SAFETY DATA SHEET

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:	November 10, 2023

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.
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 IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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 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 Skin Absorption. Injection.

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

Chemical Name	CAS#	Ingredient Percent	EC Num.

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.
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

Personal 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

Physical State:	Liquid solution.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	126 - 131 °C
Solubility:	Insoluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	314.47
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Progesterone :

NTP:	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 progesterone-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 :

RTECS Number:	TW0175000
Skin:	Administration onto the skin - Rabbit TDLo: 500 ug/kg [Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)] Administration onto the skin - Rabbit TDLo: 1 mg/kg [Reproductive - Fertility - Other measures of fertility] Administration onto the skin - Rat TDLo: 240 mg/kg [Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands]
Ingestion:	LD50 Oral Rat: > 5000 mg/kg

Other Toxicological Information:

Intravenous. - Mouse LDLo: 100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Rabbit DNA damage: 100 ug/kg
Subcutaneous - Rat TDLo: 25 mg/kg [Reproductive - Maternal Effects - ovaries, fallopian tubes Biochemical - Metabolism (Intermediary) - other proteins]
Subcutaneous - Rat TDLo: 2500 ug/kg [Behavioral - changes in psychophysiological tests Reproductive - Fertility - mating performance (e.g. number sperm positive females per number females mated; number copulations per number estrus cycles)]
Subcutaneous - Rabbit TDLo: 0.15 mg/kg [Reproductive - Maternal Effects - uterus, cervix, vagina]
Subcutaneous - Rabbit TDLo: 1.3 mg/kg/5D (intermittent) [Endocrine - other changes Reproductive - Maternal Effects - uterus, cervix, vagina]
Subcutaneous - Mouse TDLo: 9 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Biochemical - Metabolism (Intermediary) - other proteins]
Subcutaneous - Mouse TDLo: 130.44 mg/kg/3D (intermittent) [Vascular - structural changes in vessels Reproductive - Maternal Effects - uterus, cervix, vagina]
Subcutaneous - Mouse Unscheduled DNA synthesis: 200 mg/kg
Subcutaneous - Mouse DNA inhibition: 200 mg/kg
Subcutaneous - Rat TDLo: 7 mg/kg [Reproductive - Fertility - abortion]
Subcutaneous - Rat TDLo: 188 mg/kg [Reproductive - Maternal Effects - menstrual cycle changes or disorders]
Subcutaneous - Rat TDLo: 420 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
Subcutaneous - Rat TDLo: 9 mg/kg [Reproductive - Specific Developmental Abnormalities - urogenital system]
Subcutaneous - Rat TDLo: 4 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System]
Subcutaneous - Rat TDLo: 1 mg/kg [Reproductive - Effects on Newborn - behavioral]
Subcutaneous - Rat TDLo: 500 ug/kg [Reproductive - Fertility - other measures of fertility]
Subcutaneous - Rat TDLo: 20 mg/kg [Reproductive - Maternal Effects - parturition Reproductive - Maternal Effects - postpartum Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain)]
Subcutaneous - Mouse TDLo: 240 mg/kg [Reproductive - Effects on Newborn - biochemical and metabolic Reproductive - Effects on Newborn - delayed effects]
Subcutaneous - Mouse TDLo: 100 mg/kg [Reproductive - Fertility - other measures of fertility]
Subcutaneous - Mouse TDLo: 20 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Mouse TDLo: 1500 ug/kg [Reproductive - Maternal Effects - uterus, cervix, vagina]
Subcutaneous - Mouse TDLo: 2400 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]
Subcutaneous - Rabbit TDLo: 50 ug/kg [Reproductive - Maternal Effects - uterus, cervix, vagina]
Subcutaneous - Rabbit TDLo: 50 ug/kg [Reproductive - Fertility - other measures of fertility]
Subcutaneous - Rabbit TDLo: 70 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count) Reproductive - Paternal Effects - other effects on male]
Subcutaneous - Rabbit TDLo: 300 ug/kg [Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)]
Subcutaneous - Rabbit TDLo: 100 ug/kg [Reproductive - Maternal Effects - ovaries, fallopian tubes]
Subcutaneous - Rabbit TDLo: 150 ug/kg [Reproductive - Fertility - mating performance (e.g. number sperm positive females per number females mated; number copulations per number estrus cycles)]
Subcutaneous - Guinea pig TDLo: 86 mg/kg [Reproductive - Specific Developmental Abnormalities - urogenital system]
Subcutaneous - Mouse TDLo: 800 mg/kg/6W (continuous) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Skin and Appendages - tumors]
Subcutaneous - Mouse TDLo: 40 mg/kg [Tumorigenic - neoplastic by RTECS criteria Skin and Appendages - tumors]
Subcutaneous - Mouse TD: 9500 mg/kg/19W (intermittent) [Tumorigenic - neoplastic by RTECS criteria Skin and Appendages - tumors]
Subcutaneous - Mouse TD: 200 mg/kg/5W (intermittent) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Blood - leukemia]
Intraperitoneal. - Rat LD50: 327 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat TDLo: 1 mg/kg [Endocrine - estrogenic]
Intraperitoneal. - Mouse TDLo: 16 mg/kg [Behavioral - general anesthetic]
Intraperitoneal. - Mouse TDLo: 5 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of classical conditioning]
Intraperitoneal. - Rat TDLo: 20 mg/kg [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Rat TDLo: 750 mg/kg/15D (intermittent) [Endocrine - changes in luteinizing hormone Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Related to Chronic Data - changes in prostate weight]
Intraperitoneal. - Mouse TDLo: 277.5 mg/kg/5D (intermittent) [Reproductive - Maternal Effects - ovaries, fallopian tubes]
Intraperitoneal. - Rat TDLo: 3500 mg/kg/2W (intermittent) [Biochemical - Metabolism (Intermediary) - other Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other oxidoreductases]
Intraperitoneal. - Rat TDLo: 500 mg/kg/3D (intermittent) [Behavioral - sleep]
Intraperitoneal. - Rat TDLo: 15 mg/kg/2D (intermittent) [Behavioral - excitement Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 105 mg/kg/1W (intermittent) [Behavioral - alteration of classical conditioning]

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
Administration onto the skin - Rat LD50: 100 pph/90M [Details of toxic effects not reported other than lethal dose value]

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

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:

HMIS Health Hazard:	2*
HMIS Fire Hazard:	1
HMIS Reactivity:	0
HMIS Personal Protection:	H

SDS Creation Date:	January 08, 2009
SDS Revision Date:	November 10, 2023
SDS Revision Notes:	Added HMIS Ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).

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