SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier

Product Name: Medroxyprogesterone Acetate Injectable Suspension

Synonyms: Medroxyprogesterone Acetate Injectable Suspension USP, 150mg/mL; Medroxyprogesterone Acetate Injection

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.

Robert J. Coury Global Center

1000 Mylan Blvd.

Canonsburg, PA 15317, USA

+1.724.514.1800

Contact e-mail: SDScontact@mylan.com

Emergency telephone number

Emergency Telephone: For Hazardous Materials Incident Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC (24 Hours) Worldwide: +1 703-741-5970

Other Contact Information

FDA Adverse Events Reporting Number: For reporting adverse health events call: +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician’s directions.

Classification

Carcinogenicity, Category 2
Reproductive toxicity, Category 1A

Label elements

Signal word:

Danger

Hazard statements:

H351 - Suspected of causing cancer
H360 - May damage fertility or the unborn child

Precautionary Statements - Prevention:

Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Medroxyprogesterone Acetate Injectable Suspension

Precautionary Statements - Response: IF exposed or concerned: Get medical advice/attention
Precautionary Statements - Storage: Store locked up
Precautionary Statements - Disposal: Dispose of contents/container to an approved waste disposal plant
Other Hazards
No information available.
Unknown acute toxicity
No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Mixture</th>
<th>Chemical name</th>
<th>CAS No.</th>
<th>Weight-%</th>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medroxyprogesterone Acetate</td>
<td>71-58-9</td>
<td>15%</td>
<td>H351 - Suspected of causing cancer  H360 - May damage fertility or the unborn child</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Description of first aid measures
Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.
General advice: Never give anything by mouth to an unconscious person, IF exposed or concerned: Get medical advice/attention, Show this safety data sheet to the doctor in attendance
Inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.
Skin contact: Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact: In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion: Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

Most important symptoms and effects, both acute and delayed
Symptoms: Menstrual irregularities, Headache, Increased body weight, Abdominal pain, and Anxiety.
Indication of any immediate medical attention and special treatment needed
Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE-FIGHTING MEASURES

Extinguishing media
Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media: None known.
Specific hazards arising from the chemical
Fire hazard: Not flammable.
Explosive hazard: Not an explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.
Hazardous combustion products: Carbon oxides.
Advice for firefighters
Precautionary measures in case of fire: Standard procedure for chemical fires.
Firefighting instructions: Use water spray or fog; do not use straight streams.
Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear
Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Personal precautions: Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

For non-emergency personnel
Personal Protective Equipment: Use personal protective equipment as required.
Emergency procedures: Evacuate personnel to safe areas.

For emergency responders
Personal Protective Equipment: Use personal protective equipment as required.
Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.
Other Information: Refer to protective measures listed in Sections 7 and 8.
Environmental precautions
Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up
Methods for containment: Prevent further leakage or spillage if safe to do so.
Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.
Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections
See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE
Precautions for safe handling
Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician’s directions.
Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities
Storage Conditions: Keep container upright. Keep containers tightly closed in a dry, cool and well-ventilated place. Store at room temperature. Keep at temperatures between 20 and 25 °C (68 and 77 °F). Store locked up.
Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Control parameters
Exposure Limits: No information available

Exposure controls
Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment
Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eye/face protection: Safety glasses with side shields are recommended for medical or industrial exposures.
Skin and body protection: Wear suitable protective clothing.
Respiratory protection: No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn.
General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES
Information on basic physical and chemical properties
Physical state: Liquid
Appearance: Suspension
Color: White to off-white
Odor: No data available
Odor threshold: No data available
pH: No data available
Melting point / freezing point: No data available
Boiling point / boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): No data available
Upper flammability limit: No data available
Lower flammability limit: No data available
Vapor pressure: No data available
Vapor density: No data available
Relative density: No data available
Water solubility: No data available
Solubility in other solvents: No data available
Partition coefficient: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
Kinematic viscosity: No data available
Dynamic viscosity: No data available
Explosive properties: No data available
Oxidizing properties: No data available
Other Information:
VOC Content (%): No data available

10. STABILITY AND REACTIVITY

Reactivity
Hazardous reactions will not occur under normal conditions.

Chemical stability
Stable under normal conditions.

Possibility of hazardous reactions
None under normal processing.

Conditions to avoid
Extremes of temperature and direct sunlight.

Incompatible materials
Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products
Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure
Inhalation: Specific test data for the substance or mixture is not available.
Ingestion: Specific test data for the substance or mixture is not available.
Eye contact: Specific test data for the substance or mixture is not available.
Skin contact: May be absorbed through the skin in harmful amounts.

Symptoms related to the physical, chemical and toxicological characteristics
Symptoms: Menstrual irregularities, Headache, Increased body weight, Abdominal pain, and Anxiety.

Delayed and immediate effects as well as chronic effects from short and long-term exposure
Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.
Respiratory or skin sensitization: Based on available data, the classification criteria are not met.
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Classification based on data available for ingredients. Contains a known or suspected carcinogen.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medroxyprogesterone Acetate (CAS #: 71-58-9)</td>
<td>-</td>
<td>Group 2B</td>
<td>-</td>
<td>X</td>
</tr>
</tbody>
</table>

Reproductive toxicity: Classification based on data available for ingredients. Contains a known or suspected reproductive toxin.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity
Acute toxicity: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity
The environmental impact of this product has not been fully investigated.

Persistence and degradability
No information available.

Bioaccumulation
No information available.

Mobility
No information available.

Other adverse effects
No information available.
13. DISPOSAL CONSIDERATIONS
Waste treatment methods.
Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

14. TRANSPORT INFORMATION
Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.
In accordance with DOT / ICAO / IATA / TDG:
UN Number
Not regulated
UN proper shipping name
Not regulated
Transport hazard class(es)
Hazard Class: Not regulated
Packing group
Not regulated
Environmental hazards
No
Special precautions for user
No information available
Transport in bulk according to Annex II of MARPOL and the IBC Code
Not applicable

15. REGULATORY INFORMATION
Safety, health and environmental regulations/legislation specific for the substance or mixture
International Regulations
Ozone-depleting substances (ODS): Not applicable
Persistent Organic Pollutants: Not applicable
The Rotterdam Convention: Not applicable
US Federal Regulations
SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.
CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).
CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.
US State Regulations
California Proposition 65: This product contains the following Proposition 65 chemicals.
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medroxyprogesterone Acetate (CAS #: 71-58-9)</td>
<td>Carcinogen</td>
</tr>
<tr>
<td></td>
<td>Developmental</td>
</tr>
</tbody>
</table>

US State Right-to-Know Regulations
US State Regulations: This product does not contain any substances regulated by state right-to-know regulations

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medroxyprogesterone Acetate (CAS #: 71-58-9)</td>
<td>-</td>
<td>X</td>
<td>-</td>
</tr>
</tbody>
</table>

Canada
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION
Revision Date: 24-August-2017
Data Sources: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard CFR 1912.1200.
Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.
Key or legend to abbreviations and acronyms used in the safety data sheet:
Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION
TWA: TWA (time-weighted average)
STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:
Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology
Phone number: 304-559-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer’s directions. 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 completeness of the information 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.

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