

**1. CHEMICAL PRODUCT AND
COMPANY IDENTIFICATION**

COMMON NAME: DEPO-PROVERA® Contraceptive Injection

USE: Human drug indicated only for the prevention of pregnancy.

MANUFACTURER/SUPPLIER:

THE UPJOHN COMPANY

7171 PORTAGE RD.

KALAMAZOO, MI 49001-0199

TELEPHONE NUMBERS:

(616) 323-5122 (24 Hours)

(616) 323-7555 (8:00 AM – 4:30 PM)

**2. COMPOSITION/INFORMATION
ON INGREDIENTS****INGREDIENT 1**

COMMON NAME: Water.

% BY WEIGHT: <81%

CAS NUMBER: 7732-18-5

EXPOSURE LIMIT(S): Not established.

INGREDIENT 2

COMMON NAME: Medroxyprogesterone Acetate.

% BY WEIGHT: 15%

CAS NUMBER: 71-58-9

EXPOSURE LIMIT(S):

UPJOHN EXPOSURE LIMIT-TWA: 5 µg/m³

INGREDIENT 3

COMMON NAME: Carbowax™ Polyethylene Glycol 3350.

% BY WEIGHT: <3%

EXPOSURE LIMIT(S): Not established.

INGREDIENT 4

COMMON NAME: Non-hazardous Ingredient(s).

% BY WEIGHT: <1%

EXPOSURE LIMIT(S): Not established.

EXPOSURE LIMIT(S) FOR THE MATERIAL:

Not established.

3. HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, ingestion or inhalation.

EFFECTS OF OVEREXPOSURE: Adverse effects are not anticipated in persons handling this material in a clinical setting. Chronic (long-term) exposure to medroxyprogesterone acetate can cause adverse effects including: breakthrough bleeding, spotting, changes in cervical secretion and cervical erosion, amenorrhea, edema, weight gain or loss, cholestatic jaundice, discoloration of the skin, mental depression, and rarely, elevated body temperature or nausea. Breast tenderness or excessive flow of milk have occasionally occurred. Exposure of the male to medroxyprogesterone acetate resulted in reversible

3. HAZARDS IDENTIFICATION, Con't

decrease in sperm production and gynecomastia.

Adverse central nervous effects include: nervousness, insomnia, fatigue and dizziness have been reported; headaches are rarely observed. Thromboembolic disorders including thromboencephalitis and pulmonary embolism have been reported.

Medroxyprogesterone acetate does have the potential to cause teratogenic effects in pregnant females, with the greatest effects occurring in the first four months of pregnancy.

MEDICAL CONDITIONS AGGRAVATED BY

EXPOSURE: This compound is contraindicated in people with a known sensitivity to medroxyprogesterone acetate, a history or active case of thrombophlebitis, thromboembolic disorders, cerebral apoplexy, carcinoma of the breast, undiagnosed vaginal bleeding or pregnancy.

4. FIRST AID MEASURES

EYES: Flush with water for 15 minutes. Hold eyelids open to assure complete contact with water.

SKIN: Wash with soap and water. Remove contaminated clothing.

INHALATION: Remove from exposure.

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: Water, carbon dioxide 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 out of drains; prevent entry to surface water, groundwater and soil. Small spills of the product can be absorbed with paper towels or other 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.

**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 to off-white suspension when mixed in 1-mL vial.
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:**

EYE IRRITATION (RABBIT): 100 mg—no irritation (medroxyprogesterone acetate).
SENSITIZATION: Hypersensitivity reactions include urticaria, pruritus, angioedema, generalized rash and anaphylaxis. Acne, alopecia or hirsutism are rare (medroxyprogesterone acetate).
INTRAVENOUS LD50 (MOUSE): 376 mg/kg (medroxyprogesterone acetate).
ORAL LD50 (DOG): >5g/kg (medroxyprogesterone acetate).
ORAL LD50 (RAT): >6.4 g/kg (medroxyprogesterone acetate); >50 g/kg (polyethylene glycol).
ORAL LD50 (MOUSE): >16 g/kg (medroxyprogesterone acetate).
INTRAPERITONEAL LD50 (RAT): >400 mg/kg (medroxyprogesterone acetate).
INTRAPERITONEAL LD50 (MOUSE): >400 mg/kg (medroxyprogesterone acetate).
SUBCUTANEOUS LD50 (RAT): >1 g/kg (medroxyprogesterone acetate).
SUBCUTANEOUS LD50 (MOUSE): >4 g/kg (medroxyprogesterone acetate).

OTHER STUDIES: Studies with medroxyprogesterone acetate: intramuscular injections in primates of concentrations up to 30 mg/kg/day showed no evidence of toxic or irritant effects. Other studies in the rat (24-month duration) and the mouse (18-month duration) with doses up to 200 mg/kg/month showed no evidence of toxic or tumorigenic responses. Intramuscular injections of medroxyprogesterone acetate in male dogs resulted in hormonal changes, reduced semen volume and dose-related repression of adrenal function. There was also some suggestion of prostatic epithelial atrophy, which was then followed by testicular interstitial hypertrophy.

**11. TOXICOLOGICAL INFORMATION,
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GENOTOXICITY: Medroxyprogesterone acetate tested by the Ames assay and micronucleus test showed no mutagenic potential.

TERATOGENICITY: Treatment of rats with intramuscular doses of up to 30 mg/kg/day of medroxyprogesterone acetate showed no teratogenic effects, but several animal studies have shown developmental abnormalities in the fetuses. Masculinization of the female fetus has reportedly occurred when progestin was used during pregnancy. Clitoral hypertrophy and fusion of the labia have been reported in female newborns and hypospadias (a congenital defect in the anterior urethra) in the male.

CARCINOGENICITY: Medroxyprogesterone acetate is listed by IARC as a Group 2B carcinogen (possibly carcinogenic to humans; IARC Monograph, supplement 7, 1987). A 10-year study of intramuscular injections of medroxyprogesterone acetate in primates (consisting of dosages up to 50 times the human therapeutic dose) showed expected hormonal effects, mammary nodular hyperplasia and endometrial carcinomas in a few of the test animals. There is no evidence that medroxyprogesterone acetate is carcinogenic in humans.

12. DISPOSAL CONSIDERATIONS

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

13. 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.

14. OTHER INFORMATION

REVIEWED BY: Health and Safety Regulatory Affairs.
DISCLAIMER: The MSDS information is believed to be correct but should only be used as a guide. The Upjohn Company disclaims any express or implied warranty as to the accuracy of the MSDS information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the information.

15. LABELING

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

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