SAFETY DATA SHEET

1. Identification

Product identifier **Warfarin**

Other means of identification

Catalog number 1719000

CAS number 81-81-2

Chemical name 2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenylbutyl)-

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 1
Acute toxicity, dermal	Category 1
Acute toxicity, inhalation	Category 1
Reproductive toxicity	Category 1A
Specific target organ toxicity, repeated exposure	Category 1

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing. In case of inadequate ventilation wear respiratory protection.

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If exposed: Immediately call a poison center/doctor.

Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Warfarin		81-81-2	100

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Call a physician or poison control center immediately. Wash contaminated clothing before reuse.
Eye contact	Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Call a physician or poison control center immediately.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	Bleeding. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of overdose may include the following: Ingestion of large amounts may require gastrointestinal decontamination. Administer charcoal as a slurry. If a large or chronic ingestion is suspected, or PT/INR are elevated, then vitamin K1 (phytonadione) may be given. Vitamin K1 may be administered orally in the absence of vomiting. With severe toxicity, parenteral dosing may be necessary. For patients presently on anticoagulants, AVOID induced vomiting and lavage due to possible trauma and subsequent bleeding. Get prothrombin time or INR immediately in patients that require anticoagulation. In patients with serious bleeding and coagulopathy, treat with fresh frozen plasma, parenteral vitamin K1, and packed red blood cells, as needed. Commercial Factor IX complex may also be given.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Material	Type	Value
Warfarin (CAS 81-81-2)	PEL	0.1 mg/m3

US. ACGIH Threshold Limit Values

Material	Type	Value	Form
Warfarin (CAS 81-81-2)	TWA	0.01 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Material	Type	Value
Warfarin (CAS 81-81-2)	TWA	0.1 mg/m3

Exposure limit values

Industrial Use

Material	Type	Value	Form
Warfarin (CAS 81-81-2)	TWA	0.002 mg/m3	Skin

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

US ACGIH Threshold Limit Values: Skin designation

Warfarin (CAS 81-81-2) Can be absorbed through the skin.

Appropriate engineering controls No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection	Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Crystals.
Color	White. Colorless.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	321.8 - 329 °F (161 - 165 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	1.35
Solubility(ies)	
Solubility (water)	Practically insoluble. 0.02 g/l
Solubility (other)	Acetone: Soluble. Alkaline solutions: Freely soluble. Ethanol: Moderately soluble. Isopropanol: Moderately soluble.
Partition coefficient (n-octanol/water)	2.7 0.7 (pH 7; 30 - 36 °C)
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Coumarin derivative.
Molecular formula	C19-H16-O4
Molecular weight	308.33 g/mol
pH in aqueous solution	5.6 (<0.2g/L)

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Strong acids. Strong bases.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Fatal if inhaled.
Skin contact	Fatal in contact with skin.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Fatal if swallowed. Based on information from therapeutic use, this material may cause: Anticoagulation.
Symptoms related to the physical, chemical, and toxicological characteristics	Bleeding or bruising. Pinpoint red spots on skin. Purple toes or feet. Gastrointestinal disturbances. Fever. Chills. Weakness. Dizziness. Shortness of breath. Lower back or side pain. Decreased urination.

Information on toxicological effects

Acute toxicity Fatal if inhaled. Fatal in contact with skin. Fatal if swallowed.

Product	Species	Test Results
Warfarin (CAS 81-81-2)		
Acute		
Dermal		
LD50	Rat	40 mg/kg
Inhalation		
LC50	Rat	< 0.005 mg/l, 255 minutes
		320 mg/m3
Oral		
LD50	Rat	5.6 mg/kg
		1.6 mg/kg
		0.77 mg/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Local effects

Eye irritation
Result: Negative.
Species: Rabbit
Skin irritation
Result: Negative.
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization	Knowledge about health hazard is incomplete.
Skin sensitization	Based on available data, the classification criteria are not met.

Sensitization
Result: Negative.
Species: Guinea pig
Organ: Skin.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Mutagenicity, Tests in cultured bacterial cells
Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity May damage fertility or the unborn child. Birth defects, mental retardation, blindness, and other serious adverse effects on fetal development have been reported in infants born to mothers taking coumarin anticoagulants during pregnancy, especially during the first trimester. Also, fetal or neonatal hemorrhage, stillbirth, miscarriage, low birth weight, growth retardation, and increased risk of maternal hemorrhage during the second and third trimesters have been reported.

Reproductivity

Reproductivity, Fetal malformations and reduced embryo and fetal viability at doses below maternally toxic doses.
Result: Positive.

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity

Product		Species	Test Results
Warfarin (CAS 81-81-2)			
Aquatic			
Fish	LC50	Channel catfish (Ictalurus punctatus)	0.0281 - 0.042 mg/l, 96 hours
Acute			
Crustacea	EC50	Daphnia magna	69 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	85 mg/l, 96 hours
		Harlequinfish, red rasbora (Rasbora heteromorpha)	12 mg/l, 96 hours
		Rainbow Trout	65 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

0.7, (pH 7; 30 - 36 °C)
2.7

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

US RCRA Hazardous Waste P List: Reference

Warfarin (CAS 81-81-2) P001

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN3027
UN proper shipping name	Coumarin derivative pesticide, solid, toxic (Warfarin)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	I
Packaging exceptions	E5

IATA

UN number	UN3027
UN proper shipping name	Coumarin derivative pesticide, solid, toxic (Warfarin)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	I
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

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

DOT; IATA

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Warfarin (CAS 81-81-2) Listed.

SARA 304 Emergency release notification

Warfarin (CAS 81-81-2) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
Warfarin	81-81-2	100		500	10000

SARA 311/312 Hazardous chemical Yes

Classified hazard categories	Acute toxicity (any route of exposure) Reproductive toxicity Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
Warfarin	81-81-2	100

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Warfarin (CAS 81-81-2)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

California Proposition 65 - CRT: Listed date/Developmental toxin

Warfarin (CAS 81-81-2) Listed: July 1, 1987

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Warfarin (CAS 81-81-2)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	01-02-2007
Revision date	01-03-2019
Version #	06
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