1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Dorzolamide Formulation

Supplier’s company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

Other hazards which do not result in classification
None known.

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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorzolamide</td>
<td>130693-82-2</td>
<td>&gt;=1 - &lt;10</td>
<td></td>
</tr>
<tr>
<td>Benzo[2]dodecinium chloride</td>
<td>139-07-1</td>
<td>&gt;=0.0025 - &lt;0.025</td>
<td>1-215/3-2694, 3-326/1-215</td>
</tr>
<tr>
<td>Miristalkonium chloride</td>
<td>139-08-2</td>
<td>&gt;=0.0025 - &lt;0.025</td>
<td>1-215/3-2694, 3-326/1-215</td>
</tr>
</tbody>
</table>

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.
### 5. FIREFIGHTING 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)  
|                                                     | Sulphur 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 firefighters       | 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 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
Methods and materials for containment and cleaning up:

Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment 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.

7. HANDLING AND STORAGE

Handling
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 vapour 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.

Avoidance of contact:
Oxidizing agents

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.

Storage
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

Packaging material:
Unsuitable material: None known.
8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>
</tbody>
</table>

Further information: Eye

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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Aqueous solution

Colour: No data available

Odour: No data available
**SAFETY DATA SHEET**

**Dorzolamide Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>2020/03/23</td>
<td>28990-00015</td>
<td>2019/09/13</td>
<td>2014/11/07</td>
</tr>
</tbody>
</table>

- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Boiling point, initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
- **Lower explosion limit and upper explosion limit / flammability limit**
  - **Upper explosion limit / Upper flammability limit**: No data available
  - **Lower explosion limit / Lower flammability limit**: No data available
- **Flash point**: No data available
- **Decomposition temperature**: No data available
- **pH**: 5.6
- **Evaporation rate**: No data available
- **Auto-ignition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: No data available
- **Solubility(ies)**
  - **Water solubility**: soluble
  - **Partition coefficient: n-octanol/water**: No data available
- **Vapour pressure**: No data available
- **Density and / or relative density**
  - **Relative density**: No data available
  - **Density**: No data available
  - **Relative vapour density**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Molecular weight**: Not applicable
- **Particle characteristics**
  - **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: > 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

**Benzododecinium chloride:**
- Acute oral toxicity: LD50 (Rat): > 300 - 2,000 mg/kg
  Remarks: Based on data from similar materials
- Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Remarks: Based on data from similar materials

**Miristalkonium chloride:**
- Acute oral toxicity: LD50 (Rat): 397.5 mg/kg
  Method: OECD Test Guideline 401
  Remarks: Based on data from similar materials
- Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.
SAFETY DATA SHEET
Dorzolamide Formulation

Version    Revision Date:    SDS Number:    Date of last issue:
5.0        2020/03/23        28990-00015    2019/09/13

Remarks: Based on data from similar materials

Acute dermal toxicity
LD50 (Rabbit): 3,412 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Benzododecinium chloride:
Species: Rabbit
Result: Corrosive after 3 minutes to 1 hour of exposure
Remarks: Based on data from similar materials

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

Components:

Dorzolamide:
Species: Monkey
Result: Mild eye irritation

Benzododecinium chloride:
Species: Rabbit
Result: Irreversible effects on the eye
Remarks: Based on data from similar materials

Miristalkonium chloride:
Species: Rabbit
Result: Irreversible effects on the eye
Remarks: Based on data from similar materials

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Weak sensitizer</td>
</tr>
</tbody>
</table>

### Benzododecinium chloride:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Miristalkonium chloride:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Dorzolamide:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosomal aberration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Alkaline elution assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: rat hepatocytes</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: Chinese hamster fibroblasts</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

#### Benzododecinium chloride:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 476</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Dorzolamide Formulation

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Miristalkonium chloride:

Genotoxicity in vitro

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Dorzolamide:

Species: Rat, male
Application Route: Oral
Exposure time: 2 Years
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

Benzododecinium chloride:
Species: Rat
Application Route: Ingestion
Exposure time: 104 weeks
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Miristalkonium chloride:
Species: Rat
Application Route: Ingestion
Exposure time: 2 y
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

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

Benzododecinium chloride:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
### SAFETY DATA SHEET

#### Dorzolamide Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>2020/03/23</td>
<td>28990-00015</td>
<td>2019/09/13</td>
<td>2014/11/07</td>
</tr>
</tbody>
</table>

**Remarks:** Based on data from similar materials

**Effects on foetal development**
- **Test Type:** Embryo-foetal development
- **Species:** Rabbit
- **Application Route:** Ingestion
- **Method:** OECD Test Guideline 414
- **Result:** negative
- **Remarks:** Based on data from similar materials

**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

**Mirtalcohol chloride:**

- **Effects on fertility**
  - **Test Type:** Two-generation study
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Method:** OECD Test Guideline 416
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.
11. HUMAN TOXICITY

**Species:** Monkey

**NOAEL:** 0.05 mg/kg

**Exposure time:** 1 yr

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

**Benzododecinium chloride:**

**Species:** Rat

**NOAEL:** > 25 mg/kg

**Application Route:** Ingestion

**Exposure time:** 52 Weeks

**Method:** OECD Test Guideline 453

**Remarks:** Based on data from similar materials

**Miristalkonium chloride:**

**Species:** Rat

**NOAEL:** 56 - 65 mg/kg

**LOAEL:** 109 - 133 mg/kg

**Application Route:** Ingestion

**Exposure time:** 52 Weeks

**Remarks:** Based on data from similar materials

**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

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

**Benzododecinium chloride:**
### Toxicity to fish
- **LC50**: > 0.1 - 1 mg/l
- **Exposure time**: 96 h
- Remarks: Based on data from similar materials

### Toxicity to daphnia and other aquatic invertebrates
- **EC50 (Daphnia magna (Water flea))**: > 0.01 - 0.1 mg/l
- **Exposure time**: 48 h
- **Method**: OECD Test Guideline 202
- Remarks: Based on data from similar materials

### Toxicity to algae/aquatic plants
- **ErC50**: > 0.01 - 0.1 mg/l
- **Exposure time**: 72 h
- Remarks: Based on data from similar materials
- **EC10**: > 0.001 - 0.01 mg/l
- **Exposure time**: 72 h
- Remarks: Based on data from similar materials

### M-Factor (Acute aquatic toxicity)
- **M**-Factor: 10

### Toxicity to fish (Chronic toxicity)
- **NOEC (Pimephales promelas (fathead minnow))**: > 0.01 - 0.1 mg/l
- **Exposure time**: 28 d
- Remarks: Based on data from similar materials

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC (Daphnia magna (Water flea))**: > 0.001 - 0.01 mg/l
- **Exposure time**: 21 d
- **Method**: OECD Test Guideline 211
- Remarks: Based on data from similar materials

### M-Factor (Chronic aquatic toxicity)
- **M**-Factor: 1

### Toxicity to microorganisms
- **EC50**: > 10 - 100 mg/l
- **Exposure time**: 30 min
- **Method**: OECD Test Guideline 209
- Remarks: Based on data from similar materials

### Miristalkonium chloride:

#### Toxicity to fish
- **LC50 (Oncorhynchus mykiss (rainbow trout))**: 0.85 mg/l
- **Exposure time**: 96 h
- **Method**: OECD Test Guideline 203
- Remarks: Based on data from similar materials

#### Toxicity to daphnia and other aquatic invertebrates
- **EC50 (Daphnia magna (Water flea))**: 0.016 mg/l
- **Exposure time**: 48 h
- **Method**: OECD Test Guideline 202
- Remarks: Based on data from similar materials

#### Toxicity to algae/aquatic plants
- **ErC50 (Pseudokirchneriella subcapitata (green algae))**: 0.049 mg/l
- **Exposure time**: 72 h
- **Method**: OECD Test Guideline 201
- Remarks: Based on data from similar materials
- **NOEC (Pseudokirchneriella subcapitata (green algae))**: 0.001 - 0.01 mg/l
- **Exposure time**: 72 h
- **Method**: OECD Test Guideline 201
- Remarks: Based on data from similar materials
### Dorzolamide Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>2020/03/23</td>
<td>28990-00015</td>
<td>2019/09/13</td>
<td>2014/11/07</td>
</tr>
</tbody>
</table>

#### Exposure Concentration: 0.0012 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

#### M-Factor (Acute aquatic toxicity):
- : 10

#### M-Factor (Chronic aquatic toxicity):
- : 1

#### Toxicity to microorganisms:
- Exposure time: 30 min
- Method: OECD Test Guideline 209
- Remarks: Based on data from similar materials

#### 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

- **Benzododecinium chloride**:
  - **Biodegradability**: Result: Readily biodegradable.
  - Remarks: Based on data from similar materials

- **Miristalkonium chloride**:
  - **Biodegradability**: Result: Readily biodegradable.
  - **Biodegradation**: 95.5%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B
  - Remarks: Based on data from similar materials

- **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

Benzododecinium chloride:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
                 Bioconcentration factor (BCF): < 500
                 Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water : log Pow: < 4
                 Remarks: Expert judgement

Miristalkonium chloride:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
                 Bioconcentration factor (BCF): 79
                 Remarks: Based on data from similar materials

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

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

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.

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
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salt of alkyl(C=12-16)(benzyl)(dimethyl)ammonium</td>
<td>184</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable
16. OTHER INFORMATION

Further information

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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.