficient: n-octanol/water: log Pow: > 4
Remarks: Based on data from similar materials

Rizatriptan:
Partition coefficient: n-octanol/water: log Pow: -0.649

Mobility in soil

Components:

Rizatriptan:
Distribution among environmental compartments: log Koc: 3.83
Method: OECD Test Guideline 106

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 : Not applicable

International Regulations

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


Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIIC - 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
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.