Section 1: Identification

Product name: Desloratadine Liquid Formulation

Manufacturer or supplier's details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

Section 2: Hazard 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.
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:

No special precautions are necessary for first aid responders.

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

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:

Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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>WES-TWA (particulate)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</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
Method : OECD Test Guideline 405
Result : No eye irritation

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

**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):
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:
Toxicity to algae/aquatic plants: 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
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 0.48 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

Toxicity to microorganisms:

- EC50 (Natural microorganism): 53.7 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

  NOEC (Natural microorganism): 12 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

Persistence and degradability

Components:

Propylene glycol:

- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 98.3%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301F

Desloratadine:

- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 67.4%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 314

  Result: Not readily biodegradable.
  - Biodegradation: 0%
  - Exposure time: 28 d
  - Method: FDA 3.11

Stability in water:

- Hydrolysis: < 10 % at50 °C(5 d)
  - Method: FDA 3.09

Bioaccumulative potential

Components:

Propylene glycol:

- Partition coefficient: n-octanol/water: log Pow: -1.07

Desloratadine:

- Partition coefficient: n-octanol/water: log Pow: 1.24
  - Method: OECD Test Guideline 107
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
NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
Not applicable

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.
SAFETY DATA SHEET

Desloratadine Liquid Formulation

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

Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations

NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

NZ OEL/WES-TWA: Workplace Exposure Standard - Time Weighted average

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 Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System
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.

NZ / EN