1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Propentofylline Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
         Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

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

GHS label elements
Hazard pictograms : 
Signal word : Warning
Hazard statements : H302 Harmful if swallowed.
                  H373 May cause damage to organs 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
SAFETY DATA SHEET

Propentofylline Formulation

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
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Propentofylline</td>
<td>55242-55-2 &gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8 &gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Talc</td>
<td>14807-96-6 &lt; 10</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
3. SAFETY DATA SHEET

Propentofylline 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>1.8</td>
<td>2021/04/09</td>
<td>2929971-00009</td>
<td>2020/10/10</td>
<td>2018/06/25</td>
</tr>
</tbody>
</table>

**Unsuitable extinguishing media**

- Carbon dioxide (CO2)
- Dry chemical

**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

**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.
SAFETY DATA SHEET

Propentofylline Formulation

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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<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>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

<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>Talc</td>
<td>14807-96-6</td>
<td>NAB (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
<td></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 expo-
sure 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.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form combustible dust concentrations in air during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Propentofylline Formulation

Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : No data available
  Solubility in other solvents : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : Not applicable
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 products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Harmful if swallowed.
### Product:
**Acute oral toxicity**
- Acute toxicity estimate: 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

#### 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
- **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
### Talc:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mouse</td>
<td>Ingestion</td>
<td></td>
<td>500 mg/kg body weight</td>
<td>No adverse effects</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Ingestion</td>
<td></td>
<td>150 mg/kg body weight</td>
<td>No teratogenic effects</td>
</tr>
</tbody>
</table>

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure if swallowed.

### Components:

#### Propentofylline:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Assessment</th>
<th>Remarks</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Oral</td>
<td>Based on human experience.</td>
<td>Blood, Lungs, Cardiovascular, Gastro-intestinal system</td>
</tr>
</tbody>
</table>

#### Starch:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 2,000 mg/kg</td>
<td>Skin contact</td>
<td>28 Days</td>
<td>OECD Test Guideline 410</td>
</tr>
</tbody>
</table>

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Propentofylline:

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood, Lungs, Cardiovascular, Gastro-intestinal system</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Propentofylline Formulation

Version 1.8  Revision Date: 2021/04/09  SDS Number: 2929971-00009  Date of last issue: 2020/10/10
Date of first issue: 2018/06/25

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

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
Not regulated as a dangerous good
IATA-DGR
SAFETY DATA SHEET

Propentofylline Formulation

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
DSL : not determined
AICS : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd
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.

ID / EN