according to the Hazardous Products Regulations



# **Warfarin Formulation**

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#### **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 : 37 McCarville Street

Charlottetown, PE C1E 2A7

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.

according to the Hazardous Products Regulations



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Precautionary Statements : Prevention:

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

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
			20 100 #
Petrolatum	White Vaseline	8009-03-8	>= 80 - < 100 *
Paraffin waxes and Hydrocarbon waxes	Synthetic Wax	8002-74-2	>= 5 - < 10 *
Warfarin	2H-1- Benzopyran-2- one, 4-hydroxy- 3-(3-oxo-1- phenylbutyl)-	81-81-2	>= 1 - < 5 *
White mineral oil (pe-troleum)	Paraffinum liquidum	8042-47-5	>= 1 - < 5 *

\* Actual concentration or concentration range is withheld as a trade secret

according to the Hazardous Products Regulations



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**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.

> 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.

If in eyes, rinse well with water. In case of eye contact

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. Contact with dust can cause mechanical irritation or drying of

the skin. and effects, both acute and

Most important symptoms

delayed

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.

First Aid responders should pay attention to self-protection, Protection of first-aiders

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

**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

Exposure to combustion products may be a hazard to health.

according to the Hazardous Products Regulations



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Hazardous combustion prod- :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec-:

tive 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.

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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

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
Petrolatum	8009-03-8	TWA (Mist)	5 mg/m <sup>3</sup>	CA AB OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (Mist	5 mg/m³	CA QC OEL
		- Inhalable		
		dust)		
		TWA (Mist)	1 mg/m³	CA BC OEL
		TWA	5 mg/m³	ACGIH
		(Inhalable		
		particulate		

according to the Hazardous Products Regulations



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		matter)		
Paraffin waxes and	8002-74-2	TWA	2 mg/m³	CA AB OEL
Hydrocarbon waxes		(Fumes)		
		TWA	2 mg/m <sup>3</sup>	CA BC OEL
		(Fumes)	_	
		TWAEV	2 mg/m³	CA QC OEL
		(Fumes)		
		TWA	2 mg/m³	ACGIH
		(Fumes)		
Warfarin	81-81-2	TWA	0.1 mg/m <sup>3</sup>	CA AB OEL
		TWA	0.1 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (in-	0.01 mg/m <sup>3</sup>	CA QC OEL
		halable dust)		
		TWA	0.01 mg/m <sup>3</sup>	ACGIH
		(Inhalable		
		particulate		
		matter)		
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	CA AB OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (Mist	5 mg/m³	CA QC OEL
		- Inhalable		
		dust)		
		TWA (Mist)	1 mg/m³	CA BC OEL
		TWA	5 mg/m³	ACGIH
		(Inhalable		
		particulate		
		matter)		

**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. Combined particulates and organic vapor type

Filter type

Hand protection

Material

: Chemical-resistant gloves

Remarks : Consider double gloving.

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.

according to the Hazardous Products Regulations



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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.

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**

Appearance : paste

Color : pink

Odor : characteristic

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

320 °C

Flash point : 178 °C

Evaporation rate : Not applicable

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

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : 0.80 - 0.84

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Density : No data available

Solubility(ies)

Water solubility : practically insoluble

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

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 reac- : May fo

tions

May form combustible dust concentrations in air.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous de

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:**

according to the Hazardous Products Regulations



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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 401

Remarks: The test was conducted according to guideline

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: The test was conducted according to guideline

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 inhala-

according to the Hazardous Products Regulations



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tion 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

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : The test was conducted according to guideline

#### 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

Remarks : The test was conducted equivalent or similar to guideline

according to the Hazardous Products Regulations



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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 Routes of exposure Species Test Type : Buehler Test : Skin contact : 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 (

: OECD Test Guideline 406: negative Method

Result

Remarks : The test was conducted according to guideline

Warfarin:

Test Type Routes of exposure : Maximization Test : 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:

according to the Hazardous Products Regulations



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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: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

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: The test was conducted according to guideline

Based on data from similar materials

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

according to the Hazardous Products Regulations



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Ш

### 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

Method : OECD Test Guideline 451

Result : negative

Remarks : The test was conducted equivalent or similar to guideline

# 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

according to the Hazardous Products Regulations



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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: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 416

Result: negative

Remarks: The test was conducted according to guideline

Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 414

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

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 - As-

sessment

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.

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#### **Components:**

#### Warfarin:

Routes of exposure : Ingestion Target Organs Blood

Assessment Shown to produce significant health effects in animals at con-

centrations 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

LOAEL > 100 mg/kg Application Route Ingestion Exposure time Method 90 Days

**OECD Test Guideline 408** 

The test was conducted according to guideline Remarks

Based on data from similar materials

Species Rat

LÖAEL > 25 mg/kg Application Route
Exposure time : Skin contact

: 2 y

Method : OECD Test Guideline 453

The test was conducted equivalent or similar to guideline Remarks

Based on data from similar materials

#### 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

according to the Hazardous Products Regulations



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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 (Chron-

ic 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

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Remarks: The test was conducted according to guideline

Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Remarks: The test was conducted equivalent or similar to

guideline

Based on data from similar materials

Toxicity to algae/aquatic : EL50 (Raphidocelis subcapitata (freshwater green alga)): >

according to the Hazardous Products Regulations



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plants 100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: The test was conducted according to guideline

Based on data from similar materials

NOELR (Raphidocelis subcapitata (freshwater green alga)): >

1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: The test was conducted according to guideline

Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOELR (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 21 d

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 211

Remarks: The test was conducted according to guideline

Based on data from similar materials

Toxicity to microorganisms NOEC: > 1 mg/l

Exposure time: 10 min

Remarks: Based on data from similar materials

Warfarin:

aquatic invertebrates

Toxicity to daphnia and other : 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

icity)

Toxicity to fish (Chronic tox- : NOEC (Oncorhynchus mykiss (rainbow trout)): 2 mg/l

Exposure time: 21 d

aquatic invertebrates (Chron-

ic toxicity)

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.059 mg/l

Exposure time: 21 d

EC50 (Photobacterium phosphoreum): 67.5 mg/l Toxicity to microorganisms

Exposure time: 5 min

White mineral oil (petroleum):

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic : NOEC (Pseudokirchneriella subcapitata (green algae)): 100

according to the Hazardous Products Regulations



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plants mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l

Exposure time: 28 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 1,000 mg/l

Exposure time: 21 d

### Persistence and degradability

#### **Components:**

#### Petrolatum:

Biodegradability Result: Not readily biodegradable.

Method: OECD Test Guideline 301F

Remarks: The test was conducted according to guideline

Based on data from similar materials

#### Paraffin waxes and Hydrocarbon waxes:

Biodegradability Result: Not readily biodegradable.

Method: OECD Test Guideline 301F

Remarks: The test was conducted according to guideline

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:**

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

according to the Hazardous Products Regulations



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#### Other adverse effects

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

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** 

**UN** number UN 2811

TOXIC SOLID, ORGANIC, N.O.S. Proper shipping name

(Warfarin)

Class 6.1 Packing group Ш Labels 6.1 Environmentally hazardous no

**IATA-DGR** 

UN/ID No. UN 2811

Toxic solid, organic, n.o.s. Proper shipping name

(Warfarin)

Class 6.1 Packing group Ш Labels Toxic Packing instruction (cargo 676

aircraft)

Packing instruction (passen-

ger aircraft)

669

**IMDG-Code** 

UN number UN 2811

Proper shipping name TOXIC SOLID, ORGANIC, N.O.S.

(Warfarin)

Class 6.1 Packing group Ш Labels 6.1 **EmS Code** F-A, S-A Marine pollutant

#### 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

TOXIC SOLID, ORGANIC, N.O.S. Proper shipping name

according to the Hazardous Products Regulations



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(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:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne 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 / TWAEV : Time-weighted average exposure value

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; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemi-

according to the Hazardous Products Regulations



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cal Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime 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 (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; TDG - 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

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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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.

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