SAFETY DATA SHEET

Propentofylline Formulation

Version 3.2  Revision Date: 2021/04/09  SDS Number: 2929969-00009  Date of last issue: 2020/10/10  Date of first issue: 2018/06/25

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Propentofylline Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuka 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

Acute toxicity (Oral) : Category 4
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Systemic toxicity)

GHS label elements

Hazard pictograms : 
Signal word : Warning
Hazard statements : H302 Harmful if swallowed. H373 May cause damage to organs (Systemic toxicity) through prolonged or repeated exposure if swallowed.
Precautionary statements : Prevention:
P260 Do not breathe dust. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth. P314 Get medical advice/attention if you feel unwell.
Disposal:
P501 Dispose of contents/container to an approved waste
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disposal plant.

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 50 %

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propentofylline</td>
<td>55242-55-2</td>
<td>&gt;= 50 - &lt; 60</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td>8-98</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>1-468</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

If inhaled:
- If inhaled, remove to fresh air.
- Get medical attention if symptoms occur.

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

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

If swallowed:
- If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
- Get medical attention.
- Rinse mouth thoroughly with water.
- Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:
- Harmful if swallowed.
- May cause damage to organs through prolonged or repeated exposure if swallowed.
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders:
- First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:
- Treat symptomatically and supportively.
5. FIREFIGHTING MEASURES

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

**Unsuitable extinguishing media:**
- None known.

**Specific hazards during 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)

**Specific extinguishing methods:**
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:**
- Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions:**
- Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up:**
- Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage
Conditions for safe storage: Keep in properly labelled containers.
Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propentofylline</td>
<td>55242-55-2</td>
<td>TWA</td>
<td>1000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>OEL-M (Respirable dust)</td>
<td>0.5 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
</tbody>
</table>

Further information: Class 1 Dust
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<table>
<thead>
<tr>
<th></th>
<th>OEL-M (Total dust)</th>
<th>JP OEL JSOH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 mg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Further information: Class 1 Dust</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>TWA (Respirable particulate matter)</th>
<th>2 mg/m3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>JP OEL JSOH</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection Material: Chemical-resistant gloves

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

Skin and body protection: Work uniform or laboratory coat.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: 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 combustible dust concentrations in air during processing, handling or other means.

Flammability (liquids): Not applicable

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
flammability limit

Flash point : Not applicable
Decomposition temperature : No data available
pH : Not applicable
Evaporation rate : Not applicable
Auto-ignition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
Solubility(ies)
  Water solubility : No data available
  Solubility in other solvents : 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.
Molecular weight : Not applicable
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 combustible dust concentrations in air during processing, handling or other means.
  Can react with strong oxidizing agents.
Conditions to avoid : Heat, flames and sparks.
  Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition : No hazardous decomposition products are known.
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11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,880 mg/kg
Method: Calculation method

Components:
Propentofylline:
Acute oral toxicity: LD50 (Rat): 940 mg/kg
Symptoms: Breathing difficulties, Convulsions, Lachrymation
LD50 (Mouse): 780 mg/kg
LD50 (Rabbit): 405 mg/kg

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

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Talc:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

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

Components:
Talc:
Species: Rabbit
Result: No skin irritation

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

Components:
Starch:
Species: Rabbit
Result: No eye irritation
Talc:
Species : Rabbit
Result  : No eye irritation

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

Components:

Starch:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Talc:
Exposure routes : Skin contact
Species : Humans
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Talc:
Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative
Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Talc:
Species : Mouse
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Application Route: inhalation (dust/mist/fume)
Exposure time: 2 Years
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

Propentofylline:
Effects on foetal development:
Test Type: Development
Species: Mouse
Application Route: Ingestion
Developmental Toxicity: NOAEL: 500 mg/kg body weight
Result: No adverse effects

Test Type: Development
Species: Rabbit
Application Route: Ingestion
Developmental Toxicity: NOAEL: 150 mg/kg body weight
Result: No teratogenic effects

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Systemic toxicity) through prolonged or repeated exposure if swallowed.

Components:

Propentofylline:
Exposure routes: Oral
Assessment: May cause damage to organs through prolonged or repeated exposure.
Remarks: Based on human experience.

Repeated dose toxicity

Components:

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410
Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Propentofylline:
Ingestion:
  Target Organs: Blood
  Target Organs: Lungs
  Target Organs: Cardiovascular
  Target Organs: Gastro-intestinal system
  Symptoms: Gastrointestinal discomfort, Nausea
  Target Organs: Nervous system
  Symptoms: Dizziness, Headache

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propentofylline:
Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

Talc:
Toxicity to fish: LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
Exposure time: 24 h

Persistence and degradability
No data available

Bioaccumulative potential

Components:

Propentofylline:
Partition coefficient: n-octanol/water: log Pow: 1.540

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable
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**: Not regulated as a dangerous good
- **IATA-DGR**: Not regulated as a dangerous good
- **IMDG-Code**: Not regulated as a dangerous good

**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.

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

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable
1.6. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

IC50: Half maximal inhibitory concentration
LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
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
PTB: Persistent, Bioaccumulative and Toxic substance
PICCS: Philippines Inventory of Chemicals and Chemical Substances
(Q)SAR: (Quantitative) Structure Activity Relationship
SDAT: Self-Accelerating Decomposition Temperature
SDS: Safety Data Sheet
TCSI: Taiwan Chemical Substance Inventory
TDG: Transportation of Dangerous Goods
TSCA: Toxic Substances Control Act (United States)
UN: United Nations

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