



Vers 4.1	sion	Revision Date: 2023/09/30		S Number: 807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06		
1. P	RODUC	T AND COMPANY IDE	ENT	IFICATION			
	Produc	t name	:	Timolol / Dorzola	mide Formulation		
	Manufa	acturer or supplier's d	letai	ls			
	Company		:	MSD			
	Address		:	126 E. Lincoln Avenue Rahway, New Jersey U.S.A. 07065			
	Telephone		:	908-740-4000			
	Emerge	ency telephone number	• :	1-908-423-6000			
	E-mail	address	:	EHSDATASTEW	'ARD@msd.com		
	Recom	mended use of the ch	nem	ical and restriction	ons on use		
	Recommended use		:	Pharmaceutical			
	Restric	tions on use	:	Not applicable			

2. HAZARDS IDENTIFICATION

GHS Classification Specific target organ toxicity - : repeated exposure	Category 1 (Cardio-vascular system, Central nervous system, Gastrointestinal tract, Lungs)		
GHS label elements			
Hazard pictograms :			
Signal word :	Danger		
Hazard statements :	H372 Causes damage to organs (Cardio-vascular system, Cen- tral nervous system, Gastrointestinal tract, Lungs) through pro- longed or repeated exposure.		
Precautionary statements :	Prevention: P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.		
	Response:		
	P314 Get medical advice/ attention if you feel unwell.		



Version	Revision Date:	SDS Number:	Date of last is
4.1	2023/09/30	28807-00021	Date of first is

Date of last issue: 2023/04/04 Date of first issue: 2014/11/06

Disposal:

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

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

4. FIRST AID MEASURES

General advice	 In the case of accident or if you feel unwell, seek medical avide 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 ple 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	: Causes damage to organs through prolonged or repeated
and effects, both acute and delayed	exposure.
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).
Notes to physician	: Treat symptomatically and supportively.

Suitable extinguishing media :

Water spray Alcohol-resistant foam Carbon dioxide (CO2)



Version 4.1	Revision Date: 2023/09/30	-	S Number: 807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06			
Unsui media	itable extinguishing	:	Dry chemical None known.				
Speci fightin	fic hazards during fire-	:	Exposure to co	mbustion products may be a hazard to health.			
	rdous combustion prod-	:	Carbon oxides Nitrogen oxides Sulphur oxides Hydrogen chlor				
Speci ods	Specific extinguishing meth- ods Special protective equipment for firefighters		 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. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. 				
6. ACCIDENTAL RELEASE MEASURE			RES				
tive e	onal precautions, protec- quipment and emer- / procedures	:	Follow safe har	rotective equipment. Indling advice (see section 7) and personal pro- ent recommendations (see section 8).			
Enviro	onmental precautions	:	Prevent further Prevent spread barriers). Retain and disp	o the environment. leakage or spillage if safe to do so. ling over a wide area (e.g. by containment or oil pose of contaminated wash water. es should be advised if significant spillages ained.			
	ods and materials for inment and cleaning up	:	For large spills, ment to keep m be pumped, sto Clean up remain bent. Local or nation posal of this ma employed in the mine which reg Sections 13 an	ert absorbent material. provide dyking or other appropriate contain- naterial from spreading. If dyked material can pre recovered material in appropriate container. ining materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- julations are applicable. d 15 of this SDS provide information regarding national requirements.			

7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation Advice on safe handling		Use only with adequate ventilation. Do not breathe mist or vapours.



Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	28807-00021	Date of first issue: 2014/11/06
	tions for safe storage als to avoid	 Wash skin thorou Handle in accord practice, based of sessment Do not eat, drink Take care to pre- environment. Keep in properly Store in accordation 	or repeated contact with skin. ughly after handling. lance with good industrial hygiene and safety on the results of the workplace exposure as- or smoke when using this product. vent spills, waste and minimize release to the labelled containers. nce with the particular national regulations. the following product types:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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 ²	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 inform	ation: Eye, Skin		
		Wipe limit	100 µg/100 cm ²	Internal

Components with workplace control parameters

Engineering measures : Personal protective equipment	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). 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.
reisonal protective equipment	
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.

Hand protection



Version 4.1	Revision Date: 2023/09/30		9S Number: 807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06		
Ma	aterial	:	Chemical-resistar	nt gloves		
Remarks Eye protection		:	Consider double gloving. 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 a	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, dis posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potential contaminated clothing.			
Hygiene measures		:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work- ing 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.			

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 range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available





Versio 4.1	n Revision Date: 2023/09/30		S Number: 307-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
	ower explosion limit / Lower ammability limit	· :	No data available	e
V	apour pressure	:	No data available	9
R	elative vapour density	:	No data available	9
R	elative density	:	1.02	
D	ensity	:	No data available	e
S	olubility(ies) Water solubility	:	soluble	
	artition coefficient: n- ctanol/water	:	No data available	9
	uto-ignition temperature	:	No data available	9
D	ecomposition temperature	:	No data available	9
Vi	iscosity Viscosity, kinematic	:	No data available	9
E	xplosive properties	:	Not explosive	
0	xidizing properties	:	The substance o	r mixture is not classified as oxidizing.
Μ	olecular weight	:	No data available	9
Pa	article size	:	No data available	e

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of bazardous reac-	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
tions Conditions to avoid		None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
-		Ingestion
		Eye contact
		•



sion	Revision Date: 2023/09/30		S Number: 807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
	e toxicity assified based on availa	able	information.	
Produ	uct:			
Acute	oral toxicity	:	Acute toxicity e Method: Calcu	estimate: > 2,000 mg/kg lation method
<u>Com</u>	oonents:			
Dorzo	plamide:			
Acute	oral toxicity	:	LD50 (Rat): 1,9	927 mg/kg
			LD50 (Mouse):	1,320 mg/kg
Acute	inhalation toxicity	:	Remarks: No c	lata available
Acute	dermal toxicity	:	Remarks: No c	lata available
(S)-3-	[3-(tert-butylamino)-2-	hyd	roxypropoxy]-4	l-morpholino-1,2,5-thiadiazole monomale
Acute	oral toxicity	:	LD50 (Rat): 1,0	000 mg/kg
			LD50 (Mouse):	1,140 mg/kg
	toxicity (other routes of nistration)	:		300 mg/kg ute: Intraperitoneal
			LD50 (Mouse): Application Ro	800 mg/kg ute: Subcutaneous
Skin	corrosion/irritation			
Not cl	assified based on availa	able	information.	
Com	oonents:			
(S)-3-	[3-(tert-butylamino)-2-	hyd	roxypropoxy]-4	l-morpholino-1,2,5-thiadiazole monomale
Speci		:	Rabbit	
Metho Resul		:	Draize Test No skin irritatio	n
1.000		•		
	us eye damage/eye irr assified based on availa			
	oonents:			
Dorzo	plamide:			
Speci		:	Monkey	
Resul		:	Mild eye irritati	on

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



rsion	Revision Date: 2023/09/30	SDS Num 28807-00		Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
Resul	t	: Mild e	ye irritation	
Speci Resul		: Dog : No ev	e irritation	
Deen		·		
-	iratory or skin sens	tisation		
-	sensitisation assified based on av	ailahle informa	tion	
	iratory sensitisation			
-	assified based on av		ition.	
Comp	oonents:			
	plamide:			
Test 7		: Maxim	isation Tes	t
Expos	sure routes	: Skin c		
Speci Resul		: Guine	a pig sensitizer	
Not cl	assified based on av	ailable informa	ition.	
<u>Comp</u>	oonents:			
	plamide:			
Geno	toxicity in vitro		ype: Chron : negative	nosomal aberration
				ne elution assay
			ystem: rat l :: negative	nepatocytes
		Test s		o mammalian cell gene mutation test nese hamster fibroblasts
			ype: Bacte negative	rial reverse mutation assay (AMES)
Geno	toxicity in vivo	Specie	ype: Cytog s: Mouse negative	enetic assay
			-	
				horpholino-1,2,5-thiadiazole monomale
Geno	toxicity in vitro	Metho		rial reverse mutation assay (AMES) est Guideline 471
Geno	toxicity in vivo	: Test T	ype: In vivo	micronucleus test
			8 / 16	



Species: Mouse Method: OECD Test Guideline 474 Result: negative Carcinogenicity Not classified based on available information. Components: Dorzolamide: Species : Rat, male Application Route : Oral Exposure time : 2 Years : 20 mg/kg body weight Result : negative Remarks : The mechanism or mode of action may not b mans. Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (5)-3-[3-(tert-butylamino)-2-hydroxypropox]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 10 Oral Exposure time : 10 Oral Exposure time : 10 Oral Ex	1/04 1/06
Method: OECD Test Guideline 474 Result: negative Carcinogenicity Not classified based on available information. Components: Dorzolamide: Species : Rat, male Application Route : Oral Exposure time : 2 Years : 20 mg/kg body weight Result : negative Result : negative Result : negative Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : 18 Months	
Method: OECD Test Guideline 474 Result: negative Carcinogenicity Not classified based on available information. Components: Dorzolamide: Species : Rat, male Application Route : Oral Exposure time : 2 Years : 2 Years : 2 Years : 2 Years : 2 Mouse Application Route : Oral Exposure time : 2 1 month(s) Result : negative Species : Rat Application Route : Oral Exposure time : 2 1 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : 18 Months LOAEL :	
Not classified based on available information. Components: Dorzolamide: Species : Result : Result : Remarks : Species : Mouse : Application Route : Comparison : Result : Result : Remarks : Species : Application Route : Oral : Exposure time : : : Species : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : <	
Not classified based on available information. Components: Dorzolamide: Species : Result : Result : Remarks : Species : Mouse : Application Route : Comparison : Result : Result : Remarks : Species : Application Route : Oral : Exposure time : : : Species : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : : <	
Dorzolamide: Species : Rat, male Application Route : Oral Exposure time : 2 Years :: 20 mg/kg body weight Result : negative Remarks : The mechanism or mode of action may not b mans. Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : negative Target Organs : Lungs, Mammary gland, Uterus (including ce Remarks : The significance of these findings for humans LOAEL : negative <tr< td=""><td></td></tr<>	
Species : Rat, male Application Route : Oral Exposure time : 2 Years : : 20 mg/kg body weight Result : negative Remarks : The mechanism or mode of action may not b mans. : Species Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (s)-3-(3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL	
Application Route : Oral Exposure time : 2 Years : : 20 mg/kg body weight Result : negative Remarks : The mechanism or mode of action may not b mans. : Species : Species : Mouse Application Route : Oral Exposure time : : : : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : : 300 mg/kg body weight Result : negative 'Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 1:8 Months LOAEL : : :	
Exposure time : 2 Years 20 mg/kg body weight Result : negative Remarks : The mechanism or mode of action may not b mans. Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including ce Remarks : The significance of these findings for humans Carcinogenicity - Assess- : Weight of evidence does not support classific ment : cinogen	
: 20 mg/kg body weight Result : negative Remarks : The mechanism or mode of action may not b mans. Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lugs, Mammary gland, Uterus (including ce Remarks : The significance of these findings	
Result : negative Remarks : The mechanism or mode of action may not b mans. Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including ce Remarks : The significance of these findings for humans Carcinogenicity - Assess- : Weight of evidence does not support classifie ment : cinogen Reproductive toxicity Xeight of evidence does not support classifie Not classified based on a	
Remarks : The mechanism or mode of action may not b mans. Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including ce Remarks : The significance of these findings for humans Carcinogenicity - Assess- ment : Weight of evidence does not support classific cinogen Reproductive toxicity Not classified based on available information.	
mans. Species : Mouse Application Route : Oral Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including cereation) Remarks : The significance of these findings for humans Carcinogenicity - Assessment : Weight of evidence does not support classified Carcinogenicity - Assessment : Weight of evidence does not support classified Carcinogenicity - Assessment : Weight of evidence does not support classified Carcinogenicity - Asseessment : Weight of evidence does not	e relevant in h
Application Route:OralExposure time:21 month(s)Result:negative(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazoSpecies:RatApplication Route:OralExposure time:2 YearsLOAEL:300 mg/kg body weightResult:rarget Organs:Adrenal glandRemarks:Species:Mouse, femaleApplication Route:OralExposure time:18 MonthsLOAEL:Species:Muse, femaleApplication Route:18 MonthsLOAEL:500 mg/kg body weightResult:rarget Organs:Lungs, Mammary gland, Uterus (including ceRemarks:The significance of these findings for humansCarcinogenicity - Assess-:Weight of evidence does not support classific cinogenReproductive toxicityNot classified based on available information.	
Exposure time : 21 month(s) Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including certarget Organs Result : negative Target Organs : Lungs, Mammary gland, Uterus (including certarget Organs Remarks : The significance of these findings for humans Carcinogenicity - Assess- : Weight of evidence does not support classified ment : cinogen Reproductive toxicity Not classified based on available information.	
Result : negative (S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazo Species : Rat Application Route : Oral Exposure time : 2 Years LOAEL : 300 mg/kg body weight Result : negative Target Organs : Adrenal gland Remarks : The significance of these findings for humans Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including certains) Species : The significance of these findings for humans Species : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including certains) Carcinogenicity - Assess- : Weight of evidence does not support classifier ment : cinogen Reproductive toxicity Not classified based on available information.	
""""""""""""""""""""""""""""""""""	
Species : Mouse, female Application Route : Oral Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including ce Remarks : The significance of these findings for humans Carcinogenicity - Assessment : Weight of evidence does not support classified cinogen Reproductive toxicity Not classified based on available information.	
Application Route:OralExposure time:18 MonthsLOAEL:500 mg/kg body weightResult:negativeTarget Organs:Lungs, Mammary gland, Uterus (including ceRemarks:The significance of these findings for humansCarcinogenicity - Assessment:Weight of evidence does not support classific cinogenReproductive toxicityNot classified based on available information.	
Exposure time : 18 Months LOAEL : 500 mg/kg body weight Result : negative Target Organs : Lungs, Mammary gland, Uterus (including ce Remarks : The significance of these findings for humans Carcinogenicity - Assessment : Weight of evidence does not support classified cinogen Reproductive toxicity Not classified based on available information.	
LOAEL: 500 mg/kg body weightResult: negativeTarget Organs: Lungs, Mammary gland, Uterus (including ceRemarks: The significance of these findings for humansCarcinogenicity - Assess- ment: Weight of evidence does not support classific cinogenReproductive toxicityNot classified based on available information.	
Result : negative Target Organs : Lungs, Mammary gland, Uterus (including ce Remarks : The significance of these findings for humans Carcinogenicity - Assessment : Weight of evidence does not support classifier Reproductive toxicity : Not classified based on available information.	
Target Organs : Lungs, Mammary gland, Uterus (including cerements) Remarks : The significance of these findings for humans Carcinogenicity - Assessment : Weight of evidence does not support classifier cinogen Reproductive toxicity Not classified based on available information.	
Remarks : The significance of these findings for humans Carcinogenicity - Assessment : Weight of evidence does not support classifier Reproductive toxicity : Not classified based on available information.	rvix)
mentcinogenReproductive toxicityNot classified based on available information.	s is not certain
Not classified based on available information.	ation as a car
Dorzolamide:	
Effects on fertility : Test Type: Fertility Species: Rat, male and female	



rsion	Revision Date: 2023/09/30	SDS Number: 28807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
			oute: Oral EL: 7.5 mg/kg body weight al testing did not show any effects on fertility.
Effect: ment	s on foetal develop-	Result: Embr spring were c Test Type: D Species: Rab Application R Development Result: Embr	bit oute: Oral cal Toxicity: NOAEL: 1 mg/kg body weight yotoxic effects and adverse effects on the off- letected only at high maternally toxic doses evelopment bit
(6) 2	[2 (tort butyloming) 2	by draw mranavy	4 membeline 195 thisdiscele menemales
• •	s on fertility	: Test Type: Fe Species: Rat Application R Fertility: NOA	-4-morpholino-1,2,5-thiadiazole monomaleat ertility/early embryonic development oute: Oral EL Mating/Fertility: 150 mg/kg body weight onic Development: NOAEL F1: 150 mg/kg body
Effect ment	s on foetal develop-	Species: Rab Development Result: Some	mbryo-foetal development abit al Toxicity: LOAEL F1: 50 mg/kg body weight e evidence of adverse effects on development, mal experiments.
Repro sessm	eductive toxicity - As-	: Some eviden animal experi	ce of adverse effects on development, based o iments.
	- single exposure assified based on avai	able information.	
STOT	- repeated exposure		
	es damage to organs (Lungs) through prolone		tem, Central nervous system, Gastrointestinal posure.
<u>Produ</u> Targe	<u>ıct:</u> t Organs	: Cardio-vascu	lar system, Central nervous system, Gastrointe

Target Organs	: Cardio-vascular system, Central nervous system, Gastrointes-
	tinal tract, Lungs
Assessment	: Causes damage to organs through prolonged or repeated
	exposure.



rsion	Revision Date: 2023/09/30	SDS Num 28807-000		Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
<u>Comp</u>	oonents:			
Dorzo	olamide:			
Targe	t Organs			system, Gastrointestinal tract, Bone, Blood
Asses	ssment	Bladde : May c expos	ause dama	ge to organs through prolonged or repeat
(S)-3-	[3-(tert-butylamino)	-2-hydroxypr	opoxy]-4-n	orpholino-1,2,5-thiadiazole monomale
• •	t Organs			scular system
	ssment		s damage	to organs through prolonged or repeated
Repe	ated dose toxicity			
<u>Comp</u>	oonents:			
Dorzo	olamide:			
Speci		: Rat		
NOAE		: 0.05 m	ng/kg	
	cation Route t Organs	: Oral : Bladde	er, Kidney	
Speci	-	: Dog		
NOAE		: 0.05 m	na/ka	
LOAE		: 2 mg/ł		
Applic	ation Route	: Oral	•	
	sure time	: 1 yr		
Targe	t Organs	: Gastro	pintestinal t	ract, Bone, Blood
Speci		: Monke		
NOAE		: 0.05 n	ng/kg	
	sure time	: 1 yr	intentinal t	raat Dana Dlaad
rarge	t Organs	. Gasire		ract, Bone, Blood
			opoxy]-4-n	norpholino-1,2,5-thiadiazole monomale
Speci		: Rat	//	
NOAE	L cation Route	: 25 mg : Oral	/ку	
	sure time	: 67 We	eks	
Speci	es	: Dog		
NOAE		: 10 mg	/kg	
	cation Route	: Oral	.1	
	sure time	: 54 We		
rarge	t Organs	: Kidney	/	
	ation toxicity			



	Revision Date: 2023/09/30		0S Number: 807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06	
Expe	rience with human exp	osu	ıre		
Prod	uct:				
_	contact	:	burning or sting Dizziness, dige	e most common side effects are:, bitter taste, ging of the eye, Blurred vision, Abdominal pai estive disorder, eye pain, Headache, hyperter upper respiratory tract infection	
Com	ponents:				
Dorz	olamide:				
Eye c	contact	:		ning or stinging of the eye, Blurred vision, te itter taste, Nausea, dry mouth, Headache	
(S)-3-	-[3-(tert-butylamino)-2-l	hyd	roxypropoxy]-4	-morpholino-1,2,5-thiadiazole monomalea	
-	contact	:	eyes, Headach libido, hair loss	ning or stinging of the eye, dryness of the e, Nausea, Dizziness, dry mouth, changes ir , Allergic reactions	
Ingestion		:		dache, Fatigue, Respiratory disorders, Gas- omfort, Allergic reactions, Rash, hair loss, tatus, Dizziness, changes in libido	
ngee				comfort, Allergic reactions, Rash, hair loss, status, Dizziness, changes in libido	
	OGICAL INFORMATION	N			
ECOL		N			
ECOL	oxicity	N			
ECOL		N			
ECOL Ecoto	oxicity	N			
ECOL Ecoto <u>Com</u> Dorze	oxicity ponents:	N :	altered mental	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg	
ECOL Ecoto Com Dorzo Toxic	oxicity ponents: olamide: ity to fish	:	altered mental LC50 (Pimepha Exposure time:	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg 96 h a magna (Water flea)): 699 mg/l	
ECOL Ecoto Com Dorzo Toxic Toxic aquat	oxicity ponents: olamide: hity to fish wity to daphnia and other	:	altered mental LC50 (Pimepha Exposure time: EC50 (Daphnia Exposure time: EC50 (Natural	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg 96 h a magna (Water flea)): 699 mg/l 48 h microorganism): > 800 mg/l	
ECOL Ecoto Com Dorzo Toxic Toxic aquat	oxicity ponents: olamide: hity to fish hity to daphnia and other tic invertebrates	:	altered mental LC50 (Pimepha Exposure time: EC50 (Daphnia Exposure time: EC50 (Natural Exposure time:	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg 96 h a magna (Water flea)): 699 mg/l 48 h microorganism): > 800 mg/l 3 h	
ECOL Ecoto Com Dorzo Toxic Toxic aquat	oxicity ponents: olamide: hity to fish hity to daphnia and other tic invertebrates	:	altered mental LC50 (Pimepha Exposure time: EC50 (Daphnia Exposure time: EC50 (Natural Exposure time: Test Type: Res	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg 96 h a magna (Water flea)): 699 mg/l 48 h microorganism): > 800 mg/l	
ECOL Ecoto Com Dorzo Toxic Toxic aquat	oxicity ponents: olamide: hity to fish hity to daphnia and other tic invertebrates hity to microorganisms	::	altered mental LC50 (Pimepha Exposure time: EC50 (Daphnia Exposure time: EC50 (Natural Exposure time: Test Type: Res Method: OECD	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg 96 h a magna (Water flea)): 699 mg/l 48 h microorganism): > 800 mg/l 3 h spiration inhibition 0 Test Guideline 209	
ECOL Ecoto Com Dorzo Toxic Toxic Toxic Toxic	oxicity ponents: olamide: hity to fish hity to daphnia and other tic invertebrates hity to microorganisms	::	altered mental LC50 (Pimepha Exposure time: EC50 (Daphnia Exposure time: EC50 (Natural Exposure time: Test Type: Res Method: OECD	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg 96 h a magna (Water flea)): 699 mg/l 48 h microorganism): > 800 mg/l 3 h spiration inhibition 0 Test Guideline 209 I-morpholino-1,2,5-thiadiazole monomalea ales promelas (fathead minnow)): 411 mg/l	
ECOL Ecoto Com Dorzo Toxic Toxic Toxic Toxic (S)-3- Toxic Toxic	oxicity ponents: olamide: ity to fish ity to daphnia and other tic invertebrates ity to microorganisms -[3-(tert-butylamino)-2-I	: : hyd	altered mental LC50 (Pimepha Exposure time: EC50 (Daphnia Exposure time: EC50 (Natural Exposure time: Test Type: Res Method: OECD roxypropoxy]-4 LC50 (Pimepha Exposure time: EC50 (Daphnia Exposure time:	status, Dizziness, changes in libido ales promelas (fathead minnow)): > 1,000 mg 96 h a magna (Water flea)): 699 mg/l 48 h microorganism): > 800 mg/l 3 h spiration inhibition 0 Test Guideline 209 I-morpholino-1,2,5-thiadiazole monomalea ales promelas (fathead minnow)): 411 mg/l 96 h	



rsion	Revision Date: 2023/09/30		OS Number: 807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
			EC50 (Photob	acterium phosphoreum): > 1,800 mg/l
Persi	stence and degrada	bility		
<u>Comp</u>	oonents:			
	blamide: gradability	:	Biodegradation Exposure time	
(S)-3-	[3-(tert-butylamino)	-2-hyd	roxypropoxy]-	4-morpholino-1,2,5-thiadiazole monomalea
	gradability	:		adily biodegradable. n: 0 %
Stabil	ity in water	:	Hydrolysis: 0 9 Method: FDA 3	
Bioad	cumulative potentia	al		
Comp	oonents:			
Dorzo	plamide:			
	on coefficient: n- ol/water	:	log Pow: 0.292	2
(S)-3-	[3-(tert-butylamino)	-2-hyd	roxypropoxy]-	4-morpholino-1,2,5-thiadiazole monomalea
	on coefficient: n- ol/water	:	log Pow: 1.48	
	ity in soil			
	ita available			
	adverse effects			
	ta available			
. DISPO	SAL CONSIDERAT	ONS		
Dispo	osal methods			
Waste	e from residues	:		e of waste into sewer.
Conta	minated packaging	:	Empty contain dling site for re	accordance with local regulations. ers should be taken to an approved waste ha ecycling or disposal. e specified: Dispose of as unused product.
. TRAN	SPORT INFORMATI	ON		



rsion	Revision Date: 2023/09/30		0S Number: 807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
UNR	TDG			
	umber	:	Not applicable	
	er shipping name	:	Not applicable	
Class		:	Not applicable	
	diary risk	:	Not applicable	
	ng group	:	Not applicable	
Label	S	:	Not applicable	
IATA	-DGR			
UN/IE) No.	:	Not applicable	
Prope	er shipping name	:	Not applicable	
Class		:	Not applicable	
	diary risk	:	Not applicable	
	ng group	:	Not applicable	
Label	-	:	Not applicable	
	ng instruction (cargo	:	Not applicable	
aircra	,		Not oppliaable	
	ng instruction (passen- rcraft)	•	Not applicable	
U				
	-Code		Net any Peakle	
	umber	:	Not applicable	
Class	er shipping name		Not applicable Not applicable	
	diary risk	:	Not applicable	
	ng group	:	Not applicable	
Label			Not applicable	
EmS		÷	Not applicable	
	e pollutant	:	Not applicable	
Trans	sport in bulk according	n to		POL 73/78 and the IBC Code
	pplicable for product as	-		
Spec	ial precautions for use	r		
	pplicable			
not a	philotolo			
REGU	LATORY INFORMATIC	N		

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

: Not applicable





rsion	Revision Date: 2023/09/30	SDS Number: 28807-00021	Date of last issue: 2023/04/04 Date of first issue: 2014/11/06
Prohit	bited substances		: Not applicable
Restricted substances			: Not applicable
Regul Mater		of Trade No. 7 of 20	022 on Distribution and Control of Hazardo
Туре	of hazardous materials ol, Annex I	subject to distributic	on and : Not applicable
	,		
Туре	of hazardous materials	subject to distributic	on and : Not applicable
Туре	of hazardous materials	subject to distributic	on and : Not applicable
Type contro	of hazardous materials I, Annex II		in the following inventories:
Type of contro The c	of hazardous materials I, Annex II	oduct are reported	in the following inventories:
Type of contro The c AICS	of hazardous materials I, Annex II omponents of this pro	oduct are reported : not determined	in the following inventories:
Type of contro The c AICS DSL IECSO	of hazardous materials I, Annex II omponents of this pro	oduct are reported : not determined : not determined	in the following inventories:
Type of contro The c AICS DSL IECSO OTHER	of hazardous materials ol, Annex II omponents of this pro	oduct are reported : not determined : not determined	in the following inventories:
Type of contro The c AICS DSL IECSO OTHEF Revisi	of hazardous materials ol, Annex II omponents of this pro	oduct are reported : not determined : not determined : not determined	in the following inventories:
Type of control The c AICS DSL IECSO OTHEF Revisi Furthe Sourc	of hazardous materials ol, Annex II omponents of this pro C R INFORMATION ion Date er information es of key data used to le the Safety Data	oduct are reported : not determined : not determined : not determined : not determined : 2023/09/30 : Internal techni	in the following inventories: d d d cal data, data from raw material SDSs, OECD search results and European Chemicals Ager
Type of control The c AICS DSL IECSO OTHEF Revisi Furtho Sourc compi Sheet	of hazardous materials ol, Annex II omponents of this pro C R INFORMATION ion Date er information es of key data used to le the Safety Data	 oduct are reported not determined not determined not determined not determined 2023/09/30 Internal techni eChem Portal 	in the following inventories: d d d cal data, data from raw material SDSs, OECD search results and European Chemicals Ager

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 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



Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	28807-00021	Date of first issue: 2014/11/06

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.

ID / EN