SAFETY DATA SHEET

Warfarin Formulation

Version: 2.1
Revision Date: 04/04/2023
SDS Number: 6111697-00009
Date of last issue: 10/01/2022
Date of first issue: 07/15/2020

SECTION 1. IDENTIFICATION

Product name: Warfarin Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln 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 Hazardous Products Regulations

Combustible dust: Category 1
Acute toxicity (Oral): Category 3
Acute toxicity (Inhalation): Category 2
Acute toxicity (Dermal): Category 4
Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure: Category 1 (Blood)

GHS label elements

Hazard pictograms:

Signal Word: Danger

Hazard Statements:
May form combustible dust concentrations in air.
H301 Toxic if swallowed.
H312 Harmful in contact with skin.
H330 Fatal if inhaled.
H360D May damage the unborn child.
H372 Causes damage to organs (Blood) through prolonged or repeated exposure.

Precautionary Statements:
Prevention:
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P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust, fume, gas, mist, vapors or spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
P284 Wear respiratory protection.

Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of soap and water. Call a doctor if you feel unwell.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER.
P308 + P313 IF exposed or concerned: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

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

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>White Vaseline</td>
<td>8009-03-8</td>
<td>91</td>
</tr>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>No data available</td>
<td>8002-74-2</td>
<td>5</td>
</tr>
<tr>
<td>Warfarin</td>
<td>2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenylbutyl)-</td>
<td>81-81-2</td>
<td>2</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>Paraffinum liquidum</td>
<td>8042-47-5</td>
<td>2</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES
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<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>
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<tr>
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<td>6111697-00009</td>
<td>10/01/2022</td>
<td>07/15/2020</td>
</tr>
</tbody>
</table>

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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

In case of skin contact: In case of contact, immediately flush skin with 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. Call a physician or poison control center immediately. 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. Toxic if swallowed. Harmful in contact with skin. Fatal if inhaled. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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: High volume water jet

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. Do not use a solid water stream as it may scatter and spread fire. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Sulfur oxides
Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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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:
Evacuate personnel to safe areas.
Only trained personnel should re-enter the area.
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:
Soak up with inert absorbent material.
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.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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:
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, fume, gas, mist, vapors or spray.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
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. 
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 locked up. 
Keep tightly closed. 
Keep in a cool, well-ventilated place. 
Store in accordance with the particular national regulations.

Materials to avoid: 
Do not store with the following product types: 
Strong oxidizing agents 
Self-reactive substances and mixtures 
Organic peroxides 
Flammable liquids 
Flammable solids 
Pyrophoric liquids 
Pyrophoric solids 
Self-heating substances and mixtures 
Substances and mixtures which in contact with water emit flammable gases 
Explosives 
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL 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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td></td>
<td>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td></td>
<td>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td></td>
<td>TWA (Fumes)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Warfarin</td>
<td>81-81-2</td>
<td>TWA</td>
<td>0.1 mg/m³</td>
<td>CA AB OEL</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Compound/Concentration</th>
<th>TWA</th>
<th>STEL</th>
<th>STEV</th>
<th>TWA (Inhalable particulate matter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil</td>
<td>0.1 mg/m³</td>
<td>0.1 mg/m³</td>
<td>100 ppm</td>
<td>0.01 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ACGIH</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 containment devices). Minimize open handling.

**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**

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**Eye protection**

**Skin and body protection**

**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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>paste</td>
</tr>
<tr>
<td>Color</td>
<td>pink</td>
</tr>
<tr>
<td>Odor</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</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>320 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>178 °C</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.</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>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>0.80 - 0.84</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>practically insoluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
</tbody>
</table>
Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
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. Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
Incompatible materials: 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
Toxic if swallowed.
Harmful in contact with skin.
Fatal if inhaled.

Product:
Acute oral toxicity: Acute toxicity estimate: 281 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: 0.25 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: 2,000 mg/kg
Method: Calculation method

Components:
Petrolatum:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

**Acute dermal toxicity**
- LD50 (Rat): > 2,000 mg/kg
- Method: OECD Test Guideline 402
- Assessment: The substance or mixture has no acute dermal toxicity
- Remarks: Based on data from similar materials

**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

**Warfarin:**

**Acute oral toxicity**
- LD50 (Rat): 5.62 mg/kg

**Acute inhalation toxicity**
- LC50 (Rat): > 0.001 - 0.005 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist

**Acute dermal toxicity**
- LD50 (Rat): 40 mg/kg

**White mineral oil (petroleum):**

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

**Acute inhalation toxicity**
- LC50 (Rat): > 5 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist
- Assessment: The substance or mixture has no acute inhalation toxicity

**Acute dermal toxicity**
- LD50 (Rabbit): > 2,000 mg/kg
- Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Petrolatum:**

- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation
- **Remarks:** Based on data from similar materials

**Paraffin waxes and Hydrocarbon waxes:**

- **Species:** Rabbit
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Method: OECD Test Guideline 404
Result: No skin irritation

**Warfarin:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**White mineral oil (petroleum):**
Species: Rabbit
Result: No skin irritation

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

**Components:**

**Petrolatum:**
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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

**Warfarin:**
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days

**White mineral oil (petroleum):**
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:**

**Petrolatum:**
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

**Paraffin waxes and Hydrocarbon waxes:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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

**White mineral oil (petroleum):**
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

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

**Components:**

**Petrolatum:**
Genotoxicity in vitro:
Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

**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

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### Genotoxicity in vitro
- **Test Type**: Bacterial reverse mutation assay (AMES)
  - Result: equivocal

- **Test Type**: In vitro mammalian cell gene mutation test
  - Result: equivocal

- **Test Type**: Chromosome aberration test in vitro
  - Result: equivocal

### Genotoxicity in vivo
- **Test Type**: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Result: negative

### White mineral oil (petroleum)
- **Genotoxicity in vitro**: Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

- **Genotoxicity in vivo**: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

### Carcinogenicity
Not classified based on available information.

### Components:

#### Petrolatum:
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 2 Years
- **Result**: negative

#### Paraffin waxes and Hydrocarbon waxes:
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 2 Years
- **Result**: negative

#### White mineral oil (petroleum):
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 24 Months
- **Result**: negative

### Reproductive toxicity
May damage the unborn child.
### Components:

**Petrolatum:**
- **Effects on fertility:**
  - Test Type: Reproduction/Developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

- **Effects on fetal development:**
  - Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative
  - Remarks: Based on data from similar materials

**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

- **Effects on fetal development:**
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative
  - Remarks: Based on data from similar materials

**Warfarin:**
- **Effects on fetal development:**
  - Test Type: Fertility/early embryonic development
  - Species: Humans, female
  - Application Route: Ingestion
  - Result: positive

**Reproductive toxicity - Assessment**
- Positive evidence of adverse effects on development from human epidemiological studies.

**White mineral oil (petroleum):**
- **Effects on fertility:**
  - Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative

- **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
Causes damage to organs (Blood) through prolonged or repeated exposure.

Components:

Paraffin waxes and Hydrocarbon waxes:
Routes of exposure : Ingestion
Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Warfarin:
Routes of exposure : Ingestion
Target Organs : Blood
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Petrolatum:
Species : Rat
NOAEL : 5,000 mg/kg
Application Route : Ingestion
Exposure time : 2 y

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

Warfarin:
Species : Rat
LOAEL : < 10 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

White mineral oil (petroleum):
Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
LOAEL : >= 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412
Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
   Exposure time: 96 h
   Test substance: Water Accommodated Fraction
   Method: OECD Test Guideline 203
   Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
   Exposure time: 48 h
   Test substance: Water Accommodated Fraction
   Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 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 daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 10 mg/l
   Exposure time: 21 d
   Test substance: Water Accommodated Fraction
   Remarks: Based on data from similar materials

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
   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
Warfarin Formulation

**Warfarin:**
- Toxidity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 105 mg/l
  Exposure time: 48 h
- Toxidity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 83.2 mg/l
  Exposure time: 72 h
- Toxidity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 2 mg/l
  Exposure time: 21 d
- Toxidity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.059 mg/l
  Exposure time: 21 d
- Toxidity to microorganisms: EC50 (Photobacterium phosphoreum): 67.5 mg/l
  Exposure time: 5 min

**White mineral oil (petroleum):**
- Toxidity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
- Toxidity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
- Toxidity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- Toxidity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
  Exposure time: 28 d
- Toxidity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 1,000 mg/l
  Exposure time: 21 d

**Persistence and degradability**

**Components:**

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

**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
Warfarin:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92.7 %
Exposure time: 28 d

White mineral oil (petroleum):
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Bioaccumulative potential

Components:

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

Warfarin:
Bioaccumulation: Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): <= 21.6
Partition coefficient: n-octanol/water
log Pow: 0.7

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
UN number: UN 2811
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S.
(Warfarin)
Class: 6.1
Packing group: II
Labels: 6.1
IATA-DGR

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SAFETY DATA SHEET

Warfarin Formulation

<table>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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UN/ID No. : UN 2811
Proper shipping name : Toxic solid, organic, n.o.s. (Warfarin)
Class : 6.1
Packing group : II
Labels : Toxic
Packing instruction (cargo aircraft) : 676
Packing instruction (passenger aircraft) : 669

IMDG-Code
UN number : UN 2811
Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S. (Warfarin)
Class : 6.1
Packing group : II
Labels : 6.1
EmS Code : F-A, S-A
Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
UN number : UN 2811
Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S. (Warfarin)
Class : 6.1
Packing group : II
Labels : 6.1
ERG Code : 154
Marine pollutant : no
Remarks : Display “inhalation hazard” mark on package in accordance with TDG 4.23.

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.

SECTION 15. REGULATORY INFORMATION

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

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<thead>
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<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
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SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH  : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL  : Canada. British Columbia OEL
CA QC OEL  : Quebec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA  : 8-hour, time-weighted average
CA AB OEL / TWA  : 8-hour Occupational exposure limit
CA AB OEL / STEL  : 15-minute occupational exposure limit
CA BC OEL / TWA  : 8-hour time weighted average
CA QC OEL / TWA  : Time-weighted average exposure value
CA QC OEL / STEV  : Short-term exposure value

All abbreviations:

ACGIH - 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; DSD - Domestic Substances List (Canada); ECx - Concentration 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 Organization 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, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 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; TG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; 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

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


Revision Date: 04/04/2023
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.

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