

MATERIAL SAFETY DATA SHEET
FOR
JANTOVEN® WARFARIN SODIUM TABLETS

1. Identification

Product Name: JANTOVEN® WARFARIN SODIUM TABLETS
Synonyms: 1-(4'-Hydroxy-3'-coumarinyl)-1-phenyl-3-butanone;
 Coumadin; Warfarin Sodium Tablets
CAS Number: Not applicable for the mixture
Product Use: Used for anticoagulation therapy
Manufacturer/Supplier: Upsher-Smith Laboratories, Inc.
Address: 6701 Evenstad Drive, Maple Grove, MN 55369
General Information: 1 - (763)-315-2000; 1-(800)-654-2299
Emergency Contact: INFOTRAC 1-(800)-535-5053

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Acute Toxicity: Category 2 Eye Corrosion: Category 2B Skin Corrosion: Category 3 Skin Sensitization: Not available Carcinogenicity: Category 2 Reproductive/Developmental: Category 1A Target Organ Toxicity (Repeated): Category 2	Not classified	Not classified

GHS Label:

Symbols:	
<u>Hazard Statements</u> May cause bloody nose, bleeding gums May cause muscle and joint pain May cause hematomas of the arms, legs, buttocks, and/or joints May cause frank blood in the urine and feces May cause anorexia, nausea, vomiting, diarrhea or abdominal pain, pallor and fatigue caused by anemia May cause paralysis caused by intracranial hemorrhage. May cause blurry vision, eye pain, blindness, skin lesions and petechiae.	<u>Precautionary Statements</u> Do not eat, drink, or use tobacco products in areas where Warfarin or a solution containing Warfarin is handled, processed, or stored. Wear eye/face protection and protective gloves when handling this product. Do not allow contact with skin. Wash hands thoroughly after handling.

3. Composition / Information on Ingredients

Component	CAS Number	Weight %
Warfarin Sodium	81-81-2	0.5–1.5
Lactose Monohydrate	64044-51-5	92-93
Pregelatinized Starch	9005-25-8	< 1
Povidone	9003-39-8	< 1
Magnesium Stearate	557-04-0	< 1
FD&C Red #40 HT Aluminum Lake	7429-90-5	< 1
Brown #75 Iron Oxide	1309-37-1	< 1

4. First Aid Measures

Eye:	In case of eye contact, flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Seek medical attention immediately.
Skin:	In case of accidental skin contact, remove contaminated clothing. Flush area with large amounts of water for 15 minutes. Use soap if available. Seek medical attention immediately. Wash contaminated clothing before reuse.
Inhalation:	In the final form not a likely route of exposure. However, in case of inhalation, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult administer oxygen. Seek medical attention immediately.
Ingestion:	In case of accidental ingestion, give the victim several glasses of water to drink and then induce vomiting by having the victim touch the back of the throat with the finger or by giving syrup of ipecac as directed on the package. Do not force an unconscious or convulsing person to drink liquids or to vomit. Get medical help immediately.

5. Fire Fighting Measures

Suitable Extinguishing Media:	Use an appropriate media including water spray jet, dry powder, foam, carbon dioxide.
Firefighting Procedures:	Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.
Unusual Fire and Explosion Hazards	Contact of Warfarin Sodium in the liquid form with strong oxidizers may cause fires and explosions.

Combustion Products When heated to decomposition it emits toxic gases (such as carbon monoxide) and fumes may be released in a fire involving Warfarin Sodium.

6. Accidental Release Measures

Spill Response

Instructions:

The following spill response instructions only apply to bulk quantities of the material. Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Remove all sources of heat and ignition. Cover spill with absorbent material and collect for disposal. Ventilate the area and clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

7. Handling and Storage

General Handling

In a manufacturing setting or other situation where exposure to aerosols may occur appropriate personal protective equipment, including respiratory protection, must be worn. Use good personal hygiene – wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts and shoes and other items that cannot be decontaminated.

Keep away from heat and flame. Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools.

Storage

When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children. Protect from physical damage. Do not cut, grind, or weld on or near containers unless precautions are taken against these hazards.

8. Exposure Controls / Personal Protection

Exposure Limits

Component Name	HSC WEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	NIOSH REL
Warfarin Sodium	N.E.	0.1 mg/m ³	0.1 mg/m ³	N.E.
Pregelatinized Starch	10 mg/m ³	N.E.	N.E.	N.E.
FD&C Red #40 HT	N.E.	15 mg/m ³	2 mg/m ³	2 mg/m ³
Aluminum Lake				
Magnesium Stearate	N.E.	N.E.	10 mg/m ³	N.E.
Brown #75 Iron Oxide	N.E.	10 mg/m ³	5 mg/m ³	5 mg/m ³

Engineering Controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. Use explosion-proof ventilation equipment.

Personal Protective Equipment (PPE)

In a manufacturing setting, the following personal protective equipment requirements apply:

Eye Protection: Wear chemical safety goggles, safety glasses or face shield. Have eyewash stations available where eye contact can occur.

Skin Protection: Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

Respiratory Protection: If exposure limits are exceeded, approved respiratory protection should be worn. Powered air-purifying respirator with HEPA filters is appropriate.

9. Physical and Chemical Properties

Flash Point: N/A	Lower Flammability Limit: N/A
Autoignition Temperature: N/A	Upper Flammability Limit: N/A
Boiling Point: N/A	Specific Gravity: N/A
Melting Point: N/A	% Volatile: N/A
Vapor Pressure: N/A	Evaporation Rate (Water=1): N/A
Vapor Density: N/A	Viscosity: N/A
% Solubility in Water: N/A	Octanol/Water Partition Coefficient: N/A
Pour Point: N/A	pH: N/A
Molecular Formula: Mixture	Molecular Weight: Mixture

Odor/Appearance: Red (1mg); Brown (3mg)

10. Stability and Reactivity

Stability/Incompatibility: The mixture is stable. Incompatible with strong oxidizing agents.

11. Toxicology Information

Signs and Symptoms of Overexposure: Bloody nose; bleeding gums; muscle and joint pain; hematomas of the arms, legs, buttocks, and/or joints; frank blood in the urine and feces; anorexia; nausea; vomiting; diarrhea or abdominal pain; pallor and fatigue caused by anemia; paralysis caused by intracranial hemorrhage; blurry vision, eye pain, and blindness; skin lesions and petechiae.

Acute Effects: Bloody nose; bleeding gums; muscle and joint pain; hematomas of the arms, legs, buttocks, and/or joints; frank blood in the urine and feces; anorexia; nausea; vomiting; diarrhea or abdominal pain; pallor and fatigue caused by anemia; paralysis caused by intracranial hemorrhage; blurry vision, eye pain, and blindness; skin lesions and petechiae.

Eye Contact: May cause irritation. Avoid contact with eyes.

Skin Contact: This substance can cause poisoning by the dermal route of exposure.

Inhalation: In the final form, not a likely route of exposure. However, in case of inhalation, respiratory tract irritation may occur.

Ingestion: Readily absorbed in the gastrointestinal tract. May cause abdominal cramps, nausea, and vomiting.

Target Organ Effects: Acts on the liver to inhibit prothrombin formation, which interfered with blood clotting.

Chronic Effects: Will cause bloody nose; bleeding gums; muscle and joint pain; hematomas of the arms, legs, buttocks, and/or joints; frank blood in the urine and feces; anorexia; nausea; vomiting; diarrhea or abdominal pain; pallor and fatigue caused by anemia; paralysis caused by intracranial hemorrhage; blurry vision, eye pain, and blindness; skin lesions and petechiae.

Acute Toxicity Values:

Subcutaneous LD50 (rat) = 1600 ug/kg (for Warfarin)

12. Ecological Information

Ecological impact data has not been determined for this mixture.

13. Disposal Considerations

Disposal Procedure: Must dispose of in accordance with all local, state, and federal regulations.

14. Transportation Information

U. S. Department of Transportation (DOT)

Proper Shipping Name: Coumarin derivative pesticide, solid, toxic.

Hazard Class: 6.1

UN/NA Number: UN3027

Packing Group: III

Labels Required: Toxic Substance, Hazard Class 6.1

International Maritime Organization (MDG)

Proper Shipping Name: N/A

Hazard Class: N/A

UN/NA: N/A

Packing Group: N/A

Labels Required: N/A

15. Regulatory Information

U. S. Federal Regulations

Warfarin Sodium is regulated as a hazardous waste by the U.S. EPA (49CFR172)

Toxic Substance Control Act (TSCA): Warfarin Sodium is included on the TSCA inventory.

Clean Water Act (CWA): Warfarin Sodium is not listed in the Clean Water Act.

Clean Air Act (CAA): Warfarin Sodium is not listed under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

Warfarin Sodium is not listed under SARA.

State Regulations

California: This product contains the following chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm: Warfarin

Canadian Environmental Protection Act: None of the compounds in this mixture are listed on the Canadian Domestic Substances list (DSL).

Canadian Workplace Hazardous Materials Information System (WHMIS):

This product is not controlled by the WHMIS

European Inventory of Existing Chemicals (EINECS): Four components contained in this product (Warfarin sodium, lactose monohydrate, Pregelatinized starch, and Brown#75 Iron Oxide) are included on the European Inventory of Existing Commercial Chemical Substances.

EU Classification: T Toxic

EU Risk (R) and Safety (S) Phrases:

R61: May cause harm to the unborn child

R48/25: Toxic: danger of serious damage to health by prolonged exposure if swallowed.

R52/53: Harmful to aquatic organisms may cause long-term adverse effects in the aquatic environment.

S53: Avoid exposure - obtain special instructions before use.

S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible)

S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

16. Other Information

National Fire Protection Association (NFPA) Warnings

Health: 2	Flammability: 1	Reactivity: 0	Other: 0
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Creation Date:	07/08/2009	Revision Date:	N/A
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