

Version 5.1	Revision Date: 30.09.2023		S Number: 320-00021		sue: 04.04.2023 sue: 06.11.2014
Section 1	: Identification				
Produ	uct name	:	Timolol / Dorzola	mide Formulatio	on
Manu	ufacturer or supplier's d	letai	ls		
Comp	bany	:	MSD		
Addre	ess	:	33 Whakatiki Str Upper Hutt - Nev		g 908
Telep	phone	:	0800 800 543		
Emer	gency telephone number	r:	0800 764 766 (0 CHEMCALL)	800 POISON)	0800 243 622 (0800
E-ma	il address	:	EHSDATASTEW	/ARD@msd.con	n
Reco	ommended use of the ch	nem	ical and restriction	ons on use	
	mmended use ictions on use	:	Pharmaceutical Not applicable		
Section 2	: Hazard identification				
GHS	Classification				
Repro	oductive toxicity		Category 2		
•	ific target organ toxicity - ated exposure	:	Category 1 (Care Gastrointestinal		tem, Central nervous system,
GHS	label elements				
Haza	rd pictograms	:			
Signa	al word	:	Danger		
Haza	rd statements	:		mage to organs em, Gastrointes	he unborn child. (Cardio-vascular system, Cen- tinal tract, Lungs) through pro-
Preca	autionary statements	:	<b>Prevention:</b> P201 Obtain spe P202 Do not han and understood.		before use. ty precautions have been read





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P260 Do not breathe mist or vapours.P264 Wash skin thoroughly after handling.P270 Do not eat, drink or smoke when using this product.P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### **Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

#### Storage:

P405 Store locked up.

### Disposal:

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

#### Other hazards which do not result in classification

None known.

#### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Dorzolamide	130693-82-2	>= 1 -< 10
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-	26921-17-5	>= 0.1 -< 1
morpholino-1,2,5-thiadiazole monomaleate		

#### Section 4: 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.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and 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	:	Flush eyes with water as a precaution. 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	:	Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated



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delay Prote	ed ction of first-aiders	:	exposure. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment
Notes	s to physician	:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.
Section 5	: Fire-fighting measure	s	
Suita	ble extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsu media	itable extinguishing a	:	None known.
fightir	0	:	Exposure to combustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides Nitrogen oxides (NOx) Sulphur oxides Hydrogen chloride
Speci ods	ific extinguishing meth-	:	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.
	ial protective equipment efighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Section 6	: Accidental release me	easi	ures
tive e	onal precautions, protec- quipment and emer- y procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Envir	onmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
	ods and materials for inment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-



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		Sections 13 a	egulations are applicable. nd 15 of this SDS provide information regarding or national requirements.
Section 7	: Handling and storag	e	
Techr	nical measures		ing measures under EXPOSURE PERSONAL PROTECTION section.
Local	/Total ventilation		adequate ventilation.
	e on safe handling	: Do not breath Do not swallo Avoid contact Avoid prolong Wash skin the Handle in acc practice, base sessment Do not eat, dr Take care to environment.	e mist or vapours. w. with eyes. led or repeated contact with skin. oroughly after handling. ordance with good industrial hygiene and safety ed on the results of the workplace exposure as- ink or smoke when using this product. orevent spills, waste and minimize release to the
Hygie	ene measures	flushing syste place. When using c Wash contam The effective engineering c appropriate d industrial hyg	chemical is likely during typical use, provide eye ms and safety showers close to the working on ot eat, drink or smoke. inated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, tene monitoring, medical surveillance and the strative controls.
Cond	itions for safe storage	: Keep in prope	rly labelled containers. dance with the particular national regulations.
Mater	rials to avoid		vith the following product types:

### Section 8: Exposure controls/personal protection

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis	
Dorzolamide	130693-82-2	TWA	10 µg/m3 (OEB 3)	Internal	
	Further information	ation: Eye			
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal	
(S)-3-[3-(tert-butylamino)-2- hydroxypropoxy]-4- morpholino-1,2,5-thiadiazole monomaleate	26921-17-5	TWA	10 µg/m3 (OEB 3)	Internal	
	Further information: Eye, Skin				



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		I		Wipe limit	100 μg/100 cm²	Internal		
Engir	neering measures	te A d C a tr ta	echnologies ess quick cor Il engineerin esign and op rotect produ- ontainment re required t	to control airbo nections). g controls sho berated in acco cts, workers, a technologies s o control at so d to uncontrolle ces).	g controls and manufa orne concentrations (en ordance with GMP prin nd the environment. uitable for controlling o urce and to prevent m ed areas (e.g., open-fa	.g., drip- y facility iciples to compounds igration of		
Perso	onal protective equip	ment						
Filter type Hand protection		S O	<ul> <li>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</li> <li>Particulates type</li> </ul>					
Ma	aterial	: C	hemical-resi	stant gloves				
Eye p	emarks protection	: V If M P a	the work en hists or aeros lear a faces otential for d erosols.	lasses with sid vironment or a sols, wear the hield or other f irect contact to	de shields or goggles. activity involves dusty of appropriate goggles. ull face protection if th o the face with dusts, r	ere is a		
Skin a	and body protection	A ta P U	dditional boo ask being pe osable suits)	rformed (e.g., to avoid expo ate degowning	coat. hould be used based u sleevelets, apron, gau ised skin surfaces. techniques to remove	ntlets, dis-		

### Section 9: Physical and chemical properties

Appearance	:	liquid
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	5.6
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available



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	range				
	Flash p	point	:	No data available	
	Evapor	ation rate	:	No data available	)
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	)
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available	
	Relative	e vapour density	:	No data available	)
	Relative	e density	:	1.02	
	Density	/	:	No data available	)
	Solubili Wat	ity(ies) er solubility	:	soluble	
		n coefficient: n-	:	No data available	)
	octanol Auto-ig	nition temperature	:	No data available	)
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	
	Particle	e 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 reac-	:	Can react with strong oxidizing agents.
tions		





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Incom	itions to avoid npatible materials rdous decomposition icts	:	None known. Oxidizing agents No hazardous d	s ecomposition products are known.
•	1: Toxicological inform	natio	on	
Expo	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity			
	lassified based on availa	able	information.	
Prod Acute	e oral toxicity	:	Acute toxicity est Method: Calculat	timate: > 2,000 mg/kg tion method
<u>Com</u>	ponents:			
Dorz	olamide:			
Acute	e oral toxicity	:	LD50 (Rat): 1,92	7 mg/kg
			LD50 (Mouse): 1	,320 mg/kg
Acute	e inhalation toxicity	:	Remarks: No dat	a available
Acute	e dermal toxicity	:	Remarks: No dat	a available
• •	-[3-(tert-butylamino)-2-	-	<b>roxypropoxy]-4-r</b> LD50 (Rat): 1,00	norpholino-1,2,5-thiadiazole monomaleat 0 mg/kg
			LD50 (Mouse): 1	,140 mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Mouse): 3 Application Route	
			LD50 (Mouse): 8 Application Route	
	corrosion/irritation lassified based on availa	able	information.	
<u>Com</u>	ponents:			
(S)-3-	-[3-(tert-butylamino)-2-	hyd	roxypropoxy]-4-r	norpholino-1,2,5-thiadiazole monomaleat
Speci Metho Resu	bc	:	Rabbit Draize Test No skin irritation	

: No skin irritation

Result





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#### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

#### Dorzolamide:

Species	:	Monkey
Result	:	Mild eye irritation

### (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:

Species Result	-	Rabbit Mild eye irritation
Species Result		Dog No eye irritation

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

### **Respiratory sensitisation**

Not classified based on available information.

#### **Components:**

#### Dorzolamide:

Test Type	:	Maximisation Test
Exposure routes	: :	Skin contact
Species	: (	Guinea pig
Result	: \	Weak sensitizer

#### **Chronic toxicity**

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Dorzolamide:

Genotoxicity in vitro	:	Test Type: Chromosomal aberration Result: negative
		Test Type: Alkaline elution assay Test system: rat hepatocytes Result: negative
		Test Type: In vitro mammalian cell gen

Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster fibroblasts Result: negative

Test Type: Bacterial reverse mutation assay (AMES)



ersion I	Revision Date: 30.09.2023	SDS Number: 28820-00021	Date of last issue: 04.04.2023 Date of first issue: 06.11.2014				
		Result: negati	ve				
Geno	toxicity in vivo	: Test Type: Cy Species: Mou Result: negati					
(S)-3-	-[3-(tert-butylamino)	-2-hydroxypropoxy]-	4-morpholino-1,2,5-thiadiazole monomale				
Geno	toxicity in vitro		cterial reverse mutation assay (AMES) D Test Guideline 471 ve				
Geno	toxicity in vivo	Species: Mou Method: OEC	: Test Type: In vivo micronucleus test Species: Mouse Method: OECD Test Guideline 474 Result: negative				
Carci	inogenicity						
	lassified based on av	ailable information.					
Com	ponents:						
Dorzo	olamide:						
Speci	es	: Rat, male					
•	cation Route	: Oral					
	sure time	: 2 Years					
		: 20 mg/kg bod	v weight				
-	lt	: negative	,				
Resul			m or mode of action may not be relevant in h				
Resul Rema	IKS						
Resul Rema	IKS	mans.					
Rema							
Rema Speci	ies	: Mouse					
Rema Speci Applic	ies cation Route	: Mouse : Oral					
Rema Speci Applic	ies cation Route sure time	: Mouse					
Rema Speci Applic Expos Resul	ies cation Route sure time It	: Mouse : Oral : 21 month(s) : negative	4-mornholino-1 2 5-thiadiazole monomale				
Rema Speci Applic Expos Resul	ies cation Route sure time It - <b>[3-(tert-butylamino</b> )	: Mouse : Oral : 21 month(s) : negative	4-morpholino-1,2,5-thiadiazole monomale				
Rema Speci Applic Expos Resul <b>(S)-3-</b> Speci	ies cation Route sure time It - <b>[3-(tert-butylamino</b> ) ies	: Mouse : Oral : 21 month(s) : negative -2-hydroxypropoxy]- : Rat	4-morpholino-1,2,5-thiadiazole monomale				
Rema Speci Applic Expos Resul <b>(S)-3-</b> Speci Applic	ies cation Route sure time It <b>-[3-(tert-butylamino)</b> ies cation Route	: Mouse : Oral : 21 month(s) : negative <b>-2-hydroxypropoxy]-</b> : Rat : Oral	4-morpholino-1,2,5-thiadiazole monomale				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time	: Mouse : Oral : 21 month(s) : negative -2-hydroxypropoxy]- : Rat : Oral : 2 Years	•				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE	ies cation Route sure time It - <b>[3-(tert-butylamino</b> ) ies cation Route sure time EL	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> -2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg box</li> </ul>	•				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time EL	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> -2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg book</li> <li>negative</li> </ul>	dy weight				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time EL It It of Organs	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> -2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg book</li> <li>negative</li> <li>Adrenal gland</li> </ul>	dy weight				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul Targe Rema	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time EL It et Organs arks	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> 9-2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg book</li> <li>negative</li> <li>Adrenal gland</li> <li>The significan</li> </ul>	dy weight ce of these findings for humans is not certain				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul Targe Rema	ies cation Route sure time [ <b>f3-(tert-butylamino</b> ) ies cation Route sure time EL It et Organs arks	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> 9-2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg boo</li> <li>negative</li> <li>Adrenal gland</li> <li>The significan</li> <li>Mouse, female</li> </ul>	dy weight ce of these findings for humans is not certain				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul Targe Rema Speci Applic	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time EL It et Organs arks ies cation Route	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> 9-2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg book</li> <li>negative</li> <li>Adrenal gland</li> <li>The significan</li> </ul>	dy weight ce of these findings for humans is not certain				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul Targe Rema Speci Applic	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time EL It et Organs arks ies cation Route sure time	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> 9-2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg boo</li> <li>negative</li> <li>Adrenal gland</li> <li>The significan</li> <li>Mouse, female</li> <li>Oral</li> <li>18 Months</li> </ul>	dy weight ce of these findings for humans is not certain e				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul Targe Rema Speci Applic Expos	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time EL It et Organs arks ies cation Route sure time EL	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> 9-2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg boo</li> <li>negative</li> <li>Adrenal gland</li> <li>The significan</li> <li>Mouse, female</li> <li>Oral</li> </ul>	dy weight ce of these findings for humans is not certain e				
Rema Speci Applic Expos Resul (S)-3- Speci Applic Expos LOAE Resul Targe Rema Speci Applic Expos LOAE Resul	ies cation Route sure time It - <b>[3-(tert-butylamino)</b> ies cation Route sure time EL It et Organs arks ies cation Route sure time EL	<ul> <li>Mouse</li> <li>Oral</li> <li>21 month(s)</li> <li>negative</li> </ul> -2-hydroxypropoxy]- <ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>300 mg/kg book</li> <li>negative</li> <li>Adrenal gland</li> <li>The significant</li> <li>Mouse, female</li> <li>Oral</li> <li>18 Months</li> <li>500 mg/kg book</li> <li>negative</li> </ul>	ce of these findings for humans is not certain				



rsion	Revision Date: 30.09.2023	-	0S Number: 820-00021	Date of last issue: 04.04.2023 Date of first issue: 06.11.2014
Carcir ment	nogenicity - Assess-	:	Weight of evide	ence does not support classification as a car-
Suspe	oductive toxicity ected of damaging the ponents:	unbo	rn child.	
Dorzo	<b>blamide:</b> s on fertility	:	Application Rou Fertility: NOAE	nale and female
Effect ment	s on foetal develop-	:	Result: Embryc	t
			Result: Embryc	t
• •	<b>[3-(tert-butylamino)-</b> 2 s on fertility	2-hyd :	Test Type: Fert Species: Rat Application Rou Fertility: NOAE	-morpholino-1,2,5-thiadiazole monomalea ility/early embryonic development ute: Oral L Mating/Fertility: 150 mg/kg body weight c Development: NOAEL F1: 150 mg/kg body
Effect ment	s on foetal develop-	:	Species: Rabbi Developmental	Toxicity: LOAEL F1: 50 mg/kg body weight vidence of adverse effects on development,
Repro sessm	ductive toxicity - As- nent	:	Some evidence animal experim	e of adverse effects on development, based o ents.

## STOT - single exposure

Not classified based on available information.



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	- repeated exposur		
	es damage to organs Lungs) through prolo		system, Central nervous system, Gastrointestina
Prod		iged of repeated	exposure.
	et Organs	· Cardio-va	ascular system, Central nervous system, Gastroin
rurge	i organo	tinal tract	
Asses	ssment	: Causes c exposure	lamage to organs through prolonged or repeated .
<u>Com</u>	oonents:		
Dorzo	olamide:		
Targe	et Organs		ervous system, Gastrointestinal tract, Bone, Bloo
Asses	ssment	· Bladder	e damage to organs through prolonged or repeat
, 10000		exposure	
(S)-3-	[3-(tert-butylamino)	2-hydroxyprop	oxy]-4-morpholino-1,2,5-thiadiazole monomale
-	et Organs		ardio-vascular system
Asses	ssment	: Causes o exposure	lamage to organs through prolonged or repeated .
Repe	ated dose toxicity		
<u>Com</u>	oonents:		
Dorzo	olamide:		
Speci		: Rat	
NOAE		: 0.05 mg/l	κg
	cation Route et Organs	: Oral : Bladder,	Kidnev
	Ū		/
Speci		: Dog	
NOAE LOAE		: 0.05 mg/l	κg
-	cation Route	: 2 mg/kg : Oral	
	sure time	: 1 yr	
	et Organs		estinal tract, Bone, Blood
rarge		: Monkey	
Speci			(a
Speci NOAE	ΞL	: 0.05 mg/l	5
Speci NOAE Expos	EL sure time	: 1 yr	-
Speci NOAE Expos	ΞL	: 1 yr	estinal tract, Bone, Blood
Speci NOAE Expos Targe	EL sure time et Organs - <b>[3-(tert-butylamino)</b> -	: 1 yr : Gastroint <b>2-hydroxyprop</b> o	estinal tract, Bone, Blood
Speci NOAE Expos Targe (S)-3- Speci	EL sure time et Organs • <b>[3-(tert-butylamino)</b> • ies	: 1 yr : Gastroint <b>2-hydroxypropo</b> : Rat	estinal tract, Bone, Blood pxy]-4-morpholino-1,2,5-thiadiazole monomale
Speci NOAE Expos Targe (S)-3- Speci NOAE	EL sure time et Organs • <b>[3-(tert-butylamino)</b> • ies	: 1 yr : Gastroint <b>2-hydroxyprop</b> o	estinal tract, Bone, Blood pxy]-4-morpholino-1,2,5-thiadiazole monomale



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Speci NOAE		:	Dog 10 mg/kg	
Applic	ation Route	:	Oral	
	sure time t Organs	÷	54 Weeks Kidney	
raige	Ulgans	•	Runey	
Aspir	ation toxicity			
Not cl	assified based on availa	able	information.	
Expe	rience with human exp	oosi	ire	
<u>Produ</u>	<u>ict:</u>			
Eye c	ontact	:	burning or stin Dizziness, dig	e most common side effects are:, bitter taste ging of the eye, Blurred vision, Abdominal pa estive disorder, eye pain, Headache, hyperte upper respiratory tract infection
Comp	oonents:			
Dorzo	olamide:			
Eye c	ontact	:		rning or stinging of the eye, Blurred vision, te bitter taste, Nausea, dry mouth, Headache
(S)-3-	[3-(tert-butylamino)-2-	hyd	roxypropoxy]-	4-morpholino-1,2,5-thiadiazole monomale
Eye c	ontact	:	eyes, Headacl	rning or stinging of the eye, dryness of the ne, Nausea, Dizziness, dry mouth, changes in s, Allergic reactions
Ingest	tion	:	Symptoms: He trointestinal dis	eadache, Fatigue, Respiratory disorders, Gas scomfort, Allergic reactions, Rash, hair loss, status, Dizziness, changes in libido
ction 12	2: Ecological informat	ion		
Ecoto	oxicity			
Comp	oonents:			
Dorzo	plamide:			
Toxici	ty to fish	:	LC50 (Pimeph Exposure time	ales promelas (fathead minnow)): > 1,000 m : 96 h
	ty to daphnia and other ic invertebrates	:	EC50 (Daphni Exposure time	a magna (Water flea)): 699 mg/l : 48 h
Toxici	ty to microorganisms	:	Exposure time	microorganism): > 800 mg/l :: 3 h spiration inhibition

**(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:** Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 411 mg/l



sion	Revision Date: 30.09.2023		OS Number: 820-00021	Date of last issue: 04.04.2023 Date of first issue: 06.11.2014
			Exposure time	: 96 h
		er :		a magna (Water flea)): 161 mg/l
aquat	ic invertebrates		Exposure time Method: OECE	: 48 h ) Test Guideline 202
Toxici	ty to microorganisms	:	EC50: > 1,000	ma/l
	i) to more engemente		Exposure time	: 3 h
				spiration inhibition
			EC50 (Photoba	acterium phosphoreum): > 1,800 mg/l
Persi	stence and degradal	oility		
<u>Comp</u>	oonents:			
Dorzo	plamide:			
Biode	gradability	:		idly degradable
			Biodegradatior Exposure time	: 28 d
			Method: OECE	) Test Guideline 314
(S)-3-	[3-(tert-butylamino)-	2-hyd	roxypropoxy]-4	I-morpholino-1,2,5-thiadiazole monomale
Biode	gradability	:		adily biodegradable.
			Biodegradatior Exposure time	
Stabil	ity in water	:	Hydrolysis: 0 %	6(61 d)
			Method: FDA 3	
Bioad	cumulative potentia	I		
<u>Comp</u>	oonents:			
Dorzo	plamide:			
	on coefficient: n- ol/water	:	log Pow: 0.292	2
• •		-		I-morpholino-1,2,5-thiadiazole monomale
	on coefficient: n- ol/water	:	log Pow: 1.48	
Mobil	ity in soil			
No da	ta available			
	adverse effects			



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### Section 13: Disposal considerations

:	Do not dispose of waste into sewer.
	Dispose of in accordance with local regulations.
:	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

#### **International Regulations**

### UNRTDG

UN number Proper shipping name Class Subsidiary risk Packing group Labels	:	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IATA-DGR		
UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passen- ger aircraft)	:	Not applicable
IMDG-Code		
TINE CONTRACTOR		Martine and Presidents

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### **National Regulations**

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable



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Labels	ng group S nem Code	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> </ul>	
-	al precautions for use plicable		

#### Section 15: Regulatory information

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

#### **HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard

#### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

#### Section 16: Other information

Revision Date	:	30.09.2023
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/
Date format	:	dd.mm.yyyy

#### Full text of other abbreviations

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 - International Air Transport Association; IBC - International Code for the Construction and



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Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration: ICAO - International Civil Aviation Organization: IECSC - Inventory of Existing Chemi-

centration; 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

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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