## SAFETY DATA SHEET



## **Dorzolamide Formulation**

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SEC	TION 1 Product	<b>IDENTIFICATION</b>	:	Dorzolamide For	mulation	
	Manufa	cturer or supplier's d	etai	ls		
	Compa	ny	:	MSD		
	Address		:	Building A - Level 1/26 Talavera Rd Macquarie Park NSW, Australia 2113		
	Telephone		:	1 800 033 461		
	Emergency telephone number		:	Poisons Informat	ion Centre: Phone 13 11 26	
	E-mail a	address	:	EHSDATASTEW	ARD@msd.com	
	Recom	mended use of the ch mended use ions on use		<b>ical and restrictic</b> Pharmaceutical Not applicable	ons on use	

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

#### **GHS Classification**

Not a hazardous substance or mixture.

#### **GHS** label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

#### 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	< 10

#### **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.

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lr If N a	n case f swalld Most im	portant symptoms acts, both acute and	::	In case of contact of water. Get medical atten Flush eyes with w Get medical atten If swallowed, DO	tion if symptoms occur. , immediately flush skin with soap and plenty tion if symptoms occur. rater as a precaution. tion if irritation develops and persists. NOT induce vomiting. tion if symptoms occur. bughly with water.	
F	Protection of first-aiders Notes to physician		:	<ul> <li>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).</li> <li>Treat symptomatically and supportively.</li> </ul>		
SECT	TION 5.	FIREFIGHTING MEA	SU	RES		
S	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical		
	Jnsuita nedia	ble extinguishing	:	None known.		
	Specific ighting	hazards during fire-	:	Exposure to comb	oustion products may be a hazard to health.	
	Hazardo ucts	ous combustion prod-	:	Carbon oxides Nitrogen oxides (I Sulphur oxides Hydrogen chloride		
	Specific ods	extinguishing meth-	:	cumstances and t Use water spray t	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	
	Special or firefi	protective equipment ghters	:		e, wear self-contained breathing apparatus. rective equipment.	

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment.





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		Prevent spread barriers). Retain and disp	leakage or spillage if safe to do so. ling over a wide area (e.g. by containment or oil pose of contaminated wash water. is should be advised if significant spillages ained.
Methods and materials for containment and cleaning up		For large spills, ment to keep m be pumped, sto Clean up remain bent. Local or national 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- ulations are applicable. d 15 of this SDS provide information regarding national requirements.

#### SECTION 7. HANDLING AND STORAGE

Technical measures Local/Total ventilation Advice on safe handling	ONTROLS/PERSON/ se only with adequate o not breathe mist or o not swallow. void contact with eyes void prolonged or rep- andle in accordance v ractice, based on the essment	vapours.
Hygiene measures	ushing systems and s ace. /hen using do not eat, /ash contaminated clo he effective operation ngineering controls, p opropriate degowning	thing before re-use. of a facility should include review of oper personal protective equipment, and decontamination procedures, toring, medical surveillance and the
Conditions for safe storage Materials to avoid	eep in properly labelle tore in accordance wi	d containers. h the particular national regulations. llowing product types:



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#### 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: Eye			
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

Engineering measures	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip- less 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 con- tainment devices). Minimize open handling.
Personal protective equipmer	nt
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type
Material	Chemical-resistant 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 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 potentially contaminated clothing.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Aqueous solution	
Colour	: No data available	

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	Odour			No data available	
			•		
		hreshold	:	No data available	
	рН		:	5.6	
		point/freezing point	:	No data available	
	Initial bo range	iling point and boiling	:	No data available	3
	Flash po	bint	:	No data available	
	Evapora	tion rate	:	No data available	)
	Flamma	bility (solid, gas)	:	Not applicable	
	Flamma	bility (liquids)	:	No data available	)
	Upper ex flammab	xplosion limit / Upper bility limit	:	No data available	
	Lower ex flammab	xplosion limit / Lower bility limit	:	No data available	
	Vapour p	pressure	:	No data available	)
	Relative	vapour density	:	No data available	)
	Relative	density	:	No data available	)
	Density		:	No data available	)
	Solubility Wate	y(ies) r solubility	:	soluble	
	Partition octanol/	coefficient: n-	:	No data available	)
		ition temperature	:	No data available	)
	Decomp	osition temperature	:	No data available	•
	Viscosity Visco	/ osity, kinematic	:	No data available	9
	Explosiv	e properties	:	Not explosive	
	Oxidizin	g properties	:	The substance of	mixture is not classified as oxidizing.
	Molecula	ar weight	:	Not applicable	



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	le characteristics le size	:	Not applicable	9
CTION	10. STABILITY AND	REAC	TIVITY	
Possi tions	nical stability bility of hazardous rea	: : c- :	Stable under Can react with	as a reactivity hazard. normal conditions. n strong oxidizing agents.
Incom	itions to avoid patible materials rdous decomposition cts		None known. Oxidizing age No hazardous	nts decomposition products are known.
CTION	11. TOXICOLOGICAI	_ INFO	ORMATION	
Expos	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity assified based on ava	ilabla	information	
Produ		liable		
Acute	oral toxicity	:	Acute toxicity e Method: Calcu	estimate: > 2,000 mg/kg lation method
<u>Com</u>	oonents:			
	plamide:			
Acute	oral toxicity	:	LD50 (Rat): 1,	927 mg/kg
			LD50 (Mouse)	: 1,320 mg/kg
Acute	inhalation toxicity	:	Remarks: No o	lata available
Acute	dermal toxicity	:	Remarks: No o	lata available
-	corrosion/irritation assified based on ava	ilable	information.	
	us eye damage/eye i assified based on ava			
<u>Com</u>	oonents:			
	olamide:		Monkey	
Speci				



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#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### **Components:**

#### Dorzolamide:

est
r

#### 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 gene mutation test Test system: Chinese hamster fibroblasts Result: negative
	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo :	Test Type: Cytogenetic assay Species: Mouse 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



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Rema	arks	: The m mans.	nechanism or mode of action may not be relevant in hu
	cation Route sure time	: Mouse : Oral : 21 mo : negati	onth(s)
-	oductive toxicity lassified based on ava	lable informa	ation.
Com	ponents:		
	<b>blamide:</b> ts on fertility	Specie Applic Fertilit	Type: Fertility es: Rat, male and female cation Route: Oral ty: NOAEL: 7.5 mg/kg body weight t: Animal testing did not show any effects on fertility.
Effect ment	ts on foetal develop-	Specie Applic Devele Result	Type: Development es: Rabbit ration Route: Oral opmental Toxicity: NOAEL: 1 mg/kg body weight t: Embryotoxic effects and adverse effects on the off- were detected only at high maternally toxic doses
		Specie Applic Devele Result	ype: Development es: Rabbit ation Route: Oral opmental Toxicity: LOAEL: 2.5 mg/kg body weight t: Embryotoxic effects and adverse effects on the off- were detected only at high maternally toxic doses
	<b>- single exposure</b> lassified based on ava	lable informa	ation.
	repeated exposure lassified based on ava		ation.
<u>Com</u>	oonents:		
Dorzo	olamide:		
Targe	et Organs	: Centra Bladd	al nervous system, Gastrointestinal tract, Bone, Blood,
Asses	ssment		ause damage to organs through prolonged or repeated

exposure.



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## Repeated dose toxicity

Components:		
<b>Dorzolamide:</b> Species NOAEL Application Route Target Organs	: : : :	Rat 0.05 mg/kg Oral Bladder, Kidney
Species NOAEL LOAEL Application Route Exposure time Target Organs		Dog 0.05 mg/kg 2 mg/kg Oral 1 yr Gastrointestinal tract, Bone, Blood
Species NOAEL Exposure time Target Organs	: : :	Monkey 0.05 mg/kg 1 yr Gastrointestinal tract, Bone, Blood

#### Aspiration toxicity

Not classified based on available information.

#### Experience with human exposure

#### Components:

#### Dorzolamide:

Eye contact

: Symptoms: burning or stinging of the eye, Blurred vision, tearing, asthenia, bitter taste, Nausea, dry mouth, Headache

#### SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
Dorzolamide:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 699 mg/l Exposure time: 48 h
Toxicity to microorganisms	:	EC50 (Natural microorganism): > 800 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209



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Persi	istence and degradal	oility		
Com	ponents:			
-	olamide: egradability	Biodegradat Exposure tir		
Bioa	ccumulative potentia	I		
Com	ponents:			
Partit	olamide: ion coefficient: n- iol/water	: log Pow: 0.2	292	
	<b>lity in soil</b> ata available			
	<b>r adverse effects</b> ata available			
SECTION	13. DISPOSAL CON	SIDERATIONS		
Disp	osal methods			

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

## International Regulations

UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no
IATA-DGR		
IATA-DGR UN/ID No.	:	Not applicable
	:	Not applicable Not applicable
UN/ID No.	:	
UN/ID No. Proper shipping name	:	Not applicable
UN/ID No. Proper shipping name Class	:	Not applicable Not applicable



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	Labala			Not oppligghla	
	Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft) IMDG-Code		:	Not applicable Not applicable	
			:	Not applicable	
	UN nu	mber	:	Not applicable	
	Proper	r shipping name	:	Not applicable	
	Class		:	Not applicable	
	Subsic	liary risk	:	Not applicable	
	Packir	ng group	:	Not applicable	
				<b>NI II II</b>	

# Marine pollutant : Not applicable Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: Not applicable

: Not applicable

Not applicable for product as supplied.

#### **National Regulations**

Labels EmS Code

ADG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

#### Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

#### Safety, health and environmental regulations/legislation specific for the substance or mixture Therapeutic Goods (Poisons : No poison schedule number allocated (Please use the original Standard) Instrument publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical) Prohibition/Licensing Requirements There is no applicable prohibition, : authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations. The components of this product are reported in the following inventories: AICS : not determined

DSL	:	not determined
IECSC	:	not determined



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#### SECTION 16: ANY OTHER RELEVANT INFORMATION

#### **Further information**

Revision Date Sources of key data used to compile the Safety Data Sheet	:	28.09.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, 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 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

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





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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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