

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

SECTION 1. IDENTIFICATION

Product name : Rizatriptan Orally Disintegrating Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Skin sensitization : Category 1

Reproductive toxicity : Category 2

Specific target organ
systemic toxicity - repeated
exposure (Oral) : Category 1 (Cardio-vascular system)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

Rizatriptan Orally Disintegrating Formulation

Version 1.2 Revision Date: 05/02/2017 SDS Number: 809075-00003 Date of last issue: 01/13/2017
Date of first issue: 07/22/2016

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	≥ 10 - < 20
Peppermint oil	8006-90-4	≥ 1 - < 5
Starch	9005-25-8	≥ 1 - < 5
Rizatriptan	145202-66-0	≥ 1 - < 5

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.

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

- 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 : Dust contact with the eyes can lead to mechanical irritation.
May cause an allergic skin reaction.
Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
- 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.
- 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 : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
- 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.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protection : Use personal protective equipment.

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

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|---|---|--|
| tive equipment and emergency procedures | : | Follow safe handling advice and personal protective equipment recommendations. |
| Environmental precautions | : | Discharge into the environment must be avoided. 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. Handle in accordance with good industrial hygiene and safety practice. 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. Take care to prevent spills, waste and minimize release to the environment. |
| 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 |

Rizatriptan Orally Disintegrating Formulation

Version 1.2 Revision Date: 05/02/2017 SDS Number: 809075-00003 Date of last issue: 01/13/2017
 Date of first issue: 07/22/2016

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Peppermint oil	8006-90-4	TWA (mist - total)	10 mg/m ³	NIOSH REL
		TWA (mist - respirable)	5 mg/m ³	NIOSH REL
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Rizatriptan	145202-66-0	TWA	10 µg/m ³ (OEB 3)	Merck
		Wipe limit	100 µg/100 cm ²	Merck

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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

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.
Hygiene measures	:	Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No information 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

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	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

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

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

Ingredients:**Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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 (Mouse): > 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.

Ingredients:**Cellulose:**

Result: No skin irritation
Remarks: Based on data from similar materials

Peppermint oil:

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

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.

Ingredients:**Cellulose:**

Result: No eye irritation
Remarks: Based on data from similar materials

Peppermint oil:

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

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.

Ingredients:**Cellulose:**

Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

Peppermint oil:

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

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

Assessment: Probability or evidence of skin sensitization in humans

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.

Ingredients:**Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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.

Ingredients:**Rizatriptan:**

Species: Mouse

Application Route: Oral

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

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

IARC	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

Ingredients:**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.
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.

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

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

STOT-single exposure

Not classified based on available information.

Ingredients:**Rizatriptan:**

Assessment: May cause drowsiness or dizziness.

STOT-repeated exposure

Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

Ingredients:**Rizatriptan:**

Target Organs: Cardio-vascular system

Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Ingredients:****Cellulose:**

Species: Rat

NOAEL: > 5,000 mg/kg

Application Route: Ingestion

Exposure time: 90 Days

Remarks: Based on data from similar materials

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

LOAEL: 0.2 mg/kg

Application Route: Oral

Exposure time: 1 y

Symptoms: Dilatation of the pupil

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Ingredients:****Rizatriptan:**

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

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Ingredients:****Cellulose:**

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

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 : 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 Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

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 : 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**Ingredients:****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

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

Bioaccumulative potential**Ingredients:****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
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Mobility in soil**Ingredients:****Rizatriptan:**

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

Other adverse effectsNo 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**49 CFR**Not regulated as a dangerous good

Rizatriptan Orally Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/13/2017
1.2	05/02/2017	809075-00003	Date of first issue: 07/22/2016

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Fire Hazard
Acute Health Hazard
Chronic Health Hazard

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations**Pennsylvania Right To Know**

Gelatins	9000-70-8
D-mannitol	69-65-8
Cellulose	9004-34-6
gGlycine	56-40-6
D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate	64044-51-5
Aspartame	22839-47-0
Peppermint oil	8006-90-4
Starch	9005-25-8

California Prop. 65

WARNING! This product contains a chemical known in the State of California to cause cancer.
Quartz 14808-60-7

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Starch	9005-25-8

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

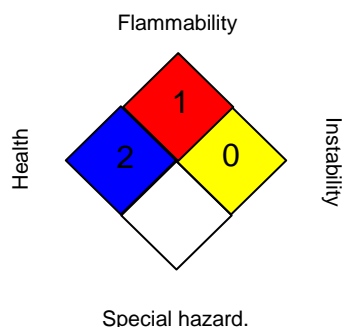
Rizatriptan Orally Disintegrating Formulation

Version 1.2 Revision Date: 05/02/2017 SDS Number: 809075-00003 Date of last issue: 01/13/2017
 Date of first issue: 07/22/2016

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

Rizatriptan Orally Disintegrating Formulation

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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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

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

Revision Date : 05/02/2017

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

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