SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Desloratadine Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : Organon & Co.
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

2.3 Other hazards
   This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 0.025 - &lt;</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of first aid measures

Protection of first-aiders: No special precautions are necessary for first aid responders.

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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particles)</td>
<td>10 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total vapour and particles)</td>
<td>150 ppm 474 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Long-term systemic effects</td>
<td>168 mg/m3</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m3</td>
<td></td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:
8.2 Exposure controls

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

**Personal protective equipment**

Eye protection: Wear the following personal protective equipment:
- Safety glasses
Equipment should conform to BS EN 166

Hand protection

- Remarks: Wash hands before breaks and at the end of workday.

Skin and body protection: Skin should be washed after contact.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Equipment should conform to BS EN 143

Filter type: Particulates type (P)

### SECTION 9: Physical and chemical properties

**9.1 Information on basic 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
Desloratadine Liquid Formulation

Version 1.12 Revision Date: 09.04.2021 SDS Number: 778689-00013 Date of last issue: 01.10.2020 Date of first issue: 23.06.2016

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9.2 Other information

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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:**

**Genotoxicity in vitro**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Chromosomal aberration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test system</td>
<td>Human lymphocytes</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

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

**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 |
| Remarks | The mechanism or mode of action may not be relevant in humans. |

**Reproductive toxicity**

Not classified based on available information.
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:

Desloratadine:
- Species: Rat
- LOAEL: 30 mg/kg
Desloratadine Liquid Formulation

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

12.1 Toxicity

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
## 12.2 Persistence and degradability

### Components:

**Desloratadine:**

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

| Stability in water | Hydrolysis: < 10 % at 50 °C(5 d)  
|                   | Method: FDA 3.09  

### 12.3 Bioaccumulative potential

#### Components:

**Desloratadine:**
12.4 Mobility in soil

Components:

Desloratadine:

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

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:
Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good
14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

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

AICS: not determined
DSL: not determined
IECS: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H302: Harmful if swallowed.
Desloratadine Liquid Formulation

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox.</td>
<td>Acute toxicity</td>
</tr>
<tr>
<td>Aquatic Chronic</td>
<td>Long-term (chronic) aquatic hazard</td>
</tr>
<tr>
<td>Eye Dam.</td>
<td>Serious eye damage</td>
</tr>
<tr>
<td>Repr.</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td>GB EH40</td>
<td>UK EH40 Workplace Exposure Limits</td>
</tr>
<tr>
<td>GB EH40 / TWA</td>
<td>Long-term exposure limit (8-hour TWA reference period)</td>
</tr>
</tbody>
</table>

Further information

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

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
### Desloratadine Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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</thead>
<tbody>
<tr>
<td>1.12</td>
<td>09.04.2021</td>
<td>778689-00013</td>
<td>01.10.2020</td>
</tr>
</tbody>
</table>

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.

GB / EN