SAFETY DATA SHEET

Propentofylline Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Propentofylline Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 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 or doctor/physician 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 disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
SAFETY DATA SHEET

Propentofylline Formulation

May form combustible dust concentrations in air during processing, handling or other means.

SECTION 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>
</tr>
</thead>
<tbody>
<tr>
<td>Propentofylline</td>
<td>55242-55-2</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

SECTION 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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam
Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : 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.
SAFETY DATA SHEET

Propentofylline Formulation

Version 2.4
Revision Date: 10.10.2020
SDS Number: 2929968-00008
Date of last issue: 23.03.2020
Date of first issue: 25.06.2018

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

SECTION 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.

SECTION 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.

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.

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.

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

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

SECTION 8. EXPOSURE CONTROLS/PERSO NAL PROTECTION

Ingredients 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>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>VLE-CT (Respirable fraction)</td>
<td>2 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

Personal protective equipment

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

Filter type: 
Particulates type

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

Skin and body protection: Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: No data available
Odor: No data available
Odor Threshold: No data available
pH: Not applicable
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form combustible dust concentrations in air during processing, handling or other means.
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor 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-
SECTION 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.

SECTION 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 sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Starch:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Talc:
Routes of exposure : Skin contact
SAFETY DATA SHEET

Propentofylline Formulation

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 fetal 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 fetal development : Test Type: Embryo-fetal development
SAFETY DATA SHEET

Propentofylline Formulation

Species: Rat
Application Route: Ingestion
Result: negative

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:
Routes of exposure: 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

SECTION 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 : \( \text{LC50 (Brachydanio rerio (zebrafish))}: > 100,000 \text{ mg/l} \)
Exposure time: 24 h

**Persistence and degradability**
No data available

**Bioaccumulative potential**

**Components:**

**Propentofylline:**
Partition coefficient: \( n\text{-octanol/water} \)
\[ \log Pow: 1.540 \]

**Mobility in soil**
No data available

**Other adverse effects**
No data available

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**SECTION 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.

---

**SECTION 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.

**Domestic regulation**

**NOM-002-SCT**
Not regulated as a dangerous good

**Special precautions for user**
Not applicable
SAFETY DATA SHEET

Propentofylline Formulation

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

The ingredients of this product are reported in the following inventories:

- DSL: not determined
- AICS: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations:

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value
- NOM-010-STPS-2014 / VLE-CT: Short term exposure limit value

Additional abbreviations:

- AIIC: 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
- ICAO: International Civil Aviation Organization
- IECSC: Inventory of Existing Chemical Substances (Japan)
- IC50: Half maximal inhibitory concentration
- ICBO: International Civil Aviation 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
- 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
SAFETY DATA SHEET

Propentofylline Formulation

<table>
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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 - Transportation 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


Revision Date: 10.10.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8