 SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine Liquid Formulation

Manufacturer or supplier’s details
Company name of supplier : MSD
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : 52 55 57284444
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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
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>Desloratadine</td>
<td>100643-71-8</td>
<td>&lt; 0.1</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 fire-fighters:
- 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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- 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 diking or other appropriate containment to keep material from spreading. If diked 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 labeled 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

**Ingredients 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: clear

Odor: sweet

Odor 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
Vapor pressure: No data available
Relative vapor 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
Autoignition 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

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

### 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 sensitization

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.
Components:

Desloratadine:
- Test Type: Maximization Test
- Routes of exposure: Dermal
- Species: Guinea pig
- Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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:

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:

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

Test Type: Embryo-fetal 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:**  
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:**

**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:**

**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:**

**Desloratadine:**

**Partition coefficient: n-octanol/water:**  
log Pow: 1.24  
Method: OECD Test Guideline 107
SAFETY DATA SHEET

Desloratadine Liquid Formulation

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.

Domestic regulation
NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.
Not applicable

The ingredients of this product are reported in the following inventories:
AICS: not determined
## SAFETY DATA SHEET

### Desloratadine Liquid 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>
</table>

- **DSL**: not determined
- **IECSC**: not determined

## SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

- AIIC - Australian Inventory of Industrial Chemicals; 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

**Sources of key data used to compile the Material Safety Data Sheet**


- **Revision Date**: 01.10.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8