SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: Warfarin Sodium Tablets USP, 1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg, 6mg, 7.5mg and 10mg

PRODUCT No.:
1mg – 51672-4027
2mg – 51672-4028
2.5mg – 51672-4029
3mg – 51672-4030
4mg – 51672-4031
5mg – 51672-4032
6mg – 51672-4033
7.5mg – 51672-4034
10mg – 51672-4035

Distributor: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA

Recommended Use: Warfarin sodium is a vitamin K antagonist indicated for:

- Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (1)
- Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement (1)
- Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction (1)

Restrictions on Use: Warfarin sodium has no direct effect on an established thrombus, nor does it reverse ischemic tissue damage

CONTRAINDICATIONS

- Pregnancy, except in women with mechanical heart valves (4)
- Hemorrhagic tendencies or blood dyscrasias

SUBSTANCE CLASS: Warfarin sodium is an anticoagulant that acts by inhibiting vitamin K-dependent coagulation

FORMULA: $C_{19}H_{15}NaO_4$

M.W.: 330.31

SECTION 2: HAZARD(S) IDENTIFICATION

Potential Health Effects This drug is in final solid dosage form for direct administration to the patient. Under normal handling conditions, this drug is not considered hazardous. For those circumstances where handling in the workplace may result in uncontrolled generation of dust, refer to the MSDS for the active ingredient(s).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Warfarin Sodium CAS#: 129-06-6
Inactive Ingredients:	All strengths contain: Anhydrous lactose, corn starch, and magnesium stearate
	1 mg: D&C Red No. 6 Barium Lake.
	2 mg: FD&C Blue No. 2 Aluminum Lake, FD&C Red No. 40 Aluminum Lake.
	2.5 mg: D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake.
	3 mg: D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Red No. 40 Aluminum Lake.
	4 mg: FD&C Blue No. 1 Aluminum Lake.
	5 mg: D&C Red No. 6 Barium Lake, D&C Yellow No. 10 Aluminum Lake.
	6 mg: D&C Yellow No.10 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake.
	7.5 mg: D&C Yellow No.10 Aluminum Lake.
	10 mg: Dye Free..

SECTION 4: FIRST-AID MEASURES

Eye:	In case of contact with dust of solid dosage form, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.
Skin:	In case of contact, immediately wash skin with soap and water. Wash contaminated clothing before reuse.
Ingestion:	If swallowed, immediately give 2 glasses of water and induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.
Inhalation:	If dust from the solid dosage form is inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SECTION 5: FIRE-FIGHTING MEASURES

Flash Point:	N/A
Extinguishing Media:	Use media appropriate for surrounding material.
Special Fire Fighting Procedures:	N/A

Unusual Fire And Explosion Hazards:	Not a fire or explosion hazard.
Hazardous Combustion Products:	N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental Precautions:	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods:	Wet down any dust to prevent generation of aerosols, if appropriate. Cover with suitable material.
Clean-up Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Use a HEPA vacuum or moisten materials to minimize dust generation during pick-up. Clean area with detergent and water after spill pick-up, if appropriate. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

SECTION 7: HANDLING AND STORAGE

HANDLING:	Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. When handling broken or crushed tablets or capsules, ensure worker exposure is below the recommended exposure limit. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
STORAGE:	Store at normal room temperature. Keep container tightly closed. Do not store or consume food, drink or tobacco in areas where they may be contaminated with this material.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls and Ventilation: Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 15 milligrams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling quantities from 15 milligrams to 1 kilogram, work in a standard laboratory using a fume hood, biological safety

cabinet(Class II, all types), or approved vented enclosure. Quantities exceeding 1 kilogram should be handled in a designated laboratory. A laminar flow/powder containment booth is recommended for handling >1 kilograms of active substance. For manufacturing and pilot plant operations, use direct coupling and closed transfer systems for all bulk transfers. Use dust tight valves as appropriate. HEPA filtration of local exhaust ventilation (LEV) is required.

Respiratory Protection: Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tightfitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.

Eye protection: Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.

Hand protection: Impervious nitrile, rubber and latex gloves are recommended (EN 420, EN 374). If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.

Skin and body protection: Wear a laboratory coat (EN 340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat(EN 340)or coverall of low permeability (EN 1149-1). For manufacturing operations, wear coverall of low permeability (EN 465/1149-1). For manufacturing operations, wear coverall of low permeability (EN 1149-1).

Hygiene: Wash hands and face before breaks and immediately after handling the product.

Environmental exposure controls: Prevent release to drains and waterways.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	N/A
Physical State (Liquid/Solid/Gas):	Solid
Specific Gravity (H_2O=1):	N/A
Evaporation Rate (Butyl Acetate=1):	N/A
Solubility:	Very soluble in water, freely soluble in alcohol, very slightly soluble in chloroform and ether.
Appearance:	*1mg* – Pink, flat beveled, capsule shaped tablet, scored and engraved "1" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *2mg* – Lavender flat beveled, capsule shaped tablet, scored and engraved "2" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *2.5mg* – Green, flat beveled, capsule shaped tablet, scored and engraved "2 1/2" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *3mg* – Tan, flat beveled, capsule shaped tablet, scored and engraved "3" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *4mg* – Blue, flat beveled, capsule shaped tablet, scored and engraved "4" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *5mg* – Peach, flat beveled, capsule shaped tablet, scored and engraved "5" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *6mg* – Teal, flat beveled, capsule shaped tablet, scored and engraved "6" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *7.5mg* – Yellow, flat beveled, capsule shaped tablet, scored and engraved "7 1/2" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side. *10mg* – White, flat beveled, capsule shaped tablet, scored and engraved "10" on one side, and engraved with "WARFARIN" on the top of "TARO" on the other side.

SECTION 10: STABILITY AND REACTIVITY

Stability

Chemical Stability:	Stable under recommended storage conditions. Material is light sensitive.
Conditions to avoid:	Light
Materials to avoid:	Strong acids and strong bases strong oxidizing agents, Acid chlorides, and, acid anhydrides
Hazardous decomposition Products:	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx), nitrogen oxides (NOx), sulphur compounds, trace aluminum, and, trace magnesium
Hazardous reactions:	None known.

Sensitivity to static discharge/Dust exp.

Summary Statements:	Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).

SECTION 11: TOXICOLOGICAL INFORMATION

Carcinogenicity Information
None of the components present in this material at concentrations equal to or greater than 0.1% are listed by the IARC, NTP, OSHA or ACGIH as a carcinogen.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity effects

Acute Toxicity to Fish

Warfarin Sodium
NOEC (Bluegill sunfish, 96 H) : 42 mg/l.
LC50 (Bluegill sunfish, 96 H) : 93 mg/l.

Acute Toxicity to Aquatic Invertebrates

Warfarin Sodium
NOEC (Daphnia magna (Water flea), 48 H) : 49 mg/l.
EC50 (20 - 25°C, 48 H) : 74 mg/l.

Toxicity to aquatic plants

Warfarin Sodium
NOEC (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae biomass, 10 Days) : 0.073 mg/l

NOEC (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae growth rate, 10 Days) : 0.34 mg/l
Minimum inhibitory concentration (MIC) (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae biomass, 10 Days) : 0.16 mg/l
Minimum inhibitory concentration (MIC) (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae growth rate, 10 Days) : 0.84 mg/l

Toxicity to microorganisms

Warfarin Sodium
EC50 (Bacteria, 15 Minute) : 192 mg/l
EC10 (Bacteria, 15 Minute) : 22 mg/l
Respiration inhibition, % inhibition (Activated Sludge, 0.5 H) : 400 mg/l, 24%

Mobility

Transport between environmental compartments

Warfarin Sodium
Low mobility in soil.

Persistence and degradability

Biodegradation

Warfarin Sodium
Anaerobic Biodegradation (56 Days) : According to the results of tests of biodegradability this product is not readily biodegradable.
Ready biodegradation (43 Days) : 12 % According to the results of tests of biodegradability this product is not readily biodegradable. Inherently biodegradable.

Stability in water

Warfarin Sodium
Hydrolysis (50 °C): Degree of hydrolysis - 5 Days (< 1 %); pH 5 pH 7 pH 9 Low level of hydrolysis at acidic and basic pH. Stable in water.

Bioaccumulative potential

Warfarin Sodium
Bioconcentration factor (BCF): 0.86 Does not bioaccumulate. Accumulation in aquatic organisms is unlikely.

PBT and vPvB Assessment: Not available

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Warfarin and its salts are regulated under RCRA (40 CFR section 261.33; 261 Appendix VIII) as P001 and U248 waste. Disposal of warfarin-containing material must be in accordance with the applicable Federal, state/provincial, and local regulations.

SECTION 14: TRANSPORT INFORMATION

This material does not constitute a hazard as defined by the US Department of Transportation provided the quantity of Warfarin Sodium does not exceed 100 lbs.

SECTION 15: REGULATORY INFORMATION

United States of America

313 Toxic Release Inventory. Listed Chemicals/Compounds: No components listed on the SARA 313 inventory.

TSCA Inventory: Not listed.

SECTION 16: OTHER INFORMATION

Contact: Taro Pharmaceuticals U.S.A., Inc., Regulatory Affairs Department
3 Skyline Drive, Hawthorne, NY 10532

Preparation and/or Revision Date: April 2016

D I S C L A I M E R

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.