1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Prednisolone / Neomycin / Tetracycline 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

Skin sensitisation: Category 1
Reproductive toxicity: Category 1A
Effects on or via lactation

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.
H360D May damage the unborn child.
H362 May cause harm to breast-fed children.
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 dust.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: 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
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 explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>&gt;= 80 - &lt; 90</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 4.0
Revision Date: 2020/03/23
SDS Number: 407514-00012
Date of last issue: 2019/09/13
Date of first issue: 2016/01/07

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:
May cause an allergic skin reaction.
May damage the unborn child.
May cause harm to breast-fed children.
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)

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
Nitrogen oxides (NOx)
Chlorine compounds
Metal oxides
Sulphur 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.
6. ACCIDENTAL RELEASE MEASURES

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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. 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>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>TWA</td>
<td>1 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 0.1 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>64-75-5</td>
<td>TWA</td>
<td>0.5 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit 300 µg/100 cm²</td>
<td></td>
<td>Internal</td>
</tr>
</tbody>
</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 con-
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

<table>
<thead>
<tr>
<th>Personal protective equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory protection</td>
</tr>
<tr>
<td>Filter type</td>
</tr>
<tr>
<td>Hand protection Material</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
<tr>
<td>Eye protection</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Skin and body protection</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical state | powder |
| 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 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 |
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

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-octanol/water : Not applicable
Vapour pressure : Not applicable
Density and / or relative density
   Relative density : No data available
Density : No data available
Relative vapour density : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle characteristics
   Particle size : No data available

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

7 / 28
Ingestion

Eye contact

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

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**

- **Acute oral toxicity**
  - LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 420

- **Acute dermal toxicity**
  - LD50 (Rabbit): > 3,600 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity

**Magnesium stearate:**

- **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 dermal toxicity**
  - LD50 (Rabbit): > 2,000 mg/kg
  - Remarks: Based on data from similar materials

**Neomycin, sulfate (salt):**

- **Acute oral toxicity**
  - LD50 (Mouse): 2,880 mg/kg
  - LD50 (Rat): 2,750 mg/kg

- **Acute toxicity (other routes of administration)**
  - LD50 (Rat): 633 mg/kg
  - Application Route: Subcutaneous
  - LD50 (Mouse): 116 mg/kg
  - Application Route: Intraperitoneal
  - LD50 (Mouse): 27.6 mg/kg
  - Application Route: Intravenous
  - LD50 (Mouse): 275 mg/kg
  - Application Route: Subcutaneous

**Tetracycline hydrochloride:**

- **Acute oral toxicity**
  - LD50 (Rat): 6,443 mg/kg
  - LD50 (Mouse): 2,759 mg/kg

- **Acute toxicity (other routes of administration)**
  - LD50 (Rat): 128 mg/kg
  - Application Route: Intravenous
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

LD50 (Mouse): 157 mg/kg
Application Route: Intravenous

Prednisolone:
Acute oral toxicity : LD50 (Mouse): 1,680 mg/kg
LD50 (Rat): > 3,857 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available
Acute toxicity (other routes of administration) : LD50 (Rat): 147 mg/kg
Application Route: Subcutaneous
LD50 (Mouse): 767 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation
Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Magnesium stearate:
Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Neomycin, sulfate (salt):
Species : Rabbit
Result : Mild skin irritation

Tetracycline hydrochloride:
Remarks : No data available

Prednisolone:
Remarks : No data available

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

Paraffin waxes and Hydrocarbon waxes:
- **Species**: Rabbit
- **Result**: No eye irritation
- **Method**: OECD Test Guideline 405

Magnesium stearate:
- **Species**: Rabbit
- **Result**: No eye irritation
- **Remarks**: Based on data from similar materials

Neomycin, sulfate (salt):
- **Species**: Rabbit
- **Result**: No eye irritation

Tetracycline hydrochloride:
- **Remarks**: No data available

Prednisolone:
- **Remarks**: No data available

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:
- **Test Type**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Method**: OECD Test Guideline 406
- **Result**: negative

Magnesium stearate:
- **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

Neomycin, sulfate (salt):
- **Exposure routes**: Dermal
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Species : Humans
Result : positive

Tetracycline hydrochloride:
Remarks : No data available

Prednisolone:
Remarks : No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:
Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Result: negative

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

Magnesium stearate:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

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

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):
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 ovary cells
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: positive
<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: in vitro micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Cytogenetic assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous injection</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Tetracycline hydrochloride:</th>
<th>Test Type: Cytogenetic assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: Chinese hamster ovary cells</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tetracycline hydrochloride:</th>
<th>Test Type: sister chromatid exchange assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prednisolone:</th>
<th>Test Type: Mouse Lymphoma</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Prednisolone:</th>
<th>Test Type: Mouse Lymphoma</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Prednisolone:</th>
<th>Test Type: sister chromatid exchange assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: sister chromatid exchange assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Humans</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 4.0  Revision Date: 2020/03/23  SDS Number: 407514-00012  Date of last issue: 2019/09/13  Date of first issue: 2016/01/07

Exposure time: 2 Years
Result: negative

Neomycin, sulfate (salt):
Species: Rat
Exposure time: 2 Years
Result: negative

Tetracycline hydrochloride:
Species: Rat
Application Route: Oral
Exposure time: 103 W
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 103 W
Result: negative

Prednisolone:
Species: Rat
Application Route: Oral
Exposure time: 18 Months
Result: negative

Reproductive toxicity
May damage the unborn child.
May cause harm to breast-fed children.

Components:

Paraffin waxes and Hydrocarbon waxes:
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Magnesium stearate:
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
Prednisolone / Neomycin / Tetracycline Formulation

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
- Result: negative
- Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

Effects on fertility:
- Test Type: Three-generation reproduction toxicity study
- Species: Rat
- Application Route: Oral
- General Toxicity - Parent: NOAEL: 25 mg/kg body weight
- Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Oral
- Embryo-foetal toxicity: NOAEL: 275 mg/kg body weight
- Result: No adverse effects, No teratogenic effects
- Test Type: Development
- Species: Rat
- Application Route: Subcutaneous
- Developmental Toxicity: LOAEL: 6 mg/kg body weight
- Result: positive
- Reproductive toxicity assessment: Some evidence of adverse effects on development, based on animal experiments.

Tetracycline hydrochloride:

Effects on fertility:
- Test Type: Fertility
- Species: Rat
- Application Route: Oral
- Fertility: NOAEL: 400 mg/kg body weight
- Result: No effects on fertility

Effects on foetal development:
- Test Type: Development
- Result: Embryo-foetal toxicity, Specific developmental abnormalities, Skeletal malformations
- Reproductive toxicity assessment: Studies indicating a hazard to babies during the lactation period, May damage the unborn child.

Prednisolone:

Effects on fertility:
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Subcutaneous
### Fertility

- **NOAEL**: 1 mg/kg body weight
- **Result**: No effects on fertility

### Effects on foetal development

- **Test Type**: Embryo-foetal development
- **Species**: Mouse
- **Application Route**: Oral
- **Developmental Toxicity**: LOAEL: 0.5 mg/kg body weight
- **Result**: Malformations were observed, Cleft palate

- **Test Type**: Embryo-foetal development
- **Species**: Rat
- **Application Route**: Oral
- **Developmental Toxicity**: LOAEL: 30 mg/kg body weight
- **Result**: decreased blood formation

- **Species**: Rat
- **Application Route**: Subcutaneous
- **Developmental Toxicity**: NOAEL: 25 mg/kg body weight
- **Result**: No effects on foetal development

### 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

Not classified based on available information.

### Components:

**Paraffin waxes and Hydrocarbon waxes:**

- **Exposure routes**: Ingestion
- **Assessment**: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Neomycin, sulfate (salt):**

- **Target Organs**: Kidney, inner ear
- **Assessment**: May cause damage to organs through prolonged or repeated exposure.
- **Remarks**: Based on human experience.

**Tetracycline hydrochloride:**

- **Exposure routes**: Oral
- **Target Organs**: Gastrointestinal tract, Nervous system, Skin, Teeth
- **Assessment**: May cause damage to organs through prolonged or repeated exposure.

**Prednisolone:**

- **Target Organs**: Bone marrow, Adrenal gland, Liver
- **Assessment**: Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 90 Days
- **Method**: OECD Test Guideline 408

**Magnesium stearate:**
- **Species**: Rat
- **NOAEL**: > 100 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days
- **Remarks**: Based on data from similar materials

**Neomycin, sulfate (salt):**
- **Species**: Mouse
  - **LOAEL**: 30 mg/kg
- **Application Route**: Subcutaneous
- **Exposure time**: 14 d
- **Target Organs**: Kidney
- **Species**: Guinea pig
  - **NOAEL**: 50 mg/kg
  - **LOAEL**: 100 mg/kg
  - **Application Route**: Intramuscular
  - **Exposure time**: 30 - 60 Weeks
- **Target Organs**: ear
- **Species**: Guinea pig
  - **NOAEL**: 10 mg/kg
  - **Application Route**: Oral
  - **Exposure time**: 90 d
  - **Remarks**: No significant adverse effects were reported
- **Species**: Guinea pig
  - **LOAEL**: 100 mg/kg
  - **Application Route**: Subcutaneous
  - **Exposure time**: 34 d
- **Species**: Dog
  - **LOAEL**: 24 mg/kg
  - **Application Route**: Intramuscular
  - **Exposure time**: 30 d
  - **Target Organs**: Kidney
- **Species**: Rat
  - **LOAEL**: 25 mg/kg
**SAFETY DATA SHEET**

**Prednisolone / Neomycin / Tetracycline 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>4.0</td>
<td>2020/03/23</td>
<td>407514-00012</td>
<td>2019/09/13</td>
<td>2016/01/07</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Route</th>
<th>oral (feed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>84 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>ear</td>
</tr>
<tr>
<td>Symptoms</td>
<td>hearing loss</td>
</tr>
<tr>
<td>Remarks</td>
<td>mortality observed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>20 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

### Tetracycline hydrochloride:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>625 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1,250 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 W</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Reduced body weight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>3,750 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>7,500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 W</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Reduced body weight</td>
</tr>
</tbody>
</table>

### Prednisolone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.6 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>63 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>2.5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.
Components:

Tetracycline hydrochloride:
Not applicable

Experience with human exposure

Components:

Neomycin, sulfate (salt):
Skin contact:
Symptoms: Sensitisation
Remarks: May irritate skin.
Eye contact:
Remarks: May cause eye irritation.
Ingestion:
Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance

Tetracycline hydrochloride:
Ingestion:
Target Organs: Teeth
Symptoms: Gastrointestinal disturbance, Nausea, Vomiting, Diarrhoea, Liver effects, skin rash, central nervous system effects
Remarks: May cause sensitisation of susceptible persons.
May cause photosensitisation.
Based on Human Evidence

Prednisolone:
Ingestion:
Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Paraffin waxes and Hydrocarbon waxes:
Toxicity to fish:
LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
SAFETY DATA SHEET
Prednisolone / Neomycin / Tetracycline Formulation

Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

Magnesium stearate:

Toxicity to fish:
LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility
NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 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:
EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 72 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

LC50 (Americamysis): 39 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants:
EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1,000
M-Factor (Chronic aquatic toxicity): 10

Toxicity to microorganisms:
EC50 (Natural microorganism): 107.6 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

EC10 (Natural microorganism): 2.8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Tetracycline hydrochloride:

Toxicity to algae/aquatic plants:
EC50 (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l
Exposure time: 72 h

NOEC (Anabaena flos-aquae (cyanobacterium)): 2.5 mg/l
Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): 3.31 mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032 mg/l
Exposure time: 72 h

EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l
Exposure time: 7 d

M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 1

Toxicity to microorganisms:
EC50: 0.08 mg/l
Exposure time: 3 h
## Prednisolone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 85 mg/l</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>To daphnia and other aquatic invertebrates</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 160 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l</td>
<td>Exposure time: 7 d</td>
</tr>
</tbody>
</table>

## Neomycin, sulfate (salt):

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 72 mg/l</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>To daphnia and other aquatic invertebrates</td>
<td>Method: OECD Test Guideline 202</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Americamysis): 39 mg/l</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: US-EPA OPPTS 850.1035</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>To algae/aquatic plants</td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50 (Natural microorganism): 107.6 mg/l</th>
<th>Exposure time: 3 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Respiration inhibition</td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Prednisolone / Neomycin / Tetracycline Formulation**

<table>
<thead>
<tr>
<th>Method</th>
<th>OECD Test Guideline 209</th>
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</thead>
<tbody>
<tr>
<td>EC10</td>
<td>2.8 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 h</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Tetracycline hydrochloride:**

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 2.5 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 3.31 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l</td>
<td>Exposure time: 7 d</td>
</tr>
</tbody>
</table>

| M-Factor (Acute aquatic toxicity) | 10 |
| M-Factor (Chronic aquatic toxicity) | 1 |
| Toxicity to microorganisms | EC50: 0.08 mg/l |
| Exposure time | 3 h |
| Test Type | Respiration inhibition |
| Method | OECD Test Guideline 209 |

**Prednisolone:**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 85 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 160 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>7 d</td>
</tr>
</tbody>
</table>
Persistence and degradability

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 31%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301F
  - Remarks: Based on data from similar materials

**Magnesium stearate:**
- Biodegradability: Result: Not biodegradable
- Remarks: Based on data from similar materials

**Neomycin, sulfate (salt):**
- Biodegradability: Result: rapidly degradable
  - Biodegradation: 50%
  - Exposure time: 1.2 d
  - Method: OECD Test Guideline 314

**Bioaccumulative potential**

**Components:**

**Paraffin waxes and Hydrocarbon waxes:**
- Partition coefficient: n-octanol/water: log Pow: 5.3 - 6.7

**Magnesium stearate:**
- Partition coefficient: n-octanol/water: log Pow: > 4

**Neomycin, sulfate (salt):**
- Partition coefficient: n-octanol/water: log Pow: < -2

**Tetracycline hydrochloride:**
- Partition coefficient: n-octanol/water: log Pow: -1.37
  - pH: 7

**Prednisolone:**
- Partition coefficient: n-octanol/water: log Pow: 1.46

**Neomycin, sulfate (salt):**
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Partition coefficient: n-octanol/water

Tetracycline hydrochloride:
Partition coefficient: n-octanol/water: log Pow: < -2
pH: 7

Prednisolone:
Partition coefficient: n-octanol/water: log Pow: 1.46

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 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. (Neomycin, sulfate (salt), Tetracycline hydrochloride)

Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt), Tetracycline hydrochloride)

Class: 9
Packing group: III
Labels: Miscellaneous,
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version 4.0
Revision Date: 2020/03/23
SDS Number: 407514-00012
Date of last issue: 2019/09/13
Date of first issue: 2016/01/07

IMDG-CODE
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
                      (Neomycin, sulfate (salt), Tetracycline hydrochloride)
Class: 9
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
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

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
SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid paraffin</td>
<td>170</td>
<td>&gt;=80 - &lt;90</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid paraffin</td>
<td>170</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

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 Y)
 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
Sources of key data used to compile the Safety Data Sheet

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

Date format: yyyy/mm/dd

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

AICS - Australian Inventory of Chemical Substances; 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, Bioaccumu-
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