1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Loratadine / Montelukast Formulation

Supplier's company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity : Category 2
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 2

GHS label elements
Hazard pictograms :

Signal word : Warning
Hazard statements : H361f Suspected of damaging fertility.
                   H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
                          P201 Obtain special instructions before use.
                          P202 Do not handle until all safety precautions have been read
                          and understood.
                          P273 Avoid release to the environment.
                          P280 Wear protective gloves/ protective clothing/ eye protec-
                          tion/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/
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attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form combustible dust concentrations in air during processing, handling or other means.

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>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 40 - &lt; 50</td>
<td></td>
</tr>
<tr>
<td>Montelukast</td>
<td>151767-02-1</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Loratadine</td>
<td>79794-75-5</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
Suspected of damaging fertility.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment.
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Notes to physician: 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: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. 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: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. 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. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.
7. HANDLING AND STORAGE

Handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- 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.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- 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>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Montelukast</td>
<td>151767-02-1</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Loratadine</td>
<td>79794-75-5</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Wipe limit</th>
<th>400 µg/100 cm²</th>
<th>Internal</th>
</tr>
</thead>
</table>

**Engineering measures**: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**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**: Chemical-resistant gloves

- **Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

- **Skin and body protection**: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Physical state**: tablet
- **Colour**: No data available
- **Odour**: No data available
- **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)**: May form combustible dust concentrations in air during processing, handling or other means.
- **Flammability (liquids)**: Not applicable
- **Lower explosion limit and upper explosion limit / flammability limit**
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks. Avoid dust formation.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**
Not classified based on available information.

**Components:**

**Cellulose:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

**Montelukast:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  LD50 (Mouse): > 5,000 mg/kg
- Acute inhalation toxicity: Remarks: No data available
- Acute dermal toxicity: Remarks: No data available

**Loratadine:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 0.05 mg/l
  Exposure time: 1 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Montelukast:**
- Species: Rabbit
- Result: Mild skin irritation

**Loratadine:**
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Species: Rabbit
Result: No skin irritation

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

Components:
Montelukast:
Species: Rabbit
Result: Severe irritation

Loratadine:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Montelukast:
Remarks: No data available

Loratadine:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitisation.
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Cellulose:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative
Montelukast:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Test system: Chinese hamster fibroblasts
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster ovary cells
  Result: negative
- Test Type: Alkaline elution assay
  Test system: rat hepatocytes
  Result: negative

Genotoxicity in vivo:
- Test Type: Chromosomal aberration
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Oral
  Result: negative

Loratadine:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Oral
  Result: negative

Germ cell mutagenicity - Assessment:
- Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity:
Not classified based on available information.

Components:

Cellulose:
Species: Rat
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Application Route: Ingestion
Exposure time: 72 weeks
Result: negative

Montelukast:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 92 weeks
Result: negative

Loratadine:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
LOAEL: 10 mg/kg body weight
Result: positive

Species: Monkey
Application Route: Oral
Exposure time: 17 Months
NOAEL: 40 mg/kg body weight
Result: negative

Reproductive toxicity
Suspected of damaging fertility.

Components:
Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Montelukast:
Effects on fertility: Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: NOAEL: 800 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Test Type: Fertility
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Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 200 mg/kg body weight
Symptoms: Reduced fertility

Test Type: Fertility
Species: Rat, female
Application Route: Oral
Fertility: NOAEL: 100 mg/kg body weight
Symptoms: Reduced fertility

Loratadine:

Effects on fertility : Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 64 mg/kg body weight
Result: Effects on fertility

Effects on foetal development : Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 48 mg/kg body weight
Result: Embryo-foetal toxicity

Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 48 mg/kg body weight
Result: Embryo-foetal toxicity

Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 12 mg/kg body weight

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, 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:

Cellulose:
Species : Rat
NOAEL : >= 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Montelukast:
Species : Monkey, male and female
NOAEL : 150 - 300 mg/kg
Application Route : Oral
## Safety Data Sheet

**Loratadine / Montelukast Formulation**

### Version

2.2

### Revision Date

2021/04/09

### SDS Number

4574878-00005

### Date of last issue

2020/10/10

### Date of first issue

2019/07/08

### Exposure time

53 Weeks

### Remarks

No significant adverse effects were reported

### Species

Rat

### NOAEL

50 mg/kg

### Application Route

Oral

### Exposure time

53 Weeks

### Remarks

No significant adverse effects were reported

### Species

Mouse

### NOAEL

50 mg/kg

### Application Route

Oral

### Exposure time

14 Weeks

### Remarks

No significant adverse effects were reported

### Loratadine:

- **Species**: Rat
- **NOAEL**: 4 mg/kg
- **LOAEL**: 8 mg/kg
- **Application Route**: Oral
- **Exposure time**: 180 Days
- **Target Organs**: Central nervous system
- **Remarks**: Effects are of limited toxicological significance.

### Species

Monkey

### NOAEL

0.4 mg/kg

### LOAEL

4 mg/kg

### Application Route

Oral

### Exposure time

180 Days

### Target Organs

Central nervous system

### Remarks

Effects are of limited toxicological significance.

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### Montelukast:

- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Symptoms: Severe irritation
- **Ingestion**: Symptoms: upper respiratory tract infection, pharyngitis, Headache, Cough, Abdominal pain, Diarrhoea, Fever

#### Loratadine:

- **Ingestion**: Symptoms: Fatigue, Headache, dry mouth, Nausea
### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Cellulose:**
- Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

**Montelukast:**
- Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 0.0778 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: No toxicity at the limit of solubility

- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 0.0675 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility

- Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility
  
  EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

- Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.073 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210
  - Remarks: No toxicity at the limit of solubility

  NOEC (Cyprinodon variegatus (sheepshead minnow)): 0.0816 mg/l
  - Exposure time: 7 d
  - Remarks: No toxicity at the limit of solubility

- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.23 mg/l
  - Exposure time: 21 d
  - Remarks: No toxicity at the limit of solubility

- Toxicity to microorganisms: EC50: > 100 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - Remarks: No toxicity at the limit of solubility
### Loratadine:

**Toxicity to fish**
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.382 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): 0.83 mg/l  
  Exposure time: 48 h  
  Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.95 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.053 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity)**
- 1

**Toxicity to fish (Chronic toxicity)**
- NOEC (Pimephales promelas (fathead minnow)): 0.084 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)): 0.078 mg/l  
  Exposure time: 21 d  
  Method: OECD Test Guideline 211

**M-Factor (Chronic aquatic toxicity)**
- 1

**Toxicity to microorganisms**
- EC50: > 1,000 mg/l  
  Exposure time: 3 h  
  Test Type: Respiration inhibition  
  Method: OECD Test Guideline 209

### Persistence and degradability

**Components:**

**Cellulose:**
- Biodegradability: Result: Readily biodegradable.

**Montelukast:**
- Biodegradability: Result: not rapidly degradable  
  Biodegradation: 0 %  
  Exposure time: 28 d

**Stability in water:**
- Hydrolysis: 50 % (21.7 h)

**Loratadine:**
- Biodegradability: Result: not rapidly degradable  
  Biodegradation: 50 %
Exposure time: 20 d
Method: OECD Test Guideline 314

Stability in water: Degradation half life (DT50): 283 d

Bioaccumulative potential

Components:

Montelukast:
Partition coefficient: n-octanol/water
log Pow: > 4.3

Loratadine:
Partition coefficient: n-octanol/water
log Pow: 2.35

Mobility in soil

Components:

Loratadine:
Distribution among environmental compartments
log Koc: 5.25
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
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Loratadine)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s.
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(Loratadine)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Loratadine)

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

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
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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
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : 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
Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

AIIIC - 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 Tem-
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