

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	809071-00015	Date of first issue: 22.07.2016

#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Rizatriptan Orally Disintegrating Formulation				
Manufacturer or supplier's details						
Company name of supplier Address	:	Organon & Co. Avenida 16 de Septiembre No. 301 Xaltocan - Xochimilco Mexico 16090				
Telephone Emergency telephone E-mail address	:	+52 55 57284444 1-215-631-6999 EHSSTEWARD@organon.com				
Recommended use of the chemical and restrictions on use						
Recommended use	:	Pharmaceutical				

: Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

Restrictions on use

GHS Classification Skin corrosion/irritation	:	Category 3
Skin sensitization	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Cardio-vascular system)
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H316 Causes mild skin irritation. 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.
Precautionary Statements	:	<ul> <li>Prevention:</li> <li>P201 Obtain special instructions before use.</li> <li>P202 Do not handle until all safety precautions have been read and understood.</li> <li>P260 Do not breathe dust.</li> <li>P264 Wash skin thoroughly after handling.</li> <li>P270 Do not eat, drink or smoke when using this product.</li> <li>P272 Contaminated work clothing should not be allowed out of the workplace.</li> </ul>



ersion 1	Revision Date: 30.09.2023	SDS Number: 809071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
		P280 Wear pro face protection	otective gloves/ protective clothing/ eye protection/
		Response:	
		P308 + P313 I attention. P333 + P313 I attention.	F ON SKIN: Wash with plenty of water. F exposed or concerned: Get medical advice/ f skin irritation or rash occurs: Get medical advice/ Fake off contaminated clothing and wash it before
		<b>Storage:</b> P405 Store loc	sked up.
		<b>Disposal:</b> P501 Dispose posal plant.	of contents/ container to an approved waste dis-
Dust		can lead to mechanica	al irritation. ssing, handling or other means.

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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. 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	:	Causes mild skin irritation.



Vers 3.1	sion	Revision Date: 30.09.2023	-	9071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016	
	and effo delayed	ects, both acute and		May cause an allergic skin reaction. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed.		
	Protect	ion of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).		
	Notes t	o physician	:		cally and supportively.	
SEC	TION 5	. FIRE-FIGHTING ME	ASU	IRES		
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical		
	Unsuita media	ble extinguishing	:	None known.		
		c hazards during fire	:	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.	
	Hazard ucts	ous combustion prod-	:	Carbon oxides Nitrogen oxides (N	NOx)	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray to	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do	
		protective equipment fighters	:		e, wear self-contained breathing apparatus. ective equipment.	
SEC	TION 6	. ACCIDENTAL RELE	ASI	EMEASURES		
	tive equ	al precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).	

Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and



Version 3.1	Revision Date: 30.09.2023	SDS Number: 809071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
		employed in the determine which Sections 13 an	material, as well as those materials and items e cleanup of releases. You will need to h regulations are applicable. d 15 of this SDS provide information regarding national requirements.
SECTION	7. HANDLING AND ST	TORAGE	
Tech	nical measures	causing an exp Provide adequa	y may accumulate and ignite suspended dust losion. ate precautions, such as electrical grounding r inert atmospheres.
	/Total ventilation e on safe handling	<ul> <li>Use only with a</li> <li>Do not get on s</li> <li>Do not breathe</li> <li>Do not swallow</li> <li>Avoid contact w</li> <li>Wash skin thor</li> <li>Handle in acco</li> <li>practice, based</li> <li>assessment</li> <li>Minimize dust g</li> <li>Keep container</li> <li>Keep away from</li> <li>Take precautio</li> <li>Do not eat, drir</li> </ul>	dequate ventilation. kin or clothing. dust.
Hygie	ene measures	flushing system place. When using do Contaminated workplace. Wash contamin The effective o engineering co appropriate deg	chemical is likely during typical use, provide eye as and safety showers close to the working not eat, drink or smoke. work clothing should not be allowed out of the nated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the trative controls.
	itions for safe storage	: Keep in proper Store in accord	ly labeled containers. ance with the particular national regulations.
Mate	rials to avoid	Strong oxidizin	ibstances and mixtures

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters



sion	Revision Date: 30.09.2023	SDS Number: 809071-00015		st issue: 04.04.2023 st issue: 22.07.2016			
Comp	ponents	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis		
Cellul	ose	9004-34-6	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010 STPS-20		
			TWA	10 mg/m <sup>3</sup>	ACGIH		
Starcl	h	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010 STPS-20		
			TWA	10 mg/m <sup>3</sup>	ACGIH		
Rizatr	riptan	145202-66-0		10 µg/m3 (OEB 3)	Internal		
			Wipe limit	100 µg/100 cm <sup>2</sup>	Internal		
Engir	neering measures	design and protect prod Containmen are required the compou containment	operated in acco ucts, workers, ar t technologies su to control at sound to uncontrolle	ald be implemented by rdance with GMP prine and the environment. uitable for controlling c arce and to prevent mig d areas (e.g., open-fac	ciples to ompounds gration of		
Perso	onal protective equip	ment					
Respi	iratory protection	exposure as	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.				
	ter type protection	: Particulates					
Ma	aterial	: Chemical-re	Chemical-resistant gloves				
	emarks protection	: Wear safety If the work e mists or aer Wear a face	nvironment or a osols, wear the a shield or other fu	e shields or goggles. ctivity involves dusty compropriate goggles. Ill face protection if the the face with dusts, m	ere is a		
Skin a	and body protection	: Work uniforn Additional b task being p disposable s	erformed (e.g., s suits) to avoid ex riate degowning	oat. ould be used based u leevelets, apron, gaur posed skin surfaces. techniques to remove	ntlets,		

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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



## **Rizatriptan Orally Disintegrating Formulation**

Vers 3.1	sion	Revision Date: 30.09.2023		5 Number: 071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
	pН		:	No data available	
	Melting	point/freezing point	:	No data available	
	Initial boiling point and boiling range		:	No data available	
	Flash p	oint	:	Not applicable	
	Evapora	ation rate	:	No data available	
	Flamma	ability (solid, gas)	:	May form explosition handling or other	ve dust-air mixture during processing, means.
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	
	Relative	e vapor density	:	No data available	
	Relative	e density	:	No data available	
	Density		:	No data available	
	Solubili Wate	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n-	:	No data available	
		ition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosit Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	
	Particle	size	:	No data available	

#### SECTION 10. STABILITY AND REACTIVITY



## **Rizatriptan Orally Disintegrating Formulation**

VersionRevision Date:SDS Number:Date of last issue: 04.04.20233.130.09.2023809071-00015Date of first issue: 22.07.2016	
Reactivity:Not classified as a reactivity hazard.Chemical stability:Stable under normal conditions.Possibility of hazardous reactions:May form explosive dust-air mixture during processing handling or other means. Can react with strong oxidizing agents.	,
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.Incompatible materials: Oxidizing agentsHazardous decomposition products: No hazardous decomposition products are known.	
SECTION 11. TOXICOLOGICAL INFORMATION Information on likely routes of exposure Inhalation Skin contact Ingestion Eye contact	
Acute toxicity Not classified based on available information. Product:	
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method	
<u>Components:</u>	
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	
Peppermint oil:	
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg	
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg	
Starch:	
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg	
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg	

Rizatriptan:

Acute oral toxicity

LD50 (Mouse): 700 - 1,631 mg/kg

: LD50 (Rat): 2,227 mg/kg



rsion	Revision Date: 30.09.2023	SDS Number: 809071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
Skin o	corrosion/irritation		
Cause	es mild skin irritation.		
Comp	oonents:		
Peppe	ermint oil:		
Specie		: Rabbit	
Result		: Skin irritation	from cimilar motorials
Rema	Irks	: Based on data	a from similar materials
Rizatr	riptan:		
Specie	es	: Rabbit	
Resul	t	: No skin irritatio	n
Serio	us eye damage/eye	irritation	
	assified based on ava		
Comp	oonents:		
Рерре	ermint oil:		
Specie		: Rabbit	
Resul			es, reversing within 21 days
Rema	rks	: Based on data	a from similar materials
Starc	h:		
Specie		: Rabbit	
Resul	t	: No eye irritatio	on
Rizatr	riptan:		
Specie	es	: Bovine cornea	l
Rema		: Moderate eye	irritation
Respi	iratory or skin sensi	tization	
Skin s	sensitization		
May c	ause an allergic skin	reaction.	
Respi	iratory sensitization		
	assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
	ermint oil: -		
Test T			ode assay (LLNA)
Specie	s of exposure	: Skin contact : Mouse	
Metho		: OECD Test G	uideline 429
Resul	t	: positive	
Domo	rks	: Based on data	a from similar materials
Rema			



Version 3.1	Revision Date: 30.09.2023	SDS Numb 809071-000	
Starc	:h:		
Test			zation Test
Route Spec	es of exposure	: Skin co : Guinea	
Resu		: negative	
Rizat	riptan:		
Test		: Maximiz	zation Test
	es of exposure	: Dermal	
Spec	ies ssment	: Guinea	i pig ot cause skin sensitization.
Resu		: negative	
	n cell mutagenicity		
	lassified based on av	ailable informati	ion.
<u>Com</u>	ponents:		
Cellu	llose:		
Geno	otoxicity in vitro		vpe: Bacterial reverse mutation assay (AMES) negative
			vpe: In vitro mammalian cell gene mutation test negative
Genc	otoxicity in vivo	cytoger Species Applica	vpe: Mammalian erythrocyte micronucleus test (in vivo netic assay) s: Mouse ition Route: Ingestion negative
Stard	:h:		
Geno	otoxicity in vitro		vpe: Bacterial reverse mutation assay (AMES) negative
Rizat	riptan:		
Geno	otoxicity in vitro		vpe: Bacterial reverse mutation assay (AMES) negative
			vpe: Alkaline elution assay negative
			vpe: In vitro mammalian cell gene mutation test negative
			vpe: Chromosome aberration test in vitro negative
Genc	otoxicity in vivo	cytoger	vpe: Mammalian erythrocyte micronucleus test (in vivo netic assay) s: Mouse



Vers 3.1	sion	Revision Date: 30.09.2023	-	0S Number: 9071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
				Application Route Result: negative	: Oral
		<b>ogenicity</b> ssified based on availa	ıble	information.	
	Compo	onents:			
	Cellulo	ose:			
		s ition Route ure time	:	Rat Ingestion 72 weeks negative	
	Rizatri	ptan:			
	Specie Applica	s ation Route ure time	:	Mouse Oral 100 weeks 125 mg/kg body w negative	veight
		ition Route ure time	:	Rat Oral 106 weeks 106 mg/kg body v negative	veight
	-	<b>ductive toxicity</b> cted of damaging the u	nbo	rn child.	
	Compo	onents:			
	Celluic Effects	on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
	Effects	on fetal development	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion
	Rizatri	ptan:			
		on fertility	:	Species: Rat, fem Application Route Fertility: LOAEL: ' Symptoms: altere Result: No effects development were	: Oral 00 mg/kg body weight d estrus cycles on fertility and early embryonic e detected.
				Test Type: Fertilit	y/early embryonic development



ersion 1	Revision Date: 30.09.2023		S Number: 071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
				ute: Oral L: 250 mg/kg body weight cts on fertility and early embryonic
Effect	ts on fetal developmer		Species: Rat Application Rou Developmental Result: No tera	oryo-fetal development ute: Oral Toxicity: LOAEL: 10 mg/kg body weight togenic effects., Embryo-fetal toxicity. oryo-fetal development
			Species: Rabbi Application Rou Developmental Result: No tera	t
Repro sessr	oductive toxicity - As-		Some evidence	of adverse effects on development, based on
	nem	ä	animal experim	ents.
STOT	Γ <b>-single exposure</b> lassified based on ava		·	ents.
STOT Not cl	-single exposure		·	ents.
STOT Not cl <u>Com</u>	<b>F-single exposure</b> lassified based on ava		·	ents.
STOT Not cl <u>Com</u> Rizat	<b>F-single exposure</b> lassified based on ava	ilable ir	nformation.	ents. wsiness or dizziness.
STOT Not cl Com Rizat Asses STOT Cause	<b>F-single exposure</b> lassified based on ava <b>ponents:</b> <b>riptan:</b> ssment <b>F-repeated exposure</b>	ilable ir : I	nformation. May cause drov	
STOT Not cl Comj Rizat Asses STOT Cause swalle	<b>T-single exposure</b> lassified based on ava <b>ponents:</b> <b>riptan:</b> ssment <b>T-repeated exposure</b> es damage to organs	ilable ir : I	nformation. May cause drov	wsiness or dizziness.
STOT Not cl Comp Rizat Asses STOT Cause swalle <u>Comp</u> Rizat	<b>T-single exposure</b> lassified based on avainable ponents: riptan: ssment <b>T-repeated exposure</b> es damage to organs bowed. ponents: riptan:	ilable ir : I	nformation. May cause drov	wsiness or dizziness. m) through prolonged or repeated exposure if
STOT Not cl Com Rizat Asses STOT Cause swalle Com Rizat Targe	<b>F-single exposure</b> lassified based on avainable ponents: riptan: ssment <b>F-repeated exposure</b> es damage to organs bowed. ponents:	ilable ir : l (Cardio : (	nformation. May cause drov -vascular syste Cardio-vascula	wsiness or dizziness. m) through prolonged or repeated exposure if
STOT Not cl Com Rizat Asses STOT Cause swalle Com Rizat Targe Asses	<b>T-single exposure</b> lassified based on avainable ponents: riptan: ssment <b>T-repeated exposure</b> es damage to organs to bwed. ponents: riptan: et Organs ssment	ilable ir : l (Cardio : (	nformation. May cause drov -vascular syste Cardio-vascula Causes damag	wsiness or dizziness. m) through prolonged or repeated exposure if r system
STOT Not cl Comp Rizat Asses STOT Cause swalle Comp Rizat Targe Asses Repe	<b>T-single exposure</b> lassified based on avainable ponents: riptan: ssment <b>T-repeated exposure</b> es damage to organs bowed. ponents: riptan: et Organs	ilable ir : l (Cardio : (	nformation. May cause drov -vascular syste Cardio-vascula Causes damag	wsiness or dizziness. m) through prolonged or repeated exposure if r system
STOT Not cl Comp Rizat Asses STOT Cause swalle Comp Rizat Targe Asses Repe	T-single exposure lassified based on avaination ponents: riptan: ssment T-repeated exposure es damage to organs of owed. ponents: riptan: et Organs ssment ated dose toxicity ponents:	ilable ir : l (Cardio : (	nformation. May cause drov -vascular syste Cardio-vascula Causes damag	wsiness or dizziness. m) through prolonged or repeated exposure if r system
STOT Not cl Com Rizat Asses STOT Cause swalle Com Rizat Targe Asses Repe Com Cellu Speci	T-single exposure lassified based on avaination ponents: riptan: ssment T-repeated exposure es damage to organs bowed. ponents: riptan: et Organs ssment ated dose toxicity ponents: lose: ies	ilable ir :   (Cardio : (	nformation. May cause drov -vascular syste Cardio-vascula Causes damag exposure.	wsiness or dizziness. m) through prolonged or repeated exposure if r system e to organs through prolonged or repeated
STOT Not cl Comj Rizat Asses STOT Cause swalle Comj Rizat Targe Asses Repe Comj Cellu Speci NOAE	T-single exposure lassified based on avaination ponents: riptan: ssment T-repeated exposure es damage to organs bowed. ponents: riptan: et Organs ssment ated dose toxicity ponents: lose: ies	ilable ir :   (Cardio : ( : ( : (	nformation. May cause drov -vascular syste Cardio-vascula Causes damag exposure.	wsiness or dizziness. m) through prolonged or repeated exposure if r system e to organs through prolonged or repeated



Ver 3.1	sion	Revision Date: 30.09.2023	-	DS Number: 99071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
	Storob				
	Starch			Det	
	Specie NOAEI			Rat >= 2,000 mg/kg	
	-	- ation Route	÷	Skin contact	
	Exposi	ure time	:	28 Days	
	Metho	b	:	OECD Test Guide	eline 410
	Rizatri	ntan			
	Specie			Rat	
	LOAEL		:	1 mg/kg	
		- ation Route	:	Oral	
		ure time	:	14 Weeks	
	Sympto	oms	:	Dilatation of the p	upil, Increased pulse rate, Redness
	Specie	s	:	Dog	
	LOAEL		:	0.05 mg/kg	
		ation Route	:	Intravenous	
		ure time	:	2 Weeks	with the second purples note. De deser
	Sympto	oms	:	Dilatation of the p	upil, Increased pulse rate, Redness
	Specie	S	:	Dog	
	LOAEL		:	0.2 mg/kg	
		ation Route	:	Oral	
		ure time	:	1 y Dilatation of the n	
	Sympto	oms	:	Dilatation of the p	upii
	Aspira	tion toxicity			
	Not cla	ssified based on avail	able	information.	
	Experi	ence with human exp	posi	ure	
	Comp	onents:			
	Rizatri				
		•		Target Organa, C	ordio vocaular avatam
	Ingesti	011	•		ardio-vascular system nia, Fatigue, Pain, Dizziness, Weakness,
				Drowsiness	
SE	CTION 1	2. ECOLOGICAL INF	ORI	MATION	
	Ecoto	kicity			
	Comp	onents:			
	Cellulo	ose:			
	Toxicit	y to fish	:	LC50 (Oryzias lat	ipes (Japanese medaka)): > 100 mg/l
		, ,		Exposure time: 48	3 h
				Remarks: Based	on data from similar materials
	Donne	rmint oil:			
		rmint oil:			(
	IOXICIT	y to fish	:	Exposure time: 96	(zebra fish)): > 10 - 100 mg/l
					on data from similar materials
				. comarko. Dabeu	



## **Rizatriptan Orally Disintegrating Formulation**

ersion .1	Revision Date: 30.09.2023		0S Number: 9071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016
	y to daphnia and other c invertebrates	:	Exposure time: 48	agna (Water flea)): > 10 - 100 mg/l 3 h on data from similar materials
Toxicit plants	y to algae/aquatic	:	mg/l Exposure time: 72	mus subspicatus (green algae)): > 10 - 100 2 h on data from similar materials
Toxicit	y to microorganisms	:	EC10: 51 mg/l Exposure time: 3 Remarks: Based	h on data from similar materials
Rizatri	intan:			
	y to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): > 1,000 mg/ 5 h
	y to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): 1,000 mg/l 3 h
Toxicit plants	y to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD T	
			NOEC (Pseudoki mg/l Exposure time: 72 Method: OECD T	
Toxicit icity)	y to fish (Chronic tox-	:	NOEC (Pimephal Exposure time: 32 Method: OECD T	
	y to daphnia and other c invertebrates (Chron- ity)	:	NOEC (Daphnia i Exposure time: 2 <sup>·</sup> Method: OECD T	
Toxicit	y to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respin Method: OECD T	h ration inhibition
			NOEC: 1,000 mg, Exposure time: 3 Test Type: Respin Method: OECD T	h ration inhibition
Persis	tence and degradabili	itv		
		.,		

#### Components:

Cellulose:



### **Rizatriptan Orally Disintegrating Formulation**

Version 3.1	Revision Date: 30.09.2023		DS Number: 99071-00015	Date of last issue: 04.04.2023 Date of first issue: 22.07.2016		
Biod	Biodegradability		: Result: Readily biodegradable.			
-	permint oil: legradability	:	Result: Readily b Remarks: Based	iodegradable. on data from similar materials		
	<b>Rizatriptan:</b> Biodegradability		Result: Not readily biodegradable. Biodegradation: 50 % Exposure time: 13 d Method: OECD Test Guideline 314			
Bioa	accumulative potential					
<u>Con</u>	nponents:					
Part	<b>permint oil:</b> ition coefficient: n- nol/water	:		on data from similar materials		
Part octa	atriptan: ition coefficient: n- nol/water	:	log Pow: -0.649			
	bility in soil					
<b>Riza</b> Disti	nponents: atriptan: ribution among environ- tal compartments	:	log Koc: 3.83 Method: OECD T	est Guideline 106		
	<b>er adverse effects</b> data available					
SECTIO	N 13. DISPOSAL CONSI	DEF	RATIONS			
-	oosal methods ste from residues		Do not dispose o	f waste into sewer.		
	taminated packaging	:	Dispose of in acc Empty containers handling site for i	sordance with local regulations. solutions should be taken to an approved waste 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



#### **Rizatriptan Orally Disintegrating Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023				
3.1	30.09.2023	809071-00015	Date of first issue: 22.07.2016				
Not re	egulated as a dangero	us 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.							
Dom	estic regulation						
NOM	-002-SCT egulated as a dangero	us good					
Not re	egalatea ae a aaligere	Special precautions for user					
	0	ser					

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

The ingredients of this product ar	e I	rep	oort	ed i	in t	he following inventories:

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

#### **SECTION 16. OTHER INFORMATION**

Revision Date Date format	:	30.09.2023 dd.mm.yyyy
Full text of other abbreviati	ons	
ACGIH NOM-010-STPS-2014		USA. ACGIH Threshold Limit Values (TLV) Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con- trol - Appendix 1 Occupational Exposure Limits
ACGIH / TWA NOM-010-STPS-2014 / VLE- PPT		8-hour, time-weighted average Time weighted average limit value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA



#### **Rizatriptan Orally Disintegrating Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	809071-00015	Date of first issue: 22.07.2016

- 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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