SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: **Fulvestrant Injection**

Other means of identification:

Recommended use of the chemical and restrictions on use:

Chemical manufacturer address and telephone number:

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

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Pictograms:

Signal Word:	DANGER!
GHS Class:	Reproductive Toxicity, Category 1B Acute Toxicity Oral, Category 4.
Hazard Statements:	May damage fertility or the unborn child. May cause harm to breast-fed children. Harmful if swallowed.
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. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. IF exposed or concerned: Get medical advice/attention. Store locked up. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Hazards not otherwise classified that have been identified during the classification process:

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.
Skin:	May cause skin irritation.
Inhalation:	May cause irritation of respiratory tract.
Ingestion:	May cause irritation.
Signs/Symptoms:	Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Aggravation of Pre-Existing Conditions:	Medical Conditions Aggravated by Accidental Exposure : Individuals who are pregnant or have a known hypersensitivity to the drug or to any of its components

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.
Alpha-Tocopherol	59-02-9	0.6 mg/mL by weight	
Super Refined Castor Oil	8001-79-4	Quantity Sufficient by weight	

Fulvestrant	129453-61-8	50 mg/mL
Ethyl Alcohol	64-17-5	100 mg/mL
Benzyl Alcohol	100-51-6	100 mg/mL
Polysorbate 80	9005-65-6	1.2 mg/mL

SECTION 4 : FIRST AID MEASURES

Description of necessary 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.

Most important symptoms/effects, acute and delayed:

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

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable 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.

Specific hazards arising from the chemical:

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.

Special protective equipment and precautions for fire-fighters:

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

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.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

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:

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

Methods and materials for containment and cleaning up:

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

Precautions for safe handling:

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.

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

Conditions for safe storage, including any incompatibilities:

Storage:	Store at 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F). [USP Controlled Room Temperature]. Fulvestrant Injection can also be store at refrigerated conditions: 2°C to 8°C (36°F to 46°F). To Protect from light, store in the original carton until time of use.

Specific end use(s):

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

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Ethyl Alcohol :

Guideline OSHA:	PEL-TWA: 1000 ppm

Appropriate engineering controls:

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.

Individual protection measures:

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.
General Hygiene Considerations:	Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Liquid solution.
Color:	Yellow
Boiling Point:	Not established.
Melting Point:	Not determined.
Solubility:	Not determined.
Vapor Density:	Not established.
Vapor Pressure:	Not determined.
Percent Volatile:	Not established.
pH:	Not determined.
Flash Point:	12 °C (54 °F)
Flash Point Method:	Not determined.
Lower Flammable/Explosive Limit:	Not determined.
Upper Flammable/Explosive Limit:	Not determined.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability:	Stable under normal temperatures and pressures.

Possibility of hazardous reactions:

Hazardous Polymerization:	Not reported.

Conditions To Avoid:

Conditions to Avoid:	Protect from light, heat, and freezing.

SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Fulvestrant :

Ingestion:	LD50 Oral Rat: 1784 mg/kg
Mutagenicity:	May cause genetic effects.
Reproductive Toxicity:	Pregnancy Category D: Fulvestrant cause d a reversible reduction in female rat fertility, as well as effects on embryo/fetal development consistent with its antiestrogenic activity.

Ethyl Alcohol :

RTECS Number:	KQ6300000
Eye:	Eye - Rabbit Rinsed with water.: 100 mg/4S
Skin:	Administration onto the skin - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Open irritation test: 400 mg Administration onto the skin - Rabbit Standard Draize test.: 20 mg/24H
Inhalation:	Inhalation - Rat LC50: 20000 ppm/10H [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 39 gm/m3/4H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Rat LD50: 7060 mg/kg [Lungs, Thorax, or Respiration - Other changes] Oral - Mouse LD50: 3450 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 7 gm/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Human TDLo: 1.6 gm/kg/6H [Biochemical - Metabolism (Intermediary) - other] Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep] Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep Behavioral - tolerance] Intravenous. - Rat LD50: 1440 mg/kg [Lungs, Thorax, or Respiration - dyspnea] Intravenous. - Rabbit LD50: 2374 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 0.5 gm/kg [Brain and Coverings - recordings from specific areas of CNS] Intravenous. - Human TDLo: 0.89 mL/kg [Vascular - regional or general arteriolar constriction Vascular - measurement of regional blood flow] Intravenous. - Mouse LD50: 1973 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intravenous. - Rat TDLo: 3 gm/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)] Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - other developmental abnormalities] Intravenous. - Rabbit TDLo: 15 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - other effects to embryo] Subcutaneous - Mouse LD50: 8285 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 5 gm/kg [Liver - hepatitis (hepatocellular necrosis), zonal] Intraperitoneal. - Rat TDLo: 3000 mg/kg [Nutritional and Gross Metabolic - body temperature decrease] Intraperitoneal. - Rat TDLo: 3500 mg/kg [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - dehydrogenases] Intraperitoneal. - Rat TDLo: 1000 mg/kg [Brain and Coverings - other degenerative changes Liver - other changes Biochemical - Metabolism (Intermediary) - lipids including transport] Intraperitoneal. - Rat TDLo: 0.25 gm/kg [Behavioral - alteration of operant conditioning] Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of operant conditioning] Intraperitoneal. - Mouse TDLo: 1.5 mg/kg [Behavioral - antianxiety] Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests] Intraperitoneal. - Mouse TDLo: 2.5 gm/kg [Behavioral - somnolence (general depressed activity) Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests] Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - somnolence (general depressed activity)] Intraperitoneal. - Mouse TDLo: 2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of classical conditioning] Intraperitoneal. - Mouse TDLo: 1 gm/kg [Behavioral - antianxiety Behavioral - changes in psychophysiological tests] Intraperitoneal. - Mouse TDLo: 1000 mg/kg [Liver - other changes] Intraperitoneal. - Mouse TDLo: 0.25 gm/kg [Behavioral - analgesia] Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - changes in psychophysiological tests] Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - food intake (animal)] Intraperitoneal. - Rat LD50: 3600 ug/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 528 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rabbit LD50: 963 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Guinea pig LD50: 3414 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse TDLo: 4.2 gm/kg [Nutritional and Gross Metabolic - body temperature decrease] Intraperitoneal. - Rat TDLo: 2.45 gm/kg [Behavioral - altered sleep time (including change in righting reflex)] Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in psychophysiological tests] Intraperitoneal. - Mouse TDLo: 1.75 gm/kg [Behavioral - ataxia] Intraperitoneal. - Mouse TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay)] Intraperitoneal. - Rat TDLo: 3000 mg/kg [Behavioral - sleep] Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Endocrine - differential effect of sex or castration on observed toxicity Biochemical - Metabolism (Intermediary) -

other]
Intraperitoneal. - Rat TDLo: 1 gm/kg [Sense Organs and Special Senses (Taste) - change in function]
Intraperitoneal. - Mouse TDLo: 4.25 gm/kg [Behavioral - sleep]
Intraperitoneal. - Rat TDLo: 2.4 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites]
Intraperitoneal. - Mouse TDLo: 2 mg/kg [Brain and Coverings - recordings from specific areas of CNS]
Intraperitoneal. - Rat TDLo: 1.5 gm/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]
Intraperitoneal. - Rat TDLo: 1.25 mg/kg [Behavioral - changes in motor activity (specific assay)]
Intraperitoneal. - Mouse LDLo: 4000 mg/kg [Behavioral - alteration of classical conditioning Nutritional and Gross Metabolic - body temperature decrease]
Intraperitoneal. - Rat TDLo: 2700 mg/kg [Behavioral - ataxia]
Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - analgesia]
Intraperitoneal. - Rat TDLo: 2000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - other]
Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - withdrawal]
Intraperitoneal. - Mouse TDLo: 2.0 gm/kg [Behavioral - ataxia Nutritional and Gross Metabolic - body temperature decrease]
Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - phosphokinase]
Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - muscle weakness]
Intraperitoneal. - Rat TDLo: 2000 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - ataxia Behavioral - alteration of operant conditioning]
Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Rat TDLo: 3000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - amino acids (including renal excretion)]
Intraperitoneal. - Mouse TDLo: 1.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety]
Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - ataxia Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 3.5 gm/kg [Behavioral - altered sleep time (including change in righting reflex)]
Intraperitoneal. - Mouse TDLo: 0.3 mg/kg [Behavioral - alteration of operant conditioning]
Intraperitoneal. - Mouse TDLo: 1.2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety Behavioral - alteration of operant conditioning]
Intraperitoneal. - Mouse TDLo: 1.8 mg/kg [Behavioral - alteration of classical conditioning Behavioral - antianxiety Behavioral - alteration of operant conditioning]
Intraperitoneal. - Mouse TDLo: 4 gm/kg/8D (intermittent) [Behavioral - alteration of classical conditioning Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 4.8 mg/kg/4D (intermittent) [Behavioral - changes in motor activity (specific assay)]
Intraperitoneal. - Mouse TDLo: 12 mg/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - tolerance Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat TDLo: 3 gm/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 37.8 mg/kg/21D (intermittent) [Behavioral - changes in motor activity (specific assay) Behavioral - tolerance Behavioral - alteration of classical conditioning]
Intraperitoneal. - Mouse TDLo: 12.6 mg/kg/21D (intermittent) [Behavioral - tolerance]
Intraperitoneal. - Rat Mutation test systems not otherwise specified: 250 gm/kg/16D (continuous)
Intraperitoneal. - Mouse Micronucleus test: 1240 mg/kg/2D
Intraperitoneal. - Rat TDLo: 15 gm/kg [Reproductive - Effects on Newborn - behavioral Reproductive - Effects on Newborn - physical]
Intraperitoneal. - Rat TDLo: 2240 mg/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord)]
Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Rat TDLo: 600 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 - extra-embryonic structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 3600 mg/kg [Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse TDLo: 5622 ug/kg [Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 4 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
Intraperitoneal. - Mouse TDLo: 4300 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
Intraperitoneal. - Mouse TDLo: 2.9 gm/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
Intraperitoneal. - Rat TDLo: 11.25 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 15 mg/kg [Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - eye/ear]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Mouse TDLo: 5.8 gm/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear]

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]

Polysorbate 80 :

RTECS Number:	WG2932500
Eye:	Eye - Rabbit Standard Draize test.: 150 mg [mild]
Ingestion:	Oral - Rat LD50: 34500 uL/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 25 gm/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 1790 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 1790 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat TDLo: 10 gm/kg/27W (intermittent) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Tumorigenic - tumors at site of application] Intraperitoneal. - Rat LD50: 6804 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 7600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat TDLo: 80 uL/kg [Reproductive - Maternal Effects - uterus, cervix, vagina Reproductive - Maternal Effects - menstrual cycle changes or disorders Reproductive - Effects on Newborn - physical]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

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

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Ethanol Solution.
DOT UN Number:	UN 1170
DOT Hazard Class:	Class 3 Flammable
DOT Packing Group:	PG II
DOT Exemption:	DOT Special Permit 9275 (DOT-SP 9275): No DOT Shipping Name required for shipments within the U.S. Must follow all DOT-SP 9275 requirements.
IATA Shipping Name:	Ethanol Solution.
IATA UN Number:	UN 1170
IATA Hazard Class:	Class 3
IATA Packing Group:	PG II

SECTION 15 : REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product:

Ethyl Alcohol :

TSCA Inventory Status:	Listed
EINECS Number:	200-578-6
Canada DSL:	Listed
Canada IDL:	: 3300 ppm

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)

Polysorbate 80 :

TSCA Inventory Status:	Listed
EINECS Number:	500-019-9
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2
HMIS Fire Hazard:	3
HMIS Reactivity:	1
HMIS Personal Protection:	X

Health Hazard	**2**
Fire Hazard	**3**
Reactivity	**1**
Personal Protection	**X**

SDS Creation Date:	October 16, 2017
SDS Revision Date:	December 28, 2020
SDS Revision Notes:	Formulation and classification update
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