

**1. CHEMICAL PRODUCT AND
COMPANY IDENTIFICATION**

COMMON NAME: DEPO-PROVERA® Sterile
Aqueous Suspension
USE: Human drug used in the treatment of female
reproductive disorders.
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: <58%
CAS NUMBER: 7732-18-5
EXPOSURE LIMIT(S): Not established.

INGREDIENT 2
COMMON NAME: Medroxyprogesterone Acetate.
% BY WEIGHT: 40%
CAS NUMBER: 71-58-9
EXPOSURE LIMIT(S):
UPJOHN EXPOSURE LIMIT-TWA: 5 µg/m³

INGREDIENT 3
COMMON NAME: Non-hazardous Ingredient.
% BY WEIGHT: <3%
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 people 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 a reversible
decrease in sperm production and gynecomastia.
Adverse central nervous system effects including:
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

3. HAZARDS IDENTIFICATION, Con't

have the potential to cause teratogenic effects in
pregnant females, with the greatest effects occurring
in the first 4 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: None.
USUAL 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 the product out of drains;
prevent entry to surface water, groundwater and soil.
Small spills should 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
clothing 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: Clear liquid in
2.5- and 10-mL vials.
MOLECULAR WEIGHT: Mixture.
SOLUBILITY IN WATER: 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.
INTRAVENOUS LD50 (MOUSE): 376 mg/kg
(medroxyprogesterone acetate).
ORAL LD50 (DOG): >5 g/kg (medroxyprogesterone
acetate).
ORAL LD50 (RAT): >6.4 g/kg (medroxyprogesterone
acetate).
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.

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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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