SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Warfarin 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>1.4</td>
<td>27.08.2021</td>
<td>6116626-00005</td>
<td>09.04.2021</td>
<td>15.07.2020</td>
</tr>
</tbody>
</table>

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Warfarin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
Kilsheelan
Clonmel Tipperary, IE
Telephone : 353-51-601000
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 3 : H301: Toxic if swallowed.
Acute toxicity, Category 2 : H330: Fatal if inhaled.
Acute toxicity, Category 4 : H312: Harmful in contact with skin.
Reproductive toxicity, Category 1A : H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1 : H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms : 🕰️ 🍓
Signal word : Danger
Hazard statements : 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 through prolonged or repeated exposure.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/ 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/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:
Warfarin

Additional Labelling
Restricted to professional users.

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin</td>
<td>81-81-2 201-377-6 607-056-00-0</td>
<td>Acute Tox. 2; H300 Acute Tox. 1; H330 Acute Tox. 1; H310</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>
## SECTION 4: First aid measures

### 4.1 Description of first aid measures

<table>
<thead>
<tr>
<th>General advice</th>
<th>Protection of first-aiders</th>
<th>If inhaled</th>
<th>In case of skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>: 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.</td>
<td>: 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).</td>
<td>: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.</td>
<td>: 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.</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
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 centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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.

Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

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. 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
Sulphur oxides
Nitrogen oxides (NOx)

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- 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).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Local/Total ventilation: 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, vapours 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents
  - 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

7.3 Specific end use(s)

Specific use(s):
- No data available
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>OELV - 8 hrs (TWA) (inhalable fraction)</td>
<td>5 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Paraffin waxes and Hydrocarbon waxes</td>
<td>8002-74-2</td>
<td>OELV - 8 hrs (TWA) (Fumes)</td>
<td>2 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 15 min (STEL) (Fumes)</td>
<td>6 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Warfarin</td>
<td>81-81-2</td>
<td>OELV - 8 hrs (TWA)</td>
<td>0.1 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Repr 1A - Substances which are known human reproductive toxicants</td>
<td>OELV - 15 min (STEL)</td>
<td>0.3 mg/m³</td>
<td>IE OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Further information: Repr 1A - Substances which are known human reproductive toxicants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>OELV - 8 hrs (TWA) (inhalable fraction)</td>
<td>5 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

**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**

**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.

**Hand protection**: Chemical-resistant gloves
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Remarks
Consider double gloving.

Skin and body protection
Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387
Filter type
Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: paste
Colour: pink
Odour: characteristic
Odour Threshold: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: 320 °C

Flammability (solid, gas): May form combustible dust concentrations in air.

Flammability (liquids): Not applicable

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: 178 °C

Auto-ignition temperature: No data available

Decomposition temperature: No data available

pH: No data available

Viscosity
Viscosity, kinematic: Not applicable

Solubility(ies)
Water solubility: practically insoluble

Partition coefficient: n-octanol/water: Not applicable

Vapour pressure: Not applicable
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Relative density : 0.80 - 0.84
Density : No data available
Relative vapour density : Not applicable
Particle characteristics
Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : Not applicable
Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form combustible dust concentrations in air. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
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:**

**Warfarin:**

- **Acute oral toxicity**
  
  - LD50 (Rat): 5.62 mg/kg  
  
  - Acute toxicity estimate: 5.62 mg/kg  
  - Method: Calculation method

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

- **Acute dermal toxicity**
  
  - LD50 (Rat): 40 mg/kg  
  
  - Acute toxicity estimate: 40 mg/kg  
  - Method: Calculation method

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Warfarin:**

- **Species**
  
  - Rabbit

- **Method**
  
  - OECD Test Guideline 404

- **Result**
  
  - No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Warfarin:**

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

### Respiratory or skin sensitisation

### Skin sensitisation
Not classified based on available information.

### Respiratory sensitisation
Not classified based on available information.

### Components:

#### Warfarin:
- **Test Type**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Result**: negative

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

### Components:

#### Warfarin:
- **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

### Carcinogenicity
Not classified based on available information.

### Reproductive toxicity
May damage the unborn child.

### Components:

#### Warfarin:
- **Effects on foetal 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.
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STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

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

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
- Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Components:
Warfarin:
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 105 mg/l
  Exposure time: 48 h
- Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 83.2 mg/l
  Exposure time: 72 h
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Toxicity to microorganisms: EC50 (Photobacterium phosphoreum): 67.5 mg/l
Exposure time: 5 min

Toxicity to fish (Chronic toxicity): NOEC: 2 mg/l
Exposure time: 21 d
Species: Oncorhynchus mykiss (rainbow trout)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.059 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

Components:

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

12.3 Bioaccumulative potential

Components:

Warfarin:
Bioaccumulation: Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): <= 21.6

Partition coefficient: n-octanol/water: log Pow: 0.7

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available
SECTION 13: Disposal considerations

13.1 Waste treatment methods

<table>
<thead>
<tr>
<th>Product</th>
<th>Waste treatment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</td>
<td></td>
</tr>
</tbody>
</table>

| 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

14.1 UN number or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 2811</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 2811</td>
</tr>
<tr>
<td>RID</td>
<td>UN 2811</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 2811</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 2811</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>TOXIC SOLID, ORGANIC, N.O.S. (Warfarin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>TOXIC SOLID, ORGANIC, N.O.S. (Warfarin)</td>
</tr>
<tr>
<td>RID</td>
<td>TOXIC SOLID, ORGANIC, N.O.S. (Warfarin)</td>
</tr>
<tr>
<td>IMDG</td>
<td>TOXIC SOLID, ORGANIC, N.O.S. (Warfarin)</td>
</tr>
<tr>
<td>IATA</td>
<td>Toxic solid, organic, n.o.s. (Warfarin)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>6.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>6.1</td>
</tr>
<tr>
<td>RID</td>
<td>6.1</td>
</tr>
<tr>
<td>IMDG</td>
<td>6.1</td>
</tr>
<tr>
<td>IATA</td>
<td>6.1</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
<th>Packing group II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Classification Code T2</td>
</tr>
</tbody>
</table>
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Hazard Identification Number : 60
Labels : 6.1

ADR
Packing group : II
Classification Code : T2
Hazard Identification Number : 60
Labels : 6.1
Tunnel restriction code : (D/E)

RID
Packing group : II
Classification Code : T2
Hazard Identification Number : 60
Labels : 6.1

IMDG
Packing group : II
Labels : 6.1
EmS Code : F-A, S-A

IATA (Cargo)
Packing instruction (cargo aircraft) : 676
Packing instruction (LQ) : Y644
Packing group : II
Labels : Toxic

IATA (Passenger)
Packing instruction (passenger aircraft) : 669
Packing instruction (LQ) : Y644
Packing group : II
Labels : Toxic

14.5 Environmental hazards

ADN
Environmentally hazardous : no

ADR
Environmentally hazardous : no

RID
Environmentally hazardous : no

IMDG
Marine pollutant : no

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.
SECTIONS 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Warfarin (Number on list 30)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Warfarin

REACH - List of substances subject to authorisation (Annex XIV): Not applicable


<table>
<thead>
<tr>
<th>Acute Toxic</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>H2:</td>
<td>50 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

- H300: Fatal if swallowed.
- H310: Fatal in contact with skin.
- H319: Causes serious eye irritation.
- H330: Fatal if inhaled.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Warfarin Formulation

Version 1.4  Revision Date: 27.08.2021  SDS Number: 6116626-00005  Date of first issue: 15.07.2020  Date of last issue: 09.04.2021

H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H411: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Irrit.: Eye irritation
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL): Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Emergency and New Chemical Substances; Ecotoxicity; ECHA - European Chemicals Agency; EC - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information
Warfarin Formulation

Classification of the mixture:

<table>
<thead>
<tr>
<th>Acute Tox. 3</th>
<th>H301</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 2</td>
<td>H330</td>
</tr>
<tr>
<td>Acute Tox. 4</td>
<td>H312</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360D</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
</tbody>
</table>

Classification procedure:

Calculation method

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.

IE / EN