1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Oxytetracycline / Diclofenac 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 : Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation : Category 2

Skin sensitisation : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements :
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360FD May damage fertility. May damage the unborn child.
H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or
H410 Very 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.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
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
None known.

### 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></td>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 50 - &lt; 60</td>
<td>5-112</td>
</tr>
<tr>
<td></td>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 20 - &lt; 25</td>
<td>9-271</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-234</td>
</tr>
<tr>
<td></td>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>&gt;= 1 - &lt; 10</td>
<td>1-465</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>General advice</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaled</td>
<td>If inhaled, remove to fresh air. Get medical attention.</td>
</tr>
<tr>
<td>In case of skin contact</td>
<td>In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.</td>
</tr>
<tr>
<td>In case of eye contact</td>
<td>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.</td>
</tr>
<tr>
<td>If swallowed</td>
<td>If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.</td>
</tr>
<tr>
<td>Most important symptoms and effects, both acute and delayed</td>
<td>May cause an allergic skin reaction. Causes serious eye irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>Protection of first-aiders</td>
<td>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).</td>
</tr>
<tr>
<td>Notes to physician</td>
<td>Treat symptomatically and supportively.</td>
</tr>
</tbody>
</table>

5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>None known.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
<tr>
<td>Specific extinguishing method</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td></td>
<td>Chlorine compounds</td>
</tr>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Sodium oxides</td>
</tr>
<tr>
<td></td>
<td>Metal oxides</td>
</tr>
</tbody>
</table>

Specific extinguishing method: Use extinguishing measures that are appropriate to local cir-
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. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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. Contaminated work clothing should not be allowed out of the workplace. 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. Keep tightly closed. 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>oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: DSEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>1309-48-4</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exp-
Filter type
: Combined particulates and organic vapour 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
: liquid

Colour
: brown, Greenish yellow

Odour
: characteristic

Odour Threshold
: No data available

Melting point/freezing point
: -33 °C

Boiling point, initial boiling point and boiling range
: 100.5 °C

Flammability (solid, gas)
: Not applicable

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
: No data available

Decomposition temperature
: No data available

pH
: No data available

Evaporation rate
: No data available

Auto-ignition temperature
: No data available

Viscosity
Viscosity, dynamic
: 50.3 - 50.7 mPa.s (25 °C)

Viscosity, kinematic
: No data available
Solubility(ies)
   Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density
   Relative density : 1.15 - 1.19 (25 °C)
   Density : No data available
   Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics
   Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
   Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
   Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
   Method: Calculation method

Components:

2-Pyrrolidone:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

**Oxytetracycline:**

Acute oral toxicity: LD50 (Rat): 4,800 mg/kg
LD50 (Mouse): 2,240 mg/kg
Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity: Remarks: No data available

Acute dermal toxicity: Remarks: No data available

Acute toxicity (other routes of administration): LD50 (Rat): 4,840 mg/kg
Application Route: Intramuscular
LD50 (Mouse): 3,500 mg/kg
Application Route: Subcutaneous

**Propylene glycol:**

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rabbit): > 159 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

**Magnesium oxide:**

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rabbit): > 2.1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Acute oral toxicity: LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of administration):  
LD50 (Rat): 97 - 161 mg/kg  
Application Route: Intravenous

LD50 (Mouse): 92 - 147 mg/kg  
Application Route: Intravenous

**Sodium hydroxymethanesulphinate:**
Acute oral toxicity:  
LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

Acute dermal toxicity:  
LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials

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

**Components:**

**2-Pyrrolidone:**
Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation

**oxytetracycline:**
Remarks: No data available

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

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
Result: irritating

**Sodium hydroxymethanesulphinate:**
Species: Rat  
Result: No skin irritation  
Remarks: Based on data from similar materials

**Serious eye damage/eye irritation:**
Causes serious eye irritation.

**Components:**

**2-Pyrrolidone:**
Species: Rabbit
Result : Irritation to eyes, reversing within 7 days

oxytetracycline:
Remarks : No data available

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

Magnesium oxide:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Result : Mild eye irritation

Sodium hydroxymethanesulphinate:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

2-Pyrrolidone:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

oxytetracycline:
Test Type : Human repeat insult patch test (HRIPT)
Result : Sensitiser

Propylene glycol:
Test Type : Maximisation Test
Exposure routes : Skin contact
## SAFETY DATA SHEET

### Oxytetracycline / Diclofenac 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>
<tbody>
<tr>
<td>5.1</td>
<td>2020/10/10</td>
<td>4156032-00008</td>
<td>2020/03/23</td>
<td>2019/04/17</td>
</tr>
</tbody>
</table>

**Species:** Guinea pig  
**Result:** negative

### Magnesium oxide:

- **Test Type:** Maximisation Test  
- **Exposure routes:** Skin contact  
- **Species:** Guinea pig  
- **Method:** OECD Test Guideline 406  
- **Result:** negative  
- **Remarks:** Based on data from similar materials

### Sodium hydroxymethanesulphinate:

- **Test Type:** Maximisation Test  
- **Exposure routes:** Skin contact  
- **Species:** Guinea pig  
- **Method:** OECD Test Guideline 406  
- **Result:** negative  
- **Remarks:** Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

- **Genotoxicity in vitro:**  
  - **Test Type:** Bacterial reverse mutation assay (AMES)  
  - Result: negative
  
  - **Test Type:** In vitro mammalian cell gene mutation test  
  - **Method:** OECD Test Guideline 476  
  - Result: negative  
  - **Remarks:** Based on data from similar materials

- **Genotoxicity in vivo:**  
  - **Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
  - **Species:** Mouse  
  - **Application Route:** Intraperitoneal injection  
  - **Method:** OECD Test Guideline 474  
  - Result: negative

#### Oxytetracycline:

- **Genotoxicity in vitro:**  
  - **Test Type:** Microbial mutagenesis assay (Ames test)  
  - Result: negative

  - **Test Type:** Mouse Lymphoma  
  - **Metabolic activation:** Metabolic activation  
  - Result: positive
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sister chromatid exchange assay</td>
<td>equivocal</td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
</tr>
<tr>
<td>Micronucleus test</td>
<td>equivocal</td>
</tr>
<tr>
<td>in vivo assay</td>
<td>negative</td>
</tr>
<tr>
<td>Mammalian erythrocyte micronucleus test</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

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

**Magnesium oxide:**
- **Genotoxicity in vitro:**
  - **Test Type:** Bacterial reverse mutation assay (AMES)
    - **Method:** OECD Test Guideline 471
    - **Result:** negative
    - **Remarks:** Based on data from similar materials

- **Chromosome aberration test in vitro**
  - **Method:** OECD Test Guideline 473
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

- **In vitro mammalian cell gene mutation test**
  - **Method:** OECD Test Guideline 476
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
- **Genotoxicity in vitro:**
  - **Test Type:** Bacterial reverse mutation assay (AMES)
    - **Result:** negative
  - **Test Type:** Mouse Lymphoma
    - **Result:** negative
Genotoxicity in vivo: Test Type: Chromosomal aberration
Species: CHO
Result: negative

Sodium hydroxymethanesulphinate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: positive
Remarks: Based on data from similar materials

Germ cell mutagenicity - Assessment: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity
Not classified based on available information.

Components:

2-Pyrrolidone:
Species: Mouse
Application Route: Ingestion
Exposure time: 18 month(s)
Result: negative
Remarks: Based on data from similar materials

Oxytetracycline:
Species: Mouse
Application Route: Oral
Exposure time: 104 weeks
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 103 weeks
Result: equivocal
Target Organs: Adrenal gland, Pituitary gland
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen
Propylene glycol:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Magnesium oxide:
Species: Mouse
Application Route: Ingestion
Exposure time: 96 weeks
Result: negative
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative
Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: negative

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

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

Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments. Clear evidence of adverse effects on development, based on animal experiments.

Oxytetracycline:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 18 mg/kg body weight
Result: No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported
Effects on foetal development:

- **Species**: Rat
- **Application Route**: Oral
- **Embryo-foetal toxicity**: LOAEL: 48 mg/kg body weight
- **Result**: Postimplantation loss, Skeletal malformations

- **Test Type**: Embryo-foetal development
- **Species**: Rat
- **Application Route**: Oral
- **General Toxicity Maternal**: LOAEL: 1,200 mg/kg body weight
- **Embryo-foetal toxicity**: NOAEL: 1,500 mg/kg body weight
- **Result**: No teratogenic effects
- **Remarks**: Maternal toxicity observed.

- **Test Type**: Embryo-foetal development
- **Species**: Mouse
- **Application Route**: Oral
- **General Toxicity Maternal**: LOAEL: 1,325 mg/kg body weight
- **Embryo-foetal toxicity**: NOAEL: 2,100 mg/kg body weight
- **Result**: No teratogenic effects
- **Remarks**: Maternal toxicity observed.

- **Test Type**: Embryo-foetal development
- **Species**: Rabbit
- **Application Route**: Intramuscular
- **Embryo-foetal toxicity**: LOAEL: 41.5 mg/kg body weight
- **Result**: Postimplantation loss, No foetal abnormalities

- **Test Type**: Embryo-foetal development
- **Species**: Dog
- **Application Route**: Intramuscular
- **Embryo-foetal toxicity**: LOAEL: 20.75 mg/kg body weight
- **Result**: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - Assessment:

- Positive evidence of adverse effects on development from human epidemiological studies.

**Propylene glycol:**

- **Effects on fertility**: Test Type: Three-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

**Magnesium oxide:**

- **Effects on fertility**: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - **Species**: Rat
  - **Application Route**: Ingestion
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

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</table>

Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

**Effects on foetal development:**
- **Test Type:** Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- **Species:** Rat
- **Application Route:** Ingestion
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
- **Effects on fertility:**
  - **Test Type:** Fertility
  - **Species:** Rat, male and female
  - **Application Route:** Oral
  - **Fertility:** NOAEL: 4 mg/kg body weight
  - **Result:** No effects on fertility

- **Effects on foetal development:**
  - **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** LOAEL: 1 mg/kg body weight
  - **Result:** Embryo-foetal toxicity, No teratogenic effects

  **Test Type:** Development
  - **Species:** Rabbit
  - **Application Route:** Oral
  - **Developmental Toxicity:** LOAEL: 5 mg/kg body weight
  - **Result:** Embryo-foetal toxicity, No teratogenic effects

**Reproductive toxicity - Assessment:**
- Suspected of damaging the unborn child.

**Sodium hydroxymethanesulphinate:**
- **Effects on fertility:**
  - **Test Type:** Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Method:** OECD Test Guideline 422
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

- **Effects on foetal development:**
  - **Test Type:** Embryo-foetal development
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Method:** OECD Test Guideline 414
  - **Result:** positive
  - **Remarks:** Based on data from similar materials

**Reproductive toxicity - Assessment:**
- Some evidence of adverse effects on development, based on animal experiments.
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Components:
Sodium [2-[2,6-dichlorophenyl]amino]phenyl]acetate:
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
2-Pyrrolidone:
Species: Rat
NOAEL: 207 mg/kg
Application Route: Ingestion
Exposure time: 3 Months
Method: OECD Test Guideline 408

oxytetracycline:
Species: Rat
LOAEL: 198 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

Species: Mouse
LOAEL: 7,990 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 125 mg/kg
LOAEL: 250 mg/kg
Application Route: Oral
Exposure time: 12 Months
Target Organs: Testis
Remarks: Significant toxicity observed in testing

Species: Rat
NOAEL: 40 mg/kg
LOAEL: 100 mg/kg
Application Route: Intraperitoneal
Exposure time: 14 Days
Target Organs: Kidney
Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Magnesium oxide:
Species: Rat
NOAEL: >= 1,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days
Method: OECD Test Guideline 407
Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Species: Rat
LOAEL: 0.25 mg/kg
Application Route: Oral
Exposure time: 98 w
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
Species: Dog
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 12 w
Target Organs: Blood
Species: Baboon
NOAEL: 0.5 mg/kg
LOAEL: 5 mg/kg
Application Route: Oral
Exposure time: 52 w
Target Organs: Gastrointestinal tract, Blood
Symptoms: constipation, Diarrhoea

Sodium hydroxymethanesulphonate:
Species: Rat
NOAEL: 600 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

oxytetracycline:
Ingestion: Symptoms: Gastrointestinal disturbance, tooth discoloration
Remarks: May cause birth defects.

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Ingestion: Symptoms: Abdominal pain, Diarrhoea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-Pyrrolidone:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Oxytetracycline:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 621 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

   EC50 (Daphnia magna (Water flea)): 669 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Anabaena): 0.032 mg/l
Exposure time: 72 h

   NOEC (Anabaena): 0.0031 mg/l
Exposure time: 72 h
M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 10
Toxicity to microorganisms:
- EC50: 17.9 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
- NOEC: 0.2 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
  - 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

**Magnesium oxide:**
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  - Exposure time: 96 h
  - Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates:
- EL50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants:
- EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials
Toxicity to microorganisms:
- EC50: > 100 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209
  - Remarks: Based on data from similar materials

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
### SAFETY DATA SHEET

**Oxytetracycline / Diclofenac 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>
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<td>5.1</td>
<td>2020/10/10</td>
<td>4156032-00008</td>
<td>2020/03/23</td>
<td>2019/04/17</td>
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</tbody>
</table>

#### Toxicity to fish

<table>
<thead>
<tr>
<th>Component</th>
<th>LC50 (Pimephales promelas (fathead minnow))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>166.6 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
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</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
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<tbody>
<tr>
<td></td>
<td>80.1 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
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</tbody>
</table>

#### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>71.9 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
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<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>49.2 mg/l</td>
<td>OECD Test Guideline 201</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>72 h</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.32 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
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#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
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</tbody>
</table>

#### Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Component</th>
<th>LC50 (Leuciscus idus (Golden orfe))</th>
<th>Exposure time:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 10,000 mg/l</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Component</th>
<th>ErC50 (Desmodesmus subspicatus (green algae))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>370 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
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<tr>
<td></td>
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</tbody>
</table>

#### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Danio rerio (zebra fish))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13.5 mg/l</td>
<td>35 d</td>
<td>OECD Test Guideline 210</td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time:</th>
<th>Method:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5.6 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
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<td></td>
</tr>
</tbody>
</table>

#### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50: &gt; 1,000 mg/l</th>
<th>Exposure time:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 h</td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Persistence and degradability

**Components:**

**2-Pyrrolidone:**
Biodegradability: Result: Readily biodegradable. Remarks: Based on data from similar materials

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

**Sodium hydroxymethanesulphinate:**

Bioaccumulative potential

**Components:**

**2-Pyrrolidone:**
Partition coefficient: n-octanol/water: log Pow: -0.71 Method: OECD Test Guideline 107

**Propylene glycol:**
Partition coefficient: n-octanol/water: log Pow: -1.07

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
Partition coefficient: n-octanol/water: log Pow: 4.51

Mobility in soil
No data available

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 han-
14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9

**IATA-DGR**
- **UN/ID No.**: UN 3082
- **Proper shipping name**: Environmentally hazardous substance, liquid, n.o.s. (oxytetracycline)
- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **Packing instruction (cargo aircraft)**: 964
- **Packing instruction (passenger aircraft)**: 964
- **Environmentally hazardous**: yes

**IMDG-Code**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxytetracycline)
- **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
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
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 : Noxious liquid substance(Category Z)
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
SAFETY DATA SHEET

Oxytetracycline / Diclofenac Formulation

Version 5.1
Revision Date: 2020/10/10
SDS Number: 4156032-00008
Date of last issue: 2020/03/23
Date of first issue: 2019/04/17

AuIC - 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 - Transport 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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

JP / EN