1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Desloratadine Liquid 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>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-234</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
</tr>
</tbody>
</table>

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.
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

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.

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
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: 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.

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/PERSONAL 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>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</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.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: liquid
Colour: clear
Odour: sweet
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: No data available
Evaporation rate: No data available
Auto-ignition temperature: No data available

Viscosity
Viscosity, dynamic: No data available
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             : No data available
Particle characteristics     :
Particle size                : No data available

10. STABILITY AND REACTIVITY
Reactivity                   : Not classified as a reactivity hazard.
Chemical stability           : Stable under normal conditions.
Possibility of hazardous reac-
tions                        : Can react with strong oxidizing agents.
Conditions to avoid          : None known.
Incompatible materials       : Oxidizing agents
Hazardous decomposition pro-
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.

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
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
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 menstruation

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
- Method: OECD Test Guideline 210

## 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 % at 50 °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
12. Mobility in soil

Components:

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

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>Propane-1,2-diol</td>
<td>106</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

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**
Not applicable

**Poisonous and Deleterious Substances Control Law**
Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**
Not applicable

**High Pressure Gas Safety Act**
Not applicable

**Explosive Control Law**
Not applicable

**Vessel Safety Law**
Not regulated as a dangerous good

**Aviation Law**
Not regulated as a dangerous good
Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

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

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet

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

Date format : yyyy/mm/dd

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
SAFETY DATA SHEET

Desloratadine Liquid Formulation

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.

JP / EN