Identification

Product identifier

Trade name: Dorzolamide Hydrochloride Ophthalmic Solution USP 2%.
Recommended use and restriction on use:
Recommended use: Pharmaceutical Product
Restrictions on use: Not applicable

Details of the supplier of the Safety Data Sheet.

Manufacturer/Supplier: Somerset Therapeutics, LLC. Somerset, NJ 08873.
Emergency telephone number: 1-800-417-9175

Hazard(s) identification

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Specific target organ toxicity - repeated exposure : Category 2(Central nervous system, Gastrointestinal tract, Bone, blood, Bladder)

GHS label elements
Hazard pictograms :

Signal Word : Warning

Hazard statements : H373 May cause damage to organs (Central nervous system, Gastrointestinal tract, Bone, Blood, Bladder) through prolonged or repeated exposure.

Precautionary statements :

Prevention : P260 Do not breathe mist or vapors.
Response : P314 Get medical attention if you feel unwell.
Disposal : P501 Dispose of contents and container to an approved waste disposal plant

Other hazards
None known.

3 Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No	Concentration
Dorzolamide	130693-82-2	2%

4 First-aid measures

General information	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Get medical attention if symptoms occur.
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 if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment
Notes to physician	:	Treat symptomatically and supportively.

5 Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical.
Unsuitable extinguishing media	:	None known
Special hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NOx) Sulfur oxides Hydrogen chloride
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental 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.

Methods and material for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7 Handling and storage

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe mist or vapors. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Gases

8 Exposure controls/personal protection

Ingredients with workplace control parameters

Compounds	CAS- No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dorzolamide	130693-82-2	TWA	10 µg/m3 (OEB 3)	Internal
	Further information: Eye			
		Wipe limit	100 µg / 100cm2	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 containment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above

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

Hand Protection

Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. The usual precautionary measures for handling chemicals should be followed. Keep away from foodstuffs, beverages and feed.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9 Physical and chemical properties

Appearance	:	A clear, colorless to nearly colorless, slightly viscous solution free from visible extraneous matter.
Color	:	No data available
Odor	:	No data available
Odor threshold	:	No data available
pH	:	5.6
Melting point/freezing range	:	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
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available

Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient n-octanol/water	:	No data available
Autoignition temperature.		
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Solvent content	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle size	:	Not applicable.

10 Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
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 exposure

Inhalation

Skin contact

Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Dorzolamide:

Acute oral toxicity	:	LD50 (Rat): 1,927 mg/kg LD50 (Mouse): 1,320 mg/kg
Acute inhalation toxicity	:	Remarks: No data available

Skin corrosion/irritation

Not classified based on available information

Serious eye damage/eye irritation

Not classified based on available information. Inhalation.

Components:

Dorzolamide:

Species	:	Monkey
Result	:	Mild eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information**.**
Components:
Dorzolamide:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	Weak sensitizer

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
Remarks	:	The mechanism or mode of action may not be relevant in humans.
Species	:	Mouse
Application Route	:	Oral
Exposure time	:	21 month(s)
Result	:	negative

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

Reproductive toxicity

Not classified based on available information.

Components:

Dorzolamide:

Effects on fertility	:	Test Type: Fertility Species: Rat, male and female Application Route: Oral Fertility: NOAEL: 7.5 mg/kg body weight Result: Animal testing did not show any effects on fertility
Effects on fetal development	:	Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 1 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 2.5 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

STOT-single exposure

Not classified based on available information

STOT-repeated exposure

May cause damage to organs (Central nervous system, Gastrointestinal tract, Bone, Blood, Blad-der) through prolonged or repeated exposure.

Components:

Dorzolamide:

Target Organs	:	Central nervous system, Gastrointestinal tract, Bone, Blood, Bladder
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Dorzolamide:

Species	:	Rat
NOAEL	:	0.05 mg/kg
Application Route	:	Oral
Target Organs	:	Bladder, Kidney

Species	:	Dog
NOAEL	:	0.05 mg/kg
LOAEL	:	2 mg/kg
Application Route	:	Oral
Exposure time	:	1y
Target Organs	:	Gastrointestinal tract, Bone, Blood

Species	:	Monkey
NOAEL	:	0.05 mg/kg
Exposure time	:	1y
Target Organs	:	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, tear-ing, asthenia, bitter taste, Nausea, dry mouth, Headache

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

Persistence and degradability
Components:
Dorzolamide:
Biodegradability : Result: not rapidly degradable
Biodegradation: 5 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Bioaccumulative potential
Components:
Dorzolamide:
Partition coefficient n-octanol/water : log Pow: 0.292

Mobility in soil
No data available
Other adverse effects
No data available

13 Disposal considerations

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

14 Transport information

International Regulations

UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.
Domestic regulation
49 CFR
Not regulated as a dangerous good
Special precautions for user
Not applicable

15 Regulatory information

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.
SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.
SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	**:**	Specific target organ toxicity (single or repeated exposure)
SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know

Water	:	7732-18-5

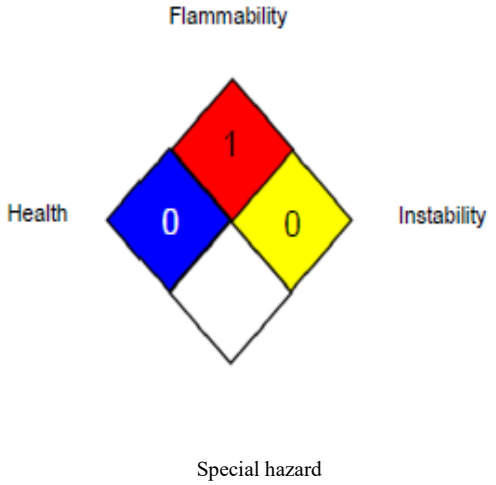
The ingredients of this product are reported in the following inventories:

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

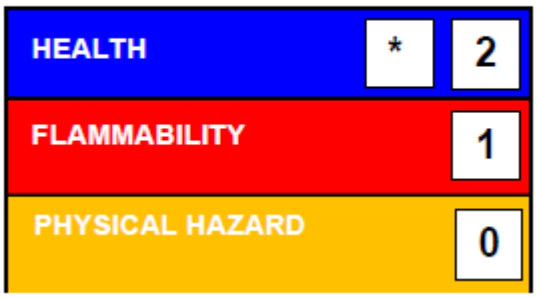
16 Other information

Further information

NFPA 704:



HMIS® IV:



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

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Sub-stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Haz-ardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-tem; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organiza-tion; 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 Chemi-cals 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 Pre-vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-erwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-tative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concern-ing the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amend-ments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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Somerset Therapeutics Private Limited believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.