

Material Safety Data Sheet

 MSDS Number:
 1102388

 Revision date:
 01/13/2010

 Print date:
 01/13/2010

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1102388

Product name: Dipyridamole Injection

Product Codes: NDC 10019-197-21, NDC 10019-197-01, NDC 10019-197-71, NDC 10019-197-02,

NDC 0641-2569-41, NDC 0641-2569-44, NDC 0641-1138-31, NDC 0641-1138-34,

NDC 0641-1139-31, NDC 0641-1139-39

Synonyms: None

Chemical Family:Coronary vasodilatorProduct Type:Regulated Prescription DrugContainer Information:10 mL single dose vials

Product Use: Pharmaceutical.

Supplier:

BAXTER HEALTHCARE CORPORATION

DEERFIELD, ILLINOIS 60015 (800) 422-9837 or (847) 948-4770

Emergency telephone number: PROSAR: USA (888) 990-0996 OUTSIDE USA (615)917-6114

CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Dipyridamole	0.5	None	None
58-32-2			
Tartaric Acid	<0.5	None	None
87-69-4			
Polyethylene Glycol	4-6	None	None
25322-68-3			
Water	>94	None	None
7732-18-5			

3. HAZARDS IDENTIFICATION

Emergency overview: CAUTION! Irritation potential to skin, eyes, and mucous membranes. Avoid skin

contact. Avoid eye contact. Wash thoroughly after handling.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions. May cause respiratrory tract

irritation.

Ingestion: Gastrointestinal effects (may include nausea, upset stomach, loss of appetite).

Cardiovascular effects (may include fluctuations in heart rate, changes in blood

pressure, chest pain). May irritate digestive tract.

HAZARDS IDENTIFICATION May cause irritation and/or allergic reactions. Skin contact: Eye contact: Irritating to eyes. FIRST AID MEASURES Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear. Skin contact: In case of contact, immediately flush skin with plenty of water. Wash contaminated skin with soap and water. Get medical attention if irritation develops. Do NOT induce vomiting unless directed to do so by medical personnel. Never give Ingestion: anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention Notes to physician: See patient package insert in shipping carton for complete information. FIRE FIGHTING MEASURES 5. Suitable extinguishing media: Use foam or all purpose dry chemicals to extinguish. Fire fighters should wear positive pressure self-contained Special protective equipment for firefighters: breathing apparatus (SCBA) and full turnout gear. Specific methods: No information available. Flash point: Not determined Autoignition temperature: Not available Flammable limits in air-lower (%): Not available Flammable limits in air-upper (%): Not available **ACCIDENTAL RELEASE MEASURES** Personal precautions: Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5). No information available. **Environmental precautions:** Methods for cleaning up: If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. 7. HANDLING AND STORAGE

Technical measures/precautions: Wash thoroughly after handling.

Storage:

7. HANDLING AND STORAGE

Technical Keep containers tightly closed in a cool, well-ventilated place. Store between 15°-

measures/Storage conditions: 25°C (59°-77°F). Avoid freezing.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Dipyridamole 58-32-2	None	None	None	None	None	None
Tartaric Acid 87-69-4	None	None	None	None	None	None
Polyethylene Glycol 25322-68-3	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: No special containment is required. Good general ventilation should be sufficient to

control airborne levels.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

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.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-

shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Appearance: Aqueous solution Color: Light yellow Odorless Odor: 2.2 - 3.2:Ha Not applicable Molecular weight: Not available. Boiling point/range: Not available. Melting point/range: Density: Not available. Not available. Vapor pressure: **Evaporation rate:** Not available. Solubility: Not available.

Partition coefficient (noctanol/water):

Not available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Viscosity: Not available. Wolatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Polymerization: Not applicable

Hazardous decomposition

products:

Not available.

Materials to avoid: Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s				
Dipyridamole	Oral LD50 Mouse = 2150 mg/kg				
58-32-2	Oral LD50 Rat = 8400 mg/kg				
	Oral LD50 Rabbit = 4250 mg/kg				
	Intravenous LD50 Rat = 195 mg/kg				
	Intravenous LD50 Mouse = 85 mg/kg				
Tartaric Acid	None				
87-69-4					
Polyethylene Glycol	Oral LD50 Rat = 28 gm/kg				
25322-68-3	Oral LD50 Mouse = 34 gm/kg				
	Dermal LD50 Rabbit >20 gm/kg				
Water	Oral LD50 Rat: >50000 mg/kg				
7732-18-5					

Acute toxicity: Gastrointestinal effects (may include nausea, upset stomach, loss of appetite).

Cardiovascular effects (may include cardiac death, myocardial infarction, ventricular fibrillation, increased heart rate, stroke, asystole (no contractions of the heart), sinus node arrest, depression, conduction block) Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision).

Chronic toxicity: No data is available on the product itself.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related

carcinogenic/tumorigenic effects based on animal data.

Mutagenic effects: Not mutagenic in a standard battery of genetic toxicological tests.

Reproductive toxicity: May impair fertility at high doses based on animal data. Not considered fetotoxic

based on animal data.

FDA Pregnancy Catagory B

12. ECOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data	
Dipyridamole 58-32-2	None.	None.	None.	None.	
Tartaric Acid 87-69-4	None.	None.	None.	None.	
Polyethylene Glycol 25322-68-3	None.	5000mg/LLC50Caras sius auratus24h	None.	100000mg/LEC50Photo bacterium phosphoreum15min	
Water 7732-18-5	None.	None.	None.	None.	

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused

products:

Waste disposal must be in accordance with appropriate Federal, State, and local

regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name:NoneUN Number:NoneDOT Packing Group:NoneDOT Hazard class:None

TDG (Canada):

TDG Proper shipping name:

TDG UN/NA Number:

None
TDG Packing Group:

None
TDG Hazard class:

None

ADR/RID:

ADR Official Transport Name:

ADR Proper shipping name:

ADR UN/NA number:

ADR Hazard Class:

None

None

ICAO / IATA:

IATA Proper shipping name:NoneIATA UN NUMBERNoneIATA Primary HazardNoneIATA Packing group:NoneICAO ERG Code:None

14. TRANSPORT INFORMATION

IMO / IMDG:

IMDG Proper Shipping Name:NoneIMDG Hazard Class and Division:NoneIMDG Packing Group:NoneIMDG Subsidiary Risks:None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List -

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS)

This product complies with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Dipyridamole	0.5	Not Listed	Not Listed	Not Listed	Not Listed
Tartaric Acid	<0.5	Not Listed	Not Listed	Not Listed	Not Listed
Polyethylene Glycol	4-6	Not Listed	Not Listed	Not Listed	Not Listed
Water	>94	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To -	Florida Right- to-Know		Massachusetts Right-to-Know		New Jersey Right-to- Know:
		Know:	Reporting List:	List:	List:	ŭ	
Dipyridamole	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Tartaric Acid	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Polyethylene Glycol	Not Listed	Present	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product does not comply with EINECS

Risk Phrases: Not determined

Safety Phrases:

Not Determined

16. OTHER INFORMATION

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:

Changes to Section 14. Additional product codes. Change to container information. Changes to Section 8. Changes to Section 11.

Additional information:

Not Available.

Prepared by: Technology Resources, Baxter Healthcare Corporation

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet: