according to Regulation (EC) No. 1907/2006



# **Rizatriptan Orally Disintegrating Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

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 09.04.2021
 818382-00011
 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- : Pharmaceutical

stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.

30 Hudson Street, 33nd 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 H373: May cause damage to organs through pro-

exposure, Category 2 longed 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.

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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.

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.

Ecological information: 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.

Toxicological information: 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.

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<br>system) | >= 1 - < 3               |

For explanation of abbreviations see section 16.

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#### **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 ad-

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

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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

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

Risks : May cause an allergic skin reaction.

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

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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### 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.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

#### 5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

#### **SECTION 6: Accidental release measures**

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avo

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.

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

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

according to Regulation (EC) No. 1907/2006



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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.

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 as-

sessment

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

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### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

### **Occupational Exposure Limits**

| Components  | CAS-No.         | Value type (Form of exposure) | Control parameters         | Basis    |
|-------------|-----------------|-------------------------------|----------------------------|----------|
| Rizatriptan | 145202-66-<br>0 | TWA                           | 10 μg/m3 (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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

Filter type : Particulates type (P)

### **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : No data available
Odour : No data available
Odour Threshold : No data available

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Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling 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

Flash point Not applicable

Auto-ignition temperature No data available

Decomposition temperature

Decomposition tempera-

No data available

pΗ No data available

Viscosity

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

No data available Vapour pressure

Relative density No data available

Density No data available

Relative vapour density No data available

Particle characteristics

Particle size No data available

9.2 Other information

**Explosives** Not explosive

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

Evaporation rate No data available

Molecular weight No data available

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### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure 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

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#### 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:

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

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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

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

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Application Route: Oral

Fertility: LOAEL: 100 mg/kg body weight

Symptoms: altered estrus cycles

Result: No effects on fertility and early embryonic develop-

ment 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 develop-

ment were detected.

Effects on foetal develop-

ment

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 dos-

es.

Reproductive toxicity - As-

sessment

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:

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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 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.

#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered 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.

### Experience with human exposure

**Components:** 

Rizatriptan:

Ingestion : Target Organs: Cardio-vascular system

Symptoms: asthenia, Fatigue, Pain, Dizziness, Weakness,

**Drowsiness** 

### **SECTION 12: Ecological information**

### 12.1 Toxicity

### **Components:**

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 : EL50 (Daphnia magna (Water flea)): > 10 - 100 mg/l

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aquatic invertebrates 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 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 tox-

icity)

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 (Chron-

NOEC: 110 mg/l

Exposure time: 21 d

ic toxicity)

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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### 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: nlog Pow: > 4

octanol/water Remarks: Based on data from similar materials

Rizatriptan:

Partition coefficient: n-

octanol/water

log Pow: -0,649

### 12.4 Mobility in soil

### **Components:**

Rizatriptan:

Distribution among environ-

mental compartments

log Koc: 3,83

Method: OECD Test Guideline 106

#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

: This substance/mixture contains no components considered Assessment

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 poten-

tial

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

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### **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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

#### 14.1 UN number or ID 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

### 14.6 Special precautions for user

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

REACH - Candidate List of Substances of Very High Not applicable

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation Not applicable

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EC) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

Not applicable

Not applicable

Not applicable

Not applicable

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Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

### Other regulations:

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

### 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

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

according to Regulation (EC) No. 1907/2006



# Rizatriptan Orally Disintegrating Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

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 09.04.2021
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 Date of first issue: 22.07.2016

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 Agen-

cy, http://echa.europa.eu/

Classification of the mixture:

Classification procedure:

Skin Sens. 1 H317 Calculation method STOT RE 2 H373 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.

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