SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Chorionic Gonadotropin for 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 10, 2015
(M)SDS Format: 

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.
GHS Class:
Respiratory sensitisation. Category 1.
Reproductive toxicity. 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.
Suspected of damaging fertility or the unborn child.
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.
Do not breathe dust/fume/gas/mist/vapours/spray.
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 exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
IF skin irritation or rash occurs: 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 Skin Absorption. Injection.

Potential Health Effects:
Eye:
Contact with eyes may cause irritation.

Signs/Symptoms:
Adverse reactions from therapeutic doses include: headache, irritability, restlessness, depression,
fatigue, edema, precocious puberty, and gynecomastia. Occupational exposure has not been fully
investigated.

Aggravation of Pre-Existing Conditions:
Individuals with sensitivity to any component of chorionic gonadotropin, pre-existing skin and
respiratory conditions, and individuals with androgen-dependent neoplasms.

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>Chorionic Gonadotropin</td>
<td>9002-61-3</td>
<td>10,000 USP Units per vial</td>
<td></td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>100 mg per vial</td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>0.9 %</td>
<td></td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>Quantity Sufficient</td>
<td></td>
</tr>
</tbody>
</table>
### 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.

**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 dust. Use proper personal protective equipment as listed in Section 8.

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

**Methods for containment:**
This material will settle out of the air.

**Methods for cleanup:**
Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

### 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 dust, 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/nppt/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

- **Physical State**: Lyophilized powder
- **Color**: White to off-white
- **Boiling Point**: Not established
- **Melting Point**: Not established
- **Solubility**: Soluble in water
- **Vapor Density**: Not established
- **Vapor Pressure**: Not established
- **Percent Volatile**: Not established
- **pH**: 6-8
- **Molecular Formula**: Mixture
- **Molecular Weight**: Not established
- **Flash Point**: Not established
- **Flash Point Method**: Not established

SECTION 10: STABILITY AND REACTIVITY

- **Chemical Stability**: Stable under normal temperatures and pressures
- **Hazardous Polymerization**: Not reported
- **Incompatible Materials**: Avoid contact with strong oxidizing agents

SECTION 11: TOXICOLOGICAL INFORMATION

**Chorionic Gonadotropin**

- **RTECS Number**: MD6953000
- **Other Toxicological Information**:
  - Intravenous. - Rat TDLo: 8890 ug/kg [Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)]
  - Subcutaneous - Rat TDLo: 2000 units/kg [Vascular - measurement of regional blood flow Reproductive - Paternal Effects - testes, epididymis, sperm duct]
  - Subcutaneous - Mouse TDLo: 3798 units/kg/3D (intermittent) [Endocrine - estrogenic Related to Chronic Data - changes in ovarian weight Related to Chronic Data - changes in uterine weight]
  - Subcutaneous - Rat TDLo: 800 units/kg/4D (intermittent) [Endocrine - changes in gonadotropins Reproductive - Maternal Effects - oogenesis Related to Chronic Data - changes in ovarian weight]
  - Subcutaneous - Rat TDLo: 875 mg/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord)]
  - Subcutaneous - Rat TDLo: 1250 ug/kg [Reproductive - Maternal Effects - ovaries, fallopian tubes Reproductive - Maternal Effects - uterus, cervix, vagina]
  - Subcutaneous - Rat TDLo: 5250 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
  - Subcutaneous - Rat TDLo: 16 mg/kg [Reproductive - Paternal Effects - other effects on male]
  - Subcutaneous - Mouse TDLo: 560 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
  - Intraperitoneal. - Rat TDLo: 150 mg/kg [Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea) Reproductive - Fertility - other measures of fertility]
  - Intraperitoneal. - Rat TDLo: 40 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
  - Intraperitoneal. - Mouse TDLo: 24 mg/kg [Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)]
  - Intraperitoneal. - Mouse TDLo: 400 iu/kg [Reproductive - Maternal Effects - oogenesis]

**Mannitol**

- **RTECS Number**: OP2060000
- **Other Toxicological Information**:
  - Intravenous. - Rat LD50: 13500 mg/kg [Details of toxic effects not reported other than lethal dose value]
  - Oral - Mouse LD50: 22 gm/kg [Behavioral - Somnolence (general depressed activity); Gastrointestinal - Ulceration or bleeding from small intestine]

**Other Toxicological Information**:

Chorionic Gonadotropin for Injection, USP

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**Benzyl Alcohol**

**RTECS Number:** DN3150000

**Skin:**
- Administration onto the skin - Rabbit LD50: 2000 mg/kg [Details of toxic effects not reported other than lethal dose value]
- Administration onto the skin - Rabbit Standard Draize test.: 100 mg/24H

**Inhalation:**
- Inhalation - Mouse LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]  
- Inhalation - Rat LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]

**Ingestion:**
- Oral - Rat LD50: 1230 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Excitement Behavioral - Coma]  
- Oral - Mouse LD50: 1360 mg/kg [Details of toxic effects not reported other than lethal dose value]
- Oral - Mouse LD50: 1360 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]  
- Oral - Rat LD50: 1660 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]  
- Oral - Rat LD50: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value]

**Other Toxicological Information:**
- Intravenous. - Rat LD50: 53 mg/kg [Lungs, Thorax, or Respiration - dyspnea]  
- Intravenous. - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value]
- Subcutaneous - Rat LDLo: 1700 mg/kg [Sense Organs and Special Senses (Eye) - Miosis (pupillary constriction) Behavioral - coma Kidney/Ureter/Bladder - other changes]  
- Intraperitoneal. - Rat LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value]
- Intraperitoneal. - Mouse LD50: 650 mg/kg [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - dyspnea]  
- Intraperitoneal. - Rat LDLo: 650 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]  
- Intraperitoneal. - Rat TDLo: 514 mg/kg [Behavioral - ataxia]

**SECTION 12 : ECOLOGICAL INFORMATION**

Ecotoxicity: No ecotoxicity data was found for the product.

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**

**EINECS Number:** 232-660-2

**Mannitol:**

**TSCA Inventory Status:** Listed

**EINECS Number:** 200-711-8

**Canada DSL:** Listed

**Benzyl Alcohol:**

**TSCA Inventory Status:** Listed

**EINECS Number:** 202-859-9

**Canada DSL:** Listed

**Water for Injection:**

**TSCA Inventory Status:** Listed

**Canada DSL:** Listed

**SECTION 16 : ADDITIONAL INFORMATION**

**HMIS Ratings:**
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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