

Dobutamine Hydrochloride Injection

ISSUED 07/01/98

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: Dobutamine Hydrochloride Injection / Dobutamine
Hydrochloride in 5% Dextrose Injection
List Number: 1241, 1242, 1243, 1244, 2025, 2344, 2345,
2346, 2347, 3724, 4729, 6130, 6131, 6132

MANUFACTURER: Hospital Products Division
Abbott Laboratories
Abbott Park, Illinois 60064

EMERGENCY TELEPHONE NUMBER: 1-847-937-7970
CHEMTREC TELEPHONE NUMBER: 1-800-424-9300

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME: Dobutamine Hydrochloride *
CAS/RTECS NUMBERS: 52663-81-7 / CZ9001000
OSHA-PEL 8HR TWA: N/L
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: N/L
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: N/A
LIMITS STEL: 500 mcg/m3 (Abbott Laboratories).
CEILING: N/A

* Hazardous per OSHA criteria.

3. HAZARDS INFORMATION

EMERGENCY OVERVIEW: In clinical use, this material is used as a cardiac
stimulant. Given by injection, the active ingredient is a potent
drug. It is an irritant/corrosive to the eyes. Target organs
include the cardiovascular system and eyes.

ROUTE(S) OF ENTRY: Skin: Unlikely
Inhalation: Unlikely

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3. HAZARDS INFORMATION, continued

Ingestion: Unlikely

INGESTION RATING: N/D

SKIN ABSORPTION RATING: N/D

INHALATION RATING: N/D

CORROSIVENESS RATING: N/D

SKIN CONTACT RATING: N/D

SKIN SENSITIZATION RATING: N/D

EYE CONTACT RATING: Possible irritant

TARGET ORGANS: Cardiovascular system, possibly eyes

CARCINOGENICITY RATING: NTP: N/L IARC: N/L OSHA: N/L

ACGIH: N/L

None

SIGNS AND SYMPTOMS: N/D. In clinical use dobutamine hydrochloride causes a marked increase in heart rate and systolic blood pressure. Adverse effects most often reported include nausea, headache, anginal pain, nonspecific chest pain, palpitations and shortness of breath. May also cause urinary urgency. Overdose can cause excessive alteration of blood pressure and rapid heart rate. Contact with the eyes may cause irritation.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: N/D. Data suggest pre-existing cardiovascular disease and eye lesions.

4. FIRST AID MEASURES

EYES: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring cardiovascular function, as necessary.

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4. FIRST AID MEASURES, continued

SKIN: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring cardiovascular function, as necessary.

INGESTION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring cardiovascular function, as necessary.

INHALATION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring cardiovascular function, as necessary.

5. FIRE FIGHTING PROCEDURES

FLASH POINT: Non-flammable

FLASH POINT METHOD: N/A

LOWER EXPLOSIVE LIMIT(%): N/D

UPPER EXPLOSIVE LIMIT(%): N/D

AUTOIGNITION TEMPERATURE: N/D

FIRE & EXPLOSION HAZARDS: N/D

EXTINGUISHING MEDIA: Use appropriate media for underlying cause of fire.

FIRE FIGHTING INSTRUCTIONS: Fire fighters should wear self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.

6. ACCIDENTAL RELEASE MEASURES

SPILL OR RELEASE PROCEDURES: N/D

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7. HANDLING AND STORAGE

HANDLING: Avoid excessive heat. Protect from freezing.

STORAGE: Store at controlled room temperature of 15-30 degrees C (59-86 degrees F).

SPECIAL PRECAUTIONS: Avoid excessive heat. Protect from freezing.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: No special provisions are required under normal use conditions.

RESPIRATORY PROTECTION: Respiratory protection is not needed under normal use conditions.

SKIN PROTECTION: If skin contact is likely, latex gloves are recommended.

EYE PROTECTION: Eye protection is not required during typical product use conditions. Eye protection is recommended, if eye contact is likely.

OTHER PROTECTION: N/D

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Clear, colorless to slight yellow solution

ODOR: Odorless

BOILING POINT: Water (approx.)

MELTING/FREEZING POINT: Water (approx.)

VAPOR PRESSURE (mm Hg): N/D

VAPOR DENSITY (Air=1): N/D

EVAPORATION RATE: N/D

BULK DENSITY: Water (approx.)/1.000 @ 25 deg. for 2344

SPECIFIC GRAVITY: N/D

SOLUBILITY: Water, dextrose solutions

pH: 2.5 - 5.5

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9. PHYSICAL AND CHEMICAL PROPERTIES, continued

VISCOSITY: Water (approx.)/1.05 cps @ 25 deg. for 2344

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable.

INCOMPATIBILITIES: Sodium Bicarbonate or any other strong alkaline solution.

HAZARDOUS DECOMPOSITION PRODUCTS: When heated to decomposition, it emits toxic fumes of NO_x and HCl.

HAZARDOUS POLYMERIZATION: N/D

11. TOXICOLOGICAL INFORMATION

ORAL TOXICITY: N/D. LD50 = 1324-2296 mg/kg in rats and mice for dobutamine hydrochloride.

DERMAL TOXICITY: N/D. LD50 > 2000 mg/kg in rabbits; mild redness and diarrhea were observed following a 24-hour exposure for dobutamine hydrochloride.

INHALATION TOXICITY: N/D

CORROSIVENESS: N/D

DERMAL IRRITATION: N/D. Dobutamine hydrochloride was non-irritating in a skin irritation test in rabbits.

OCULAR IRRITATION: N/D. Dobutamine hydrochloride was severely irritating and corrosive in an eye irritation test in rabbits.

DERMAL SENSITIZATION: N/D. Dobutamine hydrochloride was negative in the maximization assay in guinea pigs at challenge concentrations of 25 and 50% in petrolatum.

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11. TOXICOLOGICAL INFORMATION, continued

SPECIAL TARGET ORGAN EFFECTS: N/D. Dobutamine hydrochloride is a potent, selective cardiac stimulant enhancing the contractile force of the heart. Cardiac output is increased. Peripheral vasoconstriction occurs to a limited extent. It has a rapid rate of onset and generally a short duration of action because it is rapidly degraded in the body. May cause a rapid increase in heart rate and systolic blood pressure. Rats receiving extremely large dosages (70 mg/kg IV) exhibited some signs of embryo toxicity and altered neonatal development.

CARCINOGENICITY INFORMATION: N/D.

12. ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/D

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHODS: Dispose of in accordance with local, state and federal regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS: Not Regulated
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A

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14. TRANSPORTATION INFORMATION, continued

IATA/ICAO STATUS: Not Regulated

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

UN NUMBER: N/A

PACKING GROUP: N/A

REPORTABLE QUANTITY: N/A

IMO STATUS: Regulated

PROPER SHIPPING NAME: N/A

HAZARD CLASS: N/A

UN NUMBER: N/A

PACKING GROUP: N/A

REPORTABLE QUANTITY: N/A

FLASH POINT: Non-flammable

15. REGULATORY INFORMATION

TSCA STATUS: N/A

CERCLA STATUS: N/L

SARA STATUS: N/L

RCRA STATUS: N/L

PROP 65 (CA): N/L

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16. OTHER INFORMATION

LEGEND: N/A = Not Applicable
N/D = Not Determined
N/L = Not Listed
L = Listed
C = Ceiling
S = Short-term
(R) = Registered Trademark of Abbott Laboratories
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