**SAFETY DATA SHEET**

Desloratadine Liquid Formulation

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Desloratadine Liquid 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>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

**SECTION 4. FIRST AID MEASURES**

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

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.
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>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods</td>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
</tr>
<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>
<tr>
<td>Special protective equipment for firefighters</td>
<td>Wear self-contained breathing apparatus for firefighting if necessary.</td>
</tr>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
</tbody>
</table>

SECTION 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures | 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 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.

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: 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.
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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particulate)</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA (Total (vapour and particles))</td>
<td>150 ppm 474 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

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

Remarks: Wash hands before breaks and at the end of workday.
Eye protection: Wear the following personal protective equipment: Safety glasses
Skin and body protection: Skin should be washed after contact.
### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>clear</td>
</tr>
<tr>
<td>Odour</td>
<td>sweet</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
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

**Exposure routes:** Inhalation, Skin contact, Ingestion, Eye contact

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

**Components:**

**Propylene glycol:**
- **Acute oral toxicity:** LD50 (Rat): > 5,000 mg/kg
- **Acute inhalation toxicity:** LC50 (Rabbit): > 159 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- **Acute dermal toxicity:** LD50 (Rabbit): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

**Desloratadine:**
- **Acute oral toxicity:** LD50 (Rat): > 549 mg/kg
  - LD50 (Mouse): 353 mg/kg
  - LD50 (Monkey): > 250 mg/kg
  - Symptoms: Vomiting
  - Remarks: No mortality observed at this dose.

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

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Desloratadine:
Species: Rabbit
Result: No skin irritation

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

Components:

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Desloratadine:
Species: Rabbit
Remarks: Severe eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Desloratadine:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: negative

Chronic toxicity

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

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Desloratadine:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Propylene glycol:
Species: Rat  
Application Route: Ingestion  
Exposure time: 2 Years  
Result: negative

Desloratadine:
Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years  
Result: negative

Species: Rat  
Application Route: Oral  
LOAEL: 10 mg/kg body weight  
Result: equivocal  
Target Organs: Liver  
Remarks: Based on data from similar materials  
The mechanism or mode of action may not be relevant in humans.
Reproductive toxicity
Not classified based on available information.

Components:

Propylene glycol:
Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Desloratadine:
Effects on fertility : Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 12 mg/kg body weight
Symptoms: Reduced fertility
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Fertility
Species: Rat, female
Fertility: NOAEL: 3 mg/kg body weight
Symptoms: No effects on fertility
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 30 mg/kg body weight
Result: No teratogenic effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 9 mg/kg body weight
Symptoms: Preimplantation loss, Reduced body weight
Result: Specific developmental abnormalities
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Two-generation study
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 18 mg/kg body weight
Result: No adverse effects

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Desloratadine:
Species: Rat
LOAEL: 30 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Kidney
Remarks: Significant toxicity observed in testing
The mechanism or mode of action may not be relevant in humans.

Species: Monkey
NOAEL: 6 mg/kg
LOAEL: 12 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Central nervous system
Symptoms: Gastrointestinal disturbance

Species: Monkey
NOAEL: 40 mg/kg
Application Route: Oral
Exposure time: 17 Months
Remarks: No significant adverse effects were reported

Species: Monkey
NOAEL: 6 mg/kg
Application Route: Oral
Exposure time: 3 Months
Symptoms: Gastrointestinal disturbance, Fatigue

Aspiration toxicity
Not classified based on available information.
Experience with human exposure

**Components:**

**Desloratadine:**
- **Inhalation:** Remarks: May cause respiratory tract irritation.
- **Eye contact:** Symptoms: Eye irritation
- **Ingestion:** Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Propylene glycol:**
- **Toxicity to fish:** LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  Exposure time: 7 d
- **Toxicity to microorganisms:** NOEC (Pseudomonas putida): > 20,000 mg/l
  Exposure time: 18 h

**Desloratadine:**
- **Toxicity to fish:** LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l
  Exposure time: 96 h
  Method: FDA 4.11
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): 9.6 mg/l
  Exposure time: 48 h
  Method: FDA 4.08
- **Toxicity to algae/aquatic plants:** EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- **Toxicity to fish (Chronic toxicity):** NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l
  Exposure time: 32 d
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<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Daphnia magna (Water flea)): 0.48 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Natural microorganism): 53.7 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 h</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Natural microorganism): 12 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td><strong>NOEC</strong></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 h</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
</tr>
</tbody>
</table>

## Persistence and degradability

### Components:

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>98.3 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 301F</td>
</tr>
</tbody>
</table>

**Desloratadine:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Not readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>67.4 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 314</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Not readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>0 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Method</td>
<td>FDA 3.11</td>
</tr>
</tbody>
</table>

**Stability in water:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Hydrolysis: &lt; 10 % at 50 °C (5 d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Bioaccumulative potential

### Components:

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: -1.07</th>
</tr>
</thead>
</table>

**Desloratadine:**

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: 1.24</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>OECD Test Guideline 107</th>
</tr>
</thead>
</table>
Mobility in soil

Components:

Desloratadine:
Distribution among environmental compartments: log Koc: 3.00
Method: OECD Test Guideline 106

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 or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:
AICS: not determined
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SECTION 16. OTHER INFORMATION

Further information
Revision Date: 09/13/2019
Sources of key data used to compile the Safety Data Sheet:
Date format: dd.mm.yyyy

Full text of other abbreviations
AU OEL: Australia. Workplace Exposure Standards for Airborne Contaminants.
AU OEL / TWA: Exposure standard - time weighted average

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.

AU / EN