SAFETY DATA SHEET

Propentofylline Formulation

Version 3.0 Revision Date: 04/04/2023 SDS Number: 2929964-00012 Date of last issue: 10/01/2022
Date of first issue: 06/25/2018

SECTION 1. IDENTIFICATION

Product name: Propentofylline Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. LincoIn Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust

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

GHS label elements
Hazard pictograms:

Signal Word: Warning

Hazard Statements:
If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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 doctor if you feel unwell. Rinse mouth.
P314 Get medical attention if you feel unwell.
Disposal:
P501 Dispose of contents and 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propentofylline</td>
<td>Chemical name: Propentofylline, CAS-No.: 55242-55-2, Concentration (% w/w): &gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Starch</td>
<td>Chemical name: Starch, CAS-No.: 9005-25-8, Concentration (% w/w): &gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Talc</td>
<td>Chemical name: Talc, CAS-No.: 14807-96-6, Concentration (% w/w): &gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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: Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
Harmful if swallowed.
May cause damage to organs through prolonged or repeated exposure if swallowed.

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

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.

Carbon oxides
Nitrogen oxides (NOx)

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.

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

Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

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.

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

Use only with adequate ventilation.

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 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/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
<th>Value type (Form of exposure): TWA (total dust)</th>
<th>Basis: OSHA Z-3</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>15 mg/m³</td>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>15 Million particles per cubic foot</td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td>Dust, nuisance dust and particulates</td>
<td>10 mg/m³</td>
<td>Value type (Form of exposure): PEL (Total dust)</td>
<td>Basis: CAL PEL</td>
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<tr>
<td></td>
<td>5 mg/m³</td>
<td>Value type (Form of exposure): PEL (respirable dust fraction)</td>
<td>Basis: CAL PEL</td>
</tr>
</tbody>
</table>

<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></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
</tbody>
</table>
TWA (total) 10 mg/m³  NIOSH REL
TWA (total dust) 15 mg/m³  OSHA Z-1
TWA (respirable fraction) 5 mg/m³  OSHA Z-1
Talc 14807-96-6 TWA (Dust) 20 Million particles per cubic foot  OSHA Z-3
TWA (Respirable) 2 mg/m³  NIOSH REL
TWA (Respirable particulate matter) 2 mg/m³  ACGIH

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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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

Hygiene measures: Work uniform or laboratory coat.
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
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-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

use of administrative controls.
Explosive properties: Not explosive

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

Molecular weight: Not applicable

Particle size: No data available

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
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.
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**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

**IARC**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**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
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, Lungs, Cardiovascular, Gastro-intestinal system
Symptoms: Gastrointestinal discomfort, Nausea, 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: 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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Acute toxicity (any route of exposure)
- Specific target organ toxicity (single or repeated exposure)

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Propentofylline 55242-55-2
- D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate 64044-51-5
- Starch 9005-25-8
- Polyvinyl pyrrolidone 9003-39-8
- Talc 14807-96-6

California List of Hazardous Substances
- Polyvinyl pyrrolidone 9003-39-8
- Talc 14807-96-6

California Permissible Exposure Limits for Chemical Contaminants
- Starch 9005-25-8
- Talc 14807-96-6

The ingredients of this product are reported in the following inventories:
- DSL: not determined
- AICS: not determined
- IECSC: not determined
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

HEALTH

FLAMMABILITY

PHYSICAL HAZARD

HMIS® IV:

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dues
ACGIH / TWA : 8-hour, time-weighted average
CAL PEL / PEL : Permissible exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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
SAFETY DATA SHEET

Propentofylline Formulation

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<tr>
<th>Version</th>
<th>Revision Date:</th>
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<tr>
<td>3.0</td>
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</tbody>
</table>

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/04/2023

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

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.

US / Z8