SECTION 1: IDENTIFICATION

Product Name: Progesterone Injection, USP
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
          Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: January 08, 2009
SDS Revision Date: June 01, 2015

SECTION 2: HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Reproductive toxicity. Category 1A.
Eye Irritation. Category 2.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility or the unborn child.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
If ON SKIN: Wash with plenty of water.
If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
If IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy
to do. Continue rinsing.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:
This product is intended for therapeutic use only when prescribed by a physician. Potential adverse
reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms:
Adverse reactions from therapeutic doses include: Breakthrough bleeding, spotting, change in
menstrual flow, amenorrhea, edema, change in weight, changes in cervical erosion and secretions,
cholestatic jaundice, breast tenderness, galactorrhea, skin sensitivity, acne, alopecia, hirsutism, rash,
anaphylactoid reactions, mental depression, pyrexia, insomnia, nausea, and somnolence. Occupational
exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Known sensitivity to progesterone, pregnancy, current or history of thrombophlebitis, thromboembolic
disorders, or cerebral apoplexy, liver dysfunction, known or suspected malignancy of breast or genital
organs, undiagnosed vaginal bleeding, and missed abortion.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS#</th>
<th>Ingredient Percent</th>
<th>EC Num.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone Injection, USP</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Progesterone
57-83-0
50 mg/mL

Benzyl Alcohol
100-51-6
10%

Sesame Oil
526-07-8
Quantity Sufficient

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

Lower Flammable/Explosive Limit: Not established.

Upper Flammable/Explosive Limit: Not established.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Storage: Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature].

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description: Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection Description: Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Respiratory Protection: No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e., an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.

Other Protective: Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid solution.</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless.</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not established.</td>
</tr>
<tr>
<td>Melting Point</td>
<td>126 - 131 °C</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble. in water.</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not established.</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not established.</td>
</tr>
<tr>
<td>Percent Volatile</td>
<td>Not established.</td>
</tr>
<tr>
<td>pH</td>
<td>Not established.</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
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<tr>
<td>Molecular Weight</td>
<td>314.47</td>
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<tr>
<td>Flash Point</td>
<td>Not established.</td>
</tr>
<tr>
<td>Flash Point Method</td>
<td>Not established.</td>
</tr>
<tr>
<td>Auto Ignition Temperature</td>
<td>Not established.</td>
</tr>
</tbody>
</table>

SECTION 10 : STABILITY and REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal temperatures and pressures.</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Not reported.</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No conditions contributing to instability are known to exist for normal handling of this product.</td>
</tr>
</tbody>
</table>

SECTION 11 : TOXICOLOGICAL INFORMATION

**Progesterone:**

NTP: Reasonably anticipated to be a human carcinogen.

Teratogenicity: Progesterone at high doses is an antifertility drug and high doses would be expected to impair fertility until the cessation of treatment. Progesterone is a progestational drug. Progesterone or progestosterone-like drugs have been used to prevent miscarriage in the first few months of pregnancy. There is an increased risk of minor birth defects in children whose mothers take this drug during the first 4 months of pregnancy. Several reports suggest an association between mothers who take these drugs in the first trimester of pregnancy and genital abnormalities in male and female babies. Avoid using the drug during the first trimester of pregnancy.

**Progesterone Injection, USP**

Fresenius Kabi USA, LLC

Revision: 06/01/2015
Other Toxicological Information:

- **Inhalation:**
  - **RTECS Number:**
  - **Lungs, Thorax, or Respiration:**
    - **RTECS:**
      - **LD50:** 1.5 mL/kg
      - **LDLo:** 1700 mg/kg
      - **LC50:** >500 mg/m3
      - **TDLo:** 1 mg/kg

- **Subcutaneous - Rabbit:**
  - **LD50:** 50 mg/kg
  - **LDLo:** 100 mg/kg
  - **LC50:** >500 mg/m3
  - **TDLo:** 1 mg/kg

- **Subcutaneous - Rat:**
  - **LD50:** 500 mg/kg
  - **TDLo:** 20 mg/kg
  - **TDLo:** 1 mg/kg

- **Intraperitoneal - Mouse:**
  - **LD50:** 93 mg/kg
  - **LDLo:** 100 mg/kg
  - **TDLo:** 1 mg/kg

- **Intraperitoneal - Rat:**
  - **LD50:** 53 mg/kg
  - **TDLo:** 1 mg/kg

- **Oral:**
  - **Mouse:**
    - **LD50:** 1360 mg/kg
    - **TDLo:** 1 mg/kg

- **Subcutaneous - Guinea pig:**
  - **TDLo:** 800 mg/kg

- **Standard Draize test:**
  - **LD50:** 200 mg/kg

- **Behavioral:**
  - **Ataxia**
  - **Somnolence (general depressed activity)**
  - **Behavioral - alteration of classical conditioning**
  - **Behavioral - general anesthetic**
  - **Behavioral - excitement**
  - **Behavioral - behavioral effects**
  - **Behavioral - change in sleep time**

- **Biochemical:**
  - **Metabolism (Intermediary) - enzymes**
  - **Metabolism (Intermediary) - enzymes**
  - **Metabolism (Intermediary) - enzymes**

- **Intraperitoneal - Rabbit:**
  - **TDLo:** 40 mg/kg
  - **TDLo:** 1 mg/kg/weeks

- **Intraperitoneal - Mouse:**
  - **TDLo:** 3 mg/kg/weeks

- **Intraperitoneal - Rat:**
  - **TDLo:** 3 mg/kg/weeks

- **Nervous System:**
  - **Behavioral - coma**
  - **Behavioral - altered sleep time**

- **Reproductive:**
  - **Fertility - pre-implantation mortality**
  - **Fertility - other measures of fertility**
  - **Fertility - sperm morphology**

- **Blood:**
  - **Changes in serum composition**

- **Appendages:**
  - **Tumors**

- **Inhibition:**
  - **Enzyme inhibition**

- **Genetic material:**
  - **Sperm morphology**

- **Immunotoxicity:**
  - **Immunosuppression**

- **Ecotoxicity:**
  - **No ecotoxicity data was found for the product.**

**SECTION 12 : ECOLOGICAL INFORMATION**
Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.
DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Progesterone:
TSCA Inventory Status: Listed
EINECS Number: 200-350-6
California PROP 65: Listed: cancer
Canada DSL: Listed

Benzyl Alcohol:
TSCA Inventory Status: Listed
EINECS Number: 202-859-9
Canada DSL: Listed
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.169(170)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:
SDS Creation Date: January 08, 2009
SDS Revision Date: June 01, 2015
SDS Format:
Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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