SAFETY DATA SHEET

Timolol / Dorzolamide Formulation

Version 5.3  Revision Date: 09/13/2019  SDS Number: 28795-00015  Date of last issue: 24.04.2019
Date of first issue: 06.11.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Timolol / Dorzolamide Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone: 908-740-4000
Emergency telephone: 55 19 3758 2000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 1 (Cardio-vascular system, Central nervous system, Gastrointestinal tract, Lungs)

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Cardio-vascular system, Central nervous system, Gastrointestinal tract, Lungs) through prolonged or repeated exposure.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
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.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorzolamide</td>
<td>130693-82-2</td>
<td>Acute toxicity (Oral), Category 4; Specific target organ toxicity - repeated exposure (Central nervous system, Gastrointestinal tract, Bone, Blood, Bladder), Category 2</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate</td>
<td>26921-17-5</td>
<td>Acute toxicity (Oral), Category 4; Reproductive toxicity, Category 2; Specific target organ toxicity - repeated exposure (Lungs, Cardio-vascular system), Category 1</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with 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 delayed: Suspected of damaging the unborn child. Causes 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 when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
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 materials 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.

SECTION 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:
Avoid inhalation of vapor or mist.
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.

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.

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
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
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<tr>
<td>Dorzolamide</td>
<td>130693-82-2</td>
<td>TWA</td>
<td>10 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Eye</td>
<td></td>
<td></td>
<td></td>
<td>---------</td>
</tr>
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<td>26921-17-5</td>
<td>TWA</td>
<td>10 µg/m3 (OEB 3)</td>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information: Eye, Skin  
Wipe limit 100 µg/100 cm² Internal

Engineering measures:
- 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.

Personal protective equipment:

Respiratory protection:
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection:
- Material: Chemical-resistant gloves

Remarks:
- 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.

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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: colorless
Odor: No data available
Odor Threshold: No data available
pH: 5.6
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
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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 : 1.02
Density : No data available
Solubility(ies)
  Water solubility : soluble
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle 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 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.
SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

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

Components:
Dorzolamide:
Acute oral toxicity:
- LD50 (Rat): 1.927 mg/kg
- LD50 (Mouse): 1.320 mg/kg

Acute inhalation toxicity:
- Remarks: No data available

Acute dermal toxicity:
- Remarks: No data available

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
Acute oral toxicity:
- LD50 (Rat): 1.000 mg/kg
- LD50 (Mouse): 1.140 mg/kg

Acute toxicity (other routes of administration):
- LD50 (Mouse): 300 mg/kg
  Application Route: Intraperitoneal
- LD50 (Mouse): 800 mg/kg
  Application Route: Subcutaneous

Skin corrosion/irritation
Not classified based on available information.

Components:
(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
Species: Rabbit
Method: Draize Test
Result: No skin irritation

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 : Rabbit
Result : Mild eye irritation

Species : Dog
Result : No 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 : Maximation 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

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Genotoxicity in vivo:
Test Type: In vivo micronucleus test
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
Result: 20 mg/kg body weight
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

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
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 is not certain.

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 cervix)
Remarks: The significance of these findings for humans is not certain.

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Dorzolamide:
Effects on fertility: Test Type: Fertility
Species: Rat, male and female
Application Route: Oral
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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

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

Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Oral
- Fertility: NOAEL Mating/Fertility: 150 mg/kg body weight
- Early Embryonic Development: NOAEL F1: 150 mg/kg body weight

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rabbit
- Developmental Toxicity: LOAEL F1: 50 mg/kg body weight
- Result: Some evidence of adverse effects on development, based on animal experiments.

Reproductive toxicity - Assessment:
- Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (Cardio-vascular system, Central nervous system, Gastrointestinal tract, Lungs) through prolonged or repeated exposure.

Product:
- Target Organs: Cardio-vascular system, Central nervous system, Gastrointestinal tract, Lungs
- Assessment: Causes damage to organs 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.
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Target Organs: Lungs, Cardio-vascular system
Assessment: Causes 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: 1 y
Target Organs: Gastrointestinal tract, Bone, Blood

Species: Monkey
NOAEL: 0.05 mg/kg
Exposure time: 1 y
Target Organs: Gastrointestinal tract, Bone, Blood

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

Species: Rat
NOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 67 Weeks

Species: Dog
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 54 Weeks
Target Organs: Kidney

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Product:
Eye contact: Symptoms: The most common side effects are: bitter taste, burning or stinging of the eye, Blurred vision, Abdominal pain, Dizziness, digestive disorder, eye pain, Headache, hypertension, Nausea, upper respiratory tract infection
Components:

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

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
Eye contact: Symptoms: burning or stinging of the eye, dryness of the eyes, Headache, Nausea, Dizziness, dry mouth, changes in libido, hair loss, Allergic reactions
Ingestion: Symptoms: Headache, Fatigue, Respiratory disorders, Gastrointestinal discomfort, Allergic reactions, Rash, hair loss, altered mental status, Dizziness, changes in libido

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

(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
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 161 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to microorganisms: EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition

EC50 (Photobacterium phosphoreum): > 1.800 mg/l

Persistence and degradability

Components:

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

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
  Biodegradability: Not readily biodegradable.
    Biodegradation: 0 %
    Exposure time: 30 d
  Stability in water: Hydrolysis: 0 % (61 d)
    Method: FDA 3.09

Bioaccumulative potential

Components:

Dorzolamide:
  Partition coefficient: n-octanol/water: log Pow: 0,292

(S)-3-[3-(tert-butylamino)-2-hydroxypropoxy]-4-morpholino-1,2,5-thiadiazole monomaleate:
  Partition coefficient: n-octanol/water: log Pow: 1,48

Mobility in soil
  No data available

Other adverse effects
  No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
  Waste from residues: Dispose of in accordance with local regulations.
  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.

SECTION 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

ANTT
  Not regulated as a dangerous good
SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. Ordinance No. 1274 on the control and monitoring of chemicals. : Not applicable

International Regulations

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

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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 Develop-
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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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