SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Dorzolamide Formulation

Manufacturer or supplier's details

Company: MSD
Address: 26 Talavera Road, Talavera Corp Centre, Macquarie Park
         New South Wales, 2113 Australia
Telephone: (61)-02-8988-8000
Emergency telephone number: (61)-02-8988-8000
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
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

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>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorzolamide</td>
<td>130693-82-2</td>
<td>&lt; 10</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 if symptoms occur.
In case of skin contact: In case of contact, immediately flush skin with soap and plenty
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: None known.

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. FIREFIGHTING MEASURES**

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media | None known. |

<table>
<thead>
<tr>
<th>Specific hazards during firefighting</th>
<th>Exposure to combustion products may be a hazard to health.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Sulphur oxides</td>
</tr>
<tr>
<td></td>
<td>Hydrogen chloride</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific extinguishing methods</th>
<th>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Evacuate area.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Special protective equipment for firefighters</th>
<th>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</th>
</tr>
</thead>
</table>

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Use personal protective equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental precautions</th>
<th>Avoid release to the environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Prevent spreading over a wide area (e.g. by containment or oil barriers).</td>
</tr>
<tr>
<td></td>
<td>Retain and dispose of contaminated wash water.</td>
</tr>
<tr>
<td></td>
<td>Local authorities should be advised if significant spillages cannot be contained.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods and materials for containment and cleaning up</th>
<th>Soak up with inert absorbent material.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>For large spills, provide dyking or other appropriate contain-</td>
</tr>
</tbody>
</table>
ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable 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 : Do not breathe mist or vapours. 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 labelled containers. Store in accordance with the particular national regulations.
Materials to avoid : Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>
</tr>
</thead>
<tbody>
<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>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
<td></td>
</tr>
</tbody>
</table>
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 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.

**Filter type**

**Hand protection**

**Material**

**Remarks**

**Eye protection**

**Skin and body 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.
- 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
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: 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
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour 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
Auto-ignition 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 : Not applicable
Particle size : Not applicable

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
Exposure routes : Inhalation
  Skin contact
  Ingestion
Eye contact

**Acute toxicity**
Not classified based on available information.

**Product:**

**Acute oral toxicity**
- Acute toxicity estimate: > 2,000 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

**Skin corrosion/irritation**
Not classified based on available information.

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Dorzolamide:**

**Species**
- Monkey

**Result**
- Mild eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Dorzolamide:**

**Test Type**
- Maximisation Test

**Exposure routes**
- Skin contact

**Species**
- Guinea pig

**Result**
- Weak sensitizer

**Chronic toxicity**

**Germ cell mutagenicity**
Not classified based on available information.
## Components:

### Dorzolamide:

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

### 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 foetal 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**  
Not classified based on available information.  

**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: 1 yr  
Target Organs: Gastrointestinal tract, Bone, Blood  

Species: Monkey  
NOAEL: 0.05 mg/kg  
Exposure time: 1 yr  
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, 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

**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

**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.

National Regulations

ADG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

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

SECTION 16. OTHER INFORMATION

Further information

Revision Date: 16.10.2020

Date format: dd.mm.yyyy
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.