1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Desloratadine Liquid Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
         Pandaan, Jawa Timur - Indonesia
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

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.

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>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 0.025 -&lt; 0.25</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.
SAFETY DATA SHEET

Desloratadine Liquid Formulation

Version 1.6  Revision Date: 09/13/2019  SDS Number: 771469-00007  Date of last issue: 2019/05/15
Date of first issue: 2016/06/23

Most important symptoms and effects, both acute and delayed:
Rinse mouth thoroughly with water.

Protection of first-aiders:
None known.

Notes to physician:
No special precautions are necessary for first aid responders.

Treat symptomatically and supportively.

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

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.

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

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>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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

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

Components:

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:

Desloratadine:
Species: Rabbit
Result: No skin irritation

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

Components:

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:

Desloratadine:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Desloratadine:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
</tr>
<tr>
<td></td>
<td>Test system: Human lymphocytes</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Carcinogenicity
Not classified based on available information.

Components:

Desloratadine:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>LOAEL</td>
<td>10 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>equivocal</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>
Reproductive toxicity

Not classified based on available information.

**Components:**

**Desloratadine:**

Effects on fertility

<table>
<thead>
<tr>
<th>Test Type:</th>
<th>Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species:</td>
<td>Rat, male</td>
</tr>
<tr>
<td>Application Route:</td>
<td>Oral</td>
</tr>
<tr>
<td>Fertility:</td>
<td>LOAEL: 12 mg/kg body weight</td>
</tr>
<tr>
<td>Symptoms:</td>
<td>Reduced fertility</td>
</tr>
<tr>
<td>Result:</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks:</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

Test Type: Fertility

Species: Rat, female

Fertility: NOAEL: 3 mg/kg body weight

Symptoms: No effects on fertility

Result: negative

Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type:</th>
<th>Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species:</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Application Route:</td>
<td>Oral</td>
</tr>
<tr>
<td>Developmental Toxicity:</td>
<td>NOAEL: 30 mg/kg body weight</td>
</tr>
<tr>
<td>Result:</td>
<td>No teratogenic effects</td>
</tr>
</tbody>
</table>

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:**

Desloratadine:

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>30 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Kidney</td>
<td>Significant toxicity observed in testing. The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

Species: Monkey

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Central nervous system</td>
<td>Gastrointestinal disturbance</td>
</tr>
</tbody>
</table>

Species: Monkey

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 mg/kg</td>
<td>Oral</td>
<td>17 Months</td>
<td>Gastrointestinal disturbance, Fatigue</td>
</tr>
</tbody>
</table>

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

**Components:**

Desloratadine:

<table>
<thead>
<tr>
<th>Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Eye irritation</td>
</tr>
<tr>
<td>Ingestion</td>
<td>dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration</td>
</tr>
</tbody>
</table>

12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

Desloratadine:

| Toxicity to fish | LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l |
### Persistence and degradability

**Components:**

**Desloratadine:**

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability in water</td>
<td>Hydrolysis: &lt; 10 % at 50 °C</td>
<td>FDA 3.09</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
<td></td>
</tr>
<tr>
<td>Stability in water</td>
<td>Hydrolysis: &lt; 10 % at 50 °C</td>
<td>FDA 3.09</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea))</td>
<td>9.6 mg/l</td>
<td>FDA 4.11</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 h</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae))</td>
<td>1.6 mg/l</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow))</td>
<td>0.12 mg/l</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td>Exposure time</td>
<td>32 d</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia magna (Water flea))</td>
<td>0.48 mg/l</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Exposure time</td>
<td>21 d</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Natural microorganism)</td>
<td>53.7 mg/l</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 h</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>0.36 mg/l</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

**Stability in water:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Result/Resultant</th>
<th>Method/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrolysis</td>
<td>&lt; 10 % at 50 °C</td>
<td>FDA 3.09</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
<td></td>
</tr>
</tbody>
</table>

**Exposure time:**

- 96 h
  - Method: FDA 4.11
- 48 h
  - Method: FDA 4.08
- 72 h
  - Method: OECD Test Guideline 201
- 32 d
  - Method: OECD Test Guideline 210
- 21 d
  - Method: OECD Test Guideline 211
- 3 h
  - Method: OECD Test Guideline 209
- 3 h
  - Method: FDA 3.11
- 28 d
  - Method: OECD Test Guideline 314
- 28 d
  - Method: FDA 3.09
Bioaccumulative potential

Components:

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

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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
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;
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.