

## Rizatriptan Orally Disintegrating Formulation

Version 2.4      Revision Date: 09.04.2021      SDS Number: 809076-00010      Date of last issue: 10.10.2020  
Date of first issue: 22.07.2016

---

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Rizatriptan Orally Disintegrating Formulation

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Sub-stance/Mixture : Pharmaceutical

**1.3 Details of the supplier of the safety data sheet**

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

**1.4 Emergency telephone number**



215-631-6999

---

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

|  |  |
|--|--|
| Skin sensitisation, Category 1                                 | H317: May cause an allergic skin reaction.                               |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :  

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.  
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves.

## Rizatriptan Orally Disintegrating Formulation

Version 2.4      Revision Date: 09.04.2021      SDS Number: 809076-00010      Date of last issue: 10.10.2020  
Date of first issue: 22.07.2016

**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.

Hazardous components which must be listed on the label:

Peppermint oil  
Rizatriptan

**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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****3.2 Mixtures****Components**

| Chemical name  | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification   | Concentration<br>(% w/w) |
|----------------|---|--|--------------------------|
| Peppermint oil | 8006-90-4   | Skin Irrit. 2; H315<br>Eye Irrit. 2; H319<br>Skin Sens. 1; H317<br>Aquatic Chronic 3;<br>H412                                | >= 2,5 - < 10            |
| Rizatriptan    | 145202-66-0   | Acute Tox. 4; H302<br>Eye Irrit. 2; H319<br>Repr. 2; H361d<br>STOT SE 3; H336<br>STOT RE 1; H372<br>(Cardio-vascular system) | >= 1 - < 3               |

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures****4.1 Description of 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.
- Protection of first-aiders                   : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

when the potential for exposure exists (see section 8).

- |                         |   |  |
|-------------------------|---|--|
| If inhaled              | : | If inhaled, remove to fresh air.<br>Get medical attention.   |
| In case of skin contact | : | In case of contact, immediately flush skin with plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact  | : | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.   |
| If swallowed            | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.  |

**4.2 Most important symptoms and effects, both acute and delayed**

- |       |   |  |
|-------|---|--|
| Risks | : | May cause an allergic skin reaction.<br>May cause damage to organs through prolonged or repeated exposure. |
|       |   | Dust contact with the eyes can lead to mechanical irritation.  |

**4.3 Indication of any immediate medical attention and special treatment needed**

- |           |   |   |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- |                                |   |  |
|--------------------------------|---|--|
| Suitable extinguishing media   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : | None known.  |

**5.2 Special hazards arising from the substance or mixture**

- |                                       |   |   |
|---------------------------------------|---|---|
| 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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products         | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )   |

**5.3 Advice for firefighters**

- |                              |   |  |
|------------------------------|---|--|
| Special protective equipment | : | In the event of fire, wear self-contained breathing apparatus. |
|------------------------------|---|--|

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

|                                |   |   |
|--------------------------------|---|---|
| for firefighters               |   | Use personal protective equipment.  |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |

---

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

|                      |   |  |
|----------------------|---|--|
| Personal precautions | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
|----------------------|---|--|

**6.2 Environmental precautions**

|                           |   |   |
|---------------------------|---|---|
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |
|---------------------------|---|---|

**6.3 Methods and material for containment and cleaning up**

|                         |   |  |
|-------------------------|---|--|
| Methods for cleaning up | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |
|-------------------------|---|--|

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

---

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

|                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<br>Do not breathe dust.  |

## Rizatriptan Orally Disintegrating Formulation

Version 2.4      Revision Date: 09.04.2021      SDS Number: 809076-00010      Date of last issue: 10.10.2020  
Date of first issue: 22.07.2016

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.

**7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

**7.3 Specific end use(s)**

Specific use(s) : No data available

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

| Components | CAS-No.   | Value type (Form of exposure)          | Control parameters   | Basis  |
|------------|-----------|--|----------------------|--------|
| Cellulose  | 9004-34-6 | TWA OEL-RL<br>(Respirable dust)        | 5 mg/m <sup>3</sup>  | ZA OEL |
|            |           | Further information: Recommended Limit |                      |        |
|            |           | TWA OEL-RL<br>(inhalable dust)         | 10 mg/m <sup>3</sup> | ZA OEL |
|            |           | Further information: Recommended Limit |                      |        |
|            |           | STEL OEL-RL<br>(Dust)                  | 20 mg/m <sup>3</sup> | ZA OEL |
|            |           | Further information: Recommended Limit |                      |        |

## Rizatriptan Orally Disintegrating Formulation

Version 2.4      Revision Date: 09.04.2021      SDS Number: 809076-00010      Date of last issue: 10.10.2020  
Date of first issue: 22.07.2016

|  |             |                                 |                              |          |
|--|-------------|---------------------------------|------------------------------|----------|
| Starch                                 | 9005-25-8   | TWA OEL-RL<br>(Respirable dust) | 5 mg/m <sup>3</sup>          | ZA OEL   |
| Further information: Recommended Limit |             |                                 |                              |          |
|  |             | TWA OEL-RL<br>(inhalable dust)  | 10 mg/m <sup>3</sup>         | ZA OEL   |
| Further information: Recommended Limit |             |                                 |                              |          |
| Rizatriptan                            | 145202-66-0 | TWA                             | 10 µg/m <sup>3</sup> (OEB 3) | Internal |
|  |             | Wipe limit                      | 100 µg/100 cm <sup>2</sup>   | Internal |

## 8.2 Exposure controls

**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**

- 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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
- 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 (P)

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

- 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

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

|  |   |   |
|--|---|---|
| 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. |
| 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   |
| Relative 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, kinematic                             | : | No data available   |
| Explosive properties                             | : | Not explosive   |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing.                        |

**9.2 Other information**

|                        |   |                   |
|------------------------|---|-------------------|
| Flammability (liquids) | : | No data available |
| Molecular weight       | : | No data available |
| Particle size          | : | No data available |

---

**SECTION 10: Stability and reactivity****10.1 Reactivity**

Not classified as a reactivity hazard.

**10.2 Chemical stability**

Stable under normal conditions.

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

**10.3 Possibility of hazardous reactions**

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

---

**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

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: > 2.000 mg/kg  
Method: Calculation method

**Components:****Peppermint oil:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

**Rizatriptan:**

Acute oral toxicity : LD50 (Rat): 2.227 mg/kg

LD50 (Mouse): 700 - 1.631 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Peppermint oil:**

Species : Rabbit  
Result : Skin irritation  
Remarks : Based on data from similar materials



## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

**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

**Rizatriptan:**

Species : Bovine cornea  
Remarks : Moderate eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Peppermint oil:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : positive  
Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitisation in humans

**Rizatriptan:**

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Assessment : Does not cause skin sensitisation.  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Rizatriptan:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

## Rizatriptan Orally Disintegrating Formulation

Version 2.4      Revision Date: 09.04.2021      SDS Number: 809076-00010      Date of last issue: 10.10.2020  
Date of first issue: 22.07.2016

---

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:****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:****Rizatriptan:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat, female  
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.

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

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

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: No teratogenic effects, Embryo-foetal 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 through prolonged or repeated exposure.

**Components:****Rizatriptan:**

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

**Repeated dose toxicity****Components:****Rizatriptan:**

Species : Rat  
LOAEL : 1 mg/kg  
Application Route : Oral  
Exposure time : 14 Weeks  
Symptoms : Dilatation of the pupil, Increased pulse rate, Redness

Species : Dog  
LOAEL : 0,05 mg/kg  
Application Route : Intravenous  
Exposure time : 2 Weeks  
Symptoms : Dilatation of the pupil, Increased pulse rate, Redness

Species : Dog

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

|                   |   |                         |
|-------------------|---|-------------------------|
| LOAEL             | : | 0,2 mg/kg               |
| Application Route | : | Oral                    |
| Exposure time     | : | 1 yr                    |
| Symptoms          | : | Dilatation of the pupil |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Rizatriptan:**

|           |   |  |
|-----------|---|--|
| Ingestion | : | Target Organs: Cardio-vascular system<br>Symptoms: asthenia, Fatigue, Pain, Dizziness, Weakness,<br>Drowsiness |
|-----------|---|--|

---

**SECTION 12: Ecological information****12.1 Toxicity****Components:****Peppermint oil:**

|   |   |   |
|---|---|---|
| Toxicity to fish                                    | : | LL50 (Danio rerio (zebra fish)): > 10 - 100 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials              |
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Daphnia magna (Water flea)): > 10 - 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials            |
| Toxicity to algae/aquatic plants                    | : | EL50 (Desmodesmus subspicatus (green algae)): > 10 - 100 mg/l<br>Exposure time: 72 h<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms                          | : | EC10 : 51 mg/l<br>Exposure time: 3 h<br>Remarks: Based on data from similar materials   |

**Rizatriptan:**

|   |   |  |
|---|---|--|
| Toxicity to fish                                    | : | LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l<br>Exposure time: 96 h   |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1.000 mg/l<br>Exposure time: 48 h   |
| Toxicity to algae/aquatic plants                    | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 48 |

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

|  |   |   |
|--|---|---|
|  |   | mg/l  |
|  |   | Exposure time: 72 h                           |
|  |   | Method: OECD Test Guideline 201               |
| 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               |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC: 9,6 mg/l                                |
|  |   | Exposure time: 32 d                           |
|  |   | Species: Pimephales promelas (fathead minnow) |
|  |   | Method: OECD Test Guideline 210               |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 110 mg/l                                |
|  |   | Exposure time: 21 d                           |
|  |   | Species: Daphnia magna (Water flea)           |
|  |   | Method: OECD Test Guideline 211               |

**12.2 Persistence and degradability****Components:****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    |

**12.3 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 |
|--|---|-----------------|

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

**12.4 Mobility in soil****Components:****Rizatriptan:**

Distribution among environmental compartments : log Koc: 3,83  
Method: OECD Test Guideline 106

**12.5 Results of PBT and vPvB assessment****Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects****Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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****14.1 UN number**

Not regulated as a dangerous good

**14.2 UN proper shipping name**

Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

Not regulated as a dangerous good

**14.4 Packing group**

Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

---

**14.6 Special precautions for user**

Not applicable

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS : not determined

DSL : not determined

IECSC : not determined

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of H-Statements**

H302 : Harmful if swallowed.  
H315 : Causes skin irritation.  
H317 : May cause an allergic skin reaction.  
H319 : Causes serious eye irritation.  
H336 : May cause drowsiness or dizziness.  
H361d : Suspected of damaging the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.  
H412 : Harmful to aquatic life with long lasting effects.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Eye Irrit. : Eye irritation  
Repr. : Reproductive toxicity  
Skin Irrit. : Skin irritation  
Skin Sens. : Skin sensitisation  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure  
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits  
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit  
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous

## Rizatriptan Orally Disintegrating Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10.10.2020  |
| 2.4     | 09.04.2021     | 809076-00010 | Date of first issue: 22.07.2016 |

Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

**Classification of the mixture:**

|              |      |
|--------------|------|
| Skin Sens. 1 | H317 |
| STOT RE 2    | H373 |

**Classification procedure:**

|                    |
|--------------------|
| Calculation method |
| Calculation method |

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.

ZA / EN