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Hc #23

6972023

1PHARMACIA

Print Date: August 01, 2002
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Agent Id#: 57661

**** MATERIAL SAFETY DATA SHEET ****

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: CAVERJECT(R) IMPULSE SYSTEM
SYNONYMS: alprostadil for injection - impulse
0009-5181-01 - NDC NUMBER
0009-5182-01 - NDC NUMBER
MOLECULAR FORMULA: MIXTURE
USE: Human drug used for the treatment of erectile dysfunction.
MANUFACTURER/SUPPLIER: PHARMACIA & UPJOHN CO., A SUBSIDIARY OF PHARMACIA CORP.
7171 PORTAGE RD
KALAMAZOO, MI 49001-0199

TELEPHONE NUMBERS: (269) 833-5122 - (24 HOURS)
(800) 821-7000 - (8:00 a.m. - 4:30 p.m.)

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1
COMMON NAME: Lactose
% BY WEIGHT: < 90 %
CAS NUMBER: 63-42-3
EXPOSURE LIMIT(S): Not established.

INGREDIENT 2
COMMON NAME: Benzyl alcohol
% BY WEIGHT: 9 %
CAS NUMBER: 100-51-6
EXPOSURE LIMIT(S): Not established.

INGREDIENT 3
COMMON NAME: Alpha-cyclodextrin
% BY WEIGHT: 0.6 %
CAS NUMBER: 10016-20-3
EXPOSURE LIMIT(S): Not established.

INGREDIENT 4
COMMON NAME: Sodium citrate, dihydrate
% BY WEIGHT: 0.5 %
CAS NUMBER: 6132-04-3
EXPOSURE LIMIT(S): Not established.

INGREDIENT 5
COMMON NAME: Alprostadil
CHEMICAL NAME: (11alpha, 13e, 15s)-11,15-dihydroxy-9-oxoprost-13-en-1-oic aci
% BY WEIGHT: 0.02 - 0.04 %
CAS NUMBER: 745-65-3
EXPOSURE LIMIT(S):
PHARMACIA & UPJOHN EXPOSURE LIMIT-TWA: 0.5 UG/M3

EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

I-461551 C-000055/8101
I-482334 C-000055/8201

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3. HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, ingestion and inhalation.
EFFECTS OF OVEREXPOSURE: No adverse effects to persons handling this drug in a clinical setting are anticipated. This compound may cause skin or eye irritation and may be harmful if swallowed, inhaled or absorbed through the skin. Alprostadil (prostaglandin E1) is a potent vasodilator and stimulates smooth muscle contraction; side effects may include intense bronchospasm (particularly in asthmatic patients), gastrointestinal disturbances (vomiting and diarrhea) and adverse reproductive effects. Alprostadil may also cause inhibition of platelet coagulation, flushing, decrease in blood pressue and heart rate, increased bone formation, fever and possibly, difficult breathing
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Direct contact to this drug may be contraindicated during pregnancy, those with known or suspected bleeding disorders or people with asthma.

4. FIRST AID MEASURES

EYES: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical attention promptly.
SKIN: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician.
INHALATION: Move to fresh air. Provide general supportive care. Seek medical attention promptly.
INGESTION: Contact a physician or poison control center.

5. FIRE FIGHTING MEASURES

FLASH POINT: Nonflammable.
LOWER EXPLOSION LIMIT (LEL): Not applicable.
UPPER EXPLOSION LIMIT (UEL): Not applicable.
EXTINGUISHING MEDIA: Suitable extinguishing media: water, carbon dioxide (CO2) or dry chemical.
FIRE-FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full body protective equipment.
UNUSUAL FIRE OR EXPLOSION HAZARDS: None.
HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide, Carbon dioxide.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep product out of drains; prevent entry to surface water, groundwater and soil. Small spills should be absorbed with paper towels or appropriate media. Large spills can be vacuumed or scooped and placed in a suitable container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothes before reuse. Store in a cool, dry place and protect from light. Keep out of the reach of children.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required.
VENTILATION: Local exhaust.
PROTECTIVE GLOVES: Rubber.
EYE PROTECTION: Safety glasses with side shields.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: White powder (alprostadil). Disposable, single-dose, dual chamber syringe system. The system includes a glass cartridge which contains sterile, freeze-dried alprostadil in the front chamber and sterile bacteriostatic water for injection in the rear chamber.
MOLECULAR WEIGHT: Mixture.
SOLUBILITY IN WATER: Freely soluble.

10. STABILITY AND REACTIVITY

STABILITY: Stable.
PHYSICAL CONDITIONS TO AVOID: None.
INCOMPATIBILITY WITH OTHER MATERIALS: None.
HAZARDOUS DECOMPOSITION PRODUCTS: None.
HAZARDOUS POLYMERIZATION: Does not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES:
INTRAVENOUS LD50 (RAT): 19.2 mg/kg (alprostadil).
INTRAVENOUS LD50 (MOUSE): 21 mg/kg (alprostadil).
ORAL LD50 (RAT): 228 mg/kg (alprostadil).
ORAL LD50 (MOUSE): 186 mg/kg (alprostadil).
INTRAPERITONEAL LD50 (RAT): 24.9 mg/kg (alprostadil).
INTRAPERITONEAL LD50 (MOUSE): 19.8 mg/kg (alprostadil).
SUBCUTANEOUS LD50 (RAT): 18.6 mg/kg (alprostadil).
SUBCUTANEOUS LD50 (MOUSE): 26.4 mg/kg (alprostadil).
OTHER STUDIES:
GENOTOXICITY: Mutagenicity: The Ames assay, unscheduled DNA synthesis and the mammalian mutation assay (CHO/HGPRT) were all negative when tested with alprostadil.
REPRODUCTION/FERTILITY: When alprostadil was given to pregnant rats (between days 6 and 15 of gestation) at concentrations ranging from 1 to 6 mg/kg/day both dose-related maternal toxicity and adverse reproductive effects occurred. The adverse reproduction effects included a significant increase in fetal resorption and a decrease in the percentage of live fetuses.
CARCINOGENICITY: Ingredient(s) are not listed as carcinogenic by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE:
MOBILITY: The vapor pressure of alprostadil is presumed to be negligible (<10E-7 torr) because the compound occurs as a solid with a melting point in excess of 100 degrees C. A negligible vapor pressure means that the

PERSISTENCE/DEGRADABILITY: Alprostadil is anticipated to be rapidly biodegraded.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of in accordance with applicable international, national, state, and/or local waste disposal regulations.

14. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

15. OTHER INFORMATION

REVIEWED BY: Environment and Safety.

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16. LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.