1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Fidaxomicin Solid 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
Acute toxicity (Oral) : Category 4

GHS label elements
Hazard pictograms : ⚠️

Signal word : Warning
Hazard statements : H302 Harmful if swallowed.
Precautionary statements : Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
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.
SAFETY DATA SHEET

Fidaxomicin Solid Formulation

Version 3.0
Revision Date: 2021/08/27
SDS Number: 4750797-00005
Date of last issue: 2021/04/09
Date of first issue: 2019/08/15

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td>&gt;= 50 - &lt; 60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>&gt;= 1 - &lt; 10</td>
<td>3-1293, 3-1272</td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-1318</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>2-234</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 if symptoms occur.

In case of skin contact: Wash with water and soap. Get medical attention if symptoms occur.

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 unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Harmful if swallowed. 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 when the potential for exposure exists (see section 8).

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 fire-fighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Metal oxides
- Chlorine compounds

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 spillages 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.
- Wash skin thoroughly after handling.
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. 
Do not eat, drink or smoke when using this product. 
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 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 / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td>TWA</td>
<td>200 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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
Material : 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : granules
Colour : White to light yellow
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 explosive dust-air mixture during processing, handling or other means.

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 : Not applicable
Decomposition temperature : No data available
pH : No data available
Evaporation rate : Not applicable
Auto-ignition temperature : No data available
Viscosity
Viscosity, kinematic : Not applicable
Solubility(ies)
Water solubility : No data available
Partition coefficient: n- : Not applicable
10. STABILITY AND REACTIVITY

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

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

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
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 875.04 mg/kg
Method: Calculation method

Components:
Fidaxomicin:
Acute oral toxicity: LD50 (Rat): > 1,000 mg/kg
LD50 (Dog): > 120 mg/kg

Acute toxicity (other routes of administration):
LD50 (Rat): 200 mg/kg
Application Route: Intravenous

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

Sodium benzoate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Citric acid:
Acute oral toxicity: LD50 (Mouse): 5,400 mg/kg
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 404
Assessment: The substance or mixture has no acute dermal toxicity

Propylene glycol:
Acute oral toxicity: LD50 (Rat): 22,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 44.9 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

Skin corrosion/irritation
Not classified based on available information.

Components:

Sodium benzoate:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Citric acid:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

Components:
Sodium benzoate:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Citric acid:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Components:
Sodium benzoate:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative
Remarks: Based on data from similar materials

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Germ cell mutagenicity
Not classified based on available information.

Components:

Fidaxomicin:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Test system: Chinese hamster ovary cells
  Result: positive

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Intravenous
  Result: negative
- Test Type: comet assay
  Species: Rat
  Result: negative

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

Sodium benzoate:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: positive

Genotoxicity in vivo:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Rat
  Application Route: Ingestion
  Result: negative

Citric acid:

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

Test Type: in vitro micronucleus test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Propylene glycol:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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

Sodium benzoate:
Species: Rat
Application Route: Ingestion
Exposure time: 24 month(s)
Result: negative

Propylene glycol:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative
Reproductive toxicity
Not classified based on available information.

Components:

Fidaxomicin:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intravenous injection
Fertility: NOAEL: 6.3 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 12.6 mg/kg body weight
Remarks: No significant adverse effects were reported

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 7 mg/kg body weight
Remarks: No significant adverse effects were reported

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

Sodium benzoate:

Effects on fertility : Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Citric acid:

Effects on foetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Propylene glycol:

Effects on fertility:
Test Type: Two-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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Fidaxomicin:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>90 mg/kg</td>
<td>Oral</td>
<td>28 D</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Rat</td>
<td>62.5 mg/kg</td>
<td>Intravenous</td>
<td>14 D</td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>9,600 mg/kg</td>
<td>Oral</td>
<td>3 M</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Monkey</td>
<td>90 mg/kg</td>
<td>Oral</td>
<td>28 D</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Juvenile rat</td>
<td>200 mg/kg</td>
<td>Oral</td>
<td>28 D</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

Cellulose:

| Species  | |
|----------| Rat |
## NOAEL

**Application Route**: Ingestion  
**Exposure time**: 90 Days

### Sodium benzoate:

**Species**: Rat  
**NOAEL**: 1,000 mg/kg  
**Application Route**: Ingestion  
**Exposure time**: 24 Months

### Citric acid:

**Species**: Rat  
**NOAEL**: 4,000 mg/kg  
**LOAEL**: 8,000 mg/kg  
**Application Route**: Ingestion  
**Exposure time**: 10 Days

### Propylene glycol:

**Species**: Rat, male  
**NOAEL**: >= 1,700 mg/kg  
**Application Route**: Ingestion  
**Exposure time**: 2 yr

### Aspiration toxicity

Not classified based on available information.

## Experience with human exposure

### Components:

#### Fidaxomicin:

**Ingestion**: Symptoms: Abdominal pain, Nausea, Vomiting, constipation

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

**Fidaxomicin**

**Toxicity to algae/aquatic plants**

- **EC50 (Anabaena flos-aquae (cyanobacterium))**: > 18.4 mg/l  
  - **Exposure time**: 72 h  
  - **Method**: OECD Test Guideline 201  
  - **Remarks**: No toxicity at the limit of solubility

- **NOEC (Anabaena flos-aquae (cyanobacterium))**: 5.8 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))**: 8.91 mg/l
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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 19.6 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms:
- EC50: > 50 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

NOEC: 5.9 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

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

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 32 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

Citric acid:
Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): 484 mg/l
  - Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 96 h

Ecological toxicity to microorganisms:
- EC50: > 50 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

NOEC: 5.9 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

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
aquatic invertebrates  
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

Persistence and degradability

Components:

Cellulose:
Biodegradability  
Result: Readily biodegradable.

Sodium benzoate:
Biodegradability  
Result: Readily biodegradable.
Biodegradation: 75 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Citric acid:
Biodegradability  
Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Propylene glycol:
Biodegradability  
Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Fidaxomicin:
Partition coefficient: n-octanol/water  
log Pow: 4.4

Sodium benzoate:
Partition coefficient: n-octanol/water  
log Pow: 1.88

Citric acid:
Partition coefficient: n-octanol/water  
log Pow: -1.72

Propylene glycol:
### Partition coefficient: n-octanol/water

<table>
<thead>
<tr>
<th>Method</th>
<th>Value</th>
</tr>
</thead>
</table>

### Mobility in soil

**Components:**

**Fidaxomicin:**

<table>
<thead>
<tr>
<th>Distribution among environmental compartments</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>log Koc</td>
<td>0.80</td>
</tr>
</tbody>
</table>

### 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:** Not applicable
- **Proper shipping name:** Not applicable
- **Class:** Not applicable
- **Subsidiary risk:** Not applicable
- **Packing group:** Not applicable
- **Labels:** Not applicable

**IATA-DGR**

- **UN/ID No.:** Not applicable
- **Proper shipping name:** Not applicable
- **Class:** Not applicable
- **Subsidiary risk:** Not applicable
- **Packing group:** Not applicable
- **Labels:** Not applicable
- **Packing instruction (cargo aircraft):** Not applicable
- **Packing instruction (passenger aircraft):** Not applicable

**IMDG-Code**

- **UN number:** Not applicable
- **Proper shipping name:** Not applicable
- **Class:** Not applicable
- **Subsidiary risk:** Not applicable
- **Packing group:** Not applicable
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 : Not classified as noxious liquid substance

Marine Pollution and Sea Disaster Prevention etc Law
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
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Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

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