

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** Haloperidol 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:** October 30, 2023

### SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:

DANGER.

GHS Class:

Respiratory sensitisation. category 1.  
 Reproductive toxicity. Category 1A.  
 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.  
 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 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.  
**Skin:** May cause skin irritation.  
**Inhalation:** May cause irritation of respiratory tract.  
**Ingestion:** May cause irritation.

Signs/Symptoms:

Adverse reactions from therapeutic doses include: extrapyramidal symptoms, tardive dyskinesia, tardive dystonia, insomnia, restlessness, anxiety, neuroleptic malignant syndrome (NMS), tachycardia, hypotension, hypertension, leukopenia, leukocytosis, impaired liver function, maculopapular skin reactions, lactation, breast engorgement, anorexia, dry mouth, blurred vision, laryngospasm, and bronchospasm. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:

Individuals with severe toxic central nervous system depression, hypersensitivity to this drug, or have Parkinson's disease.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
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Haloperidol Lactate	52-86-8	5 mg/mL
Propylparaben	94-13-3	0.2 mg/mL
Methylparaben	99-76-3	1.8 mg/mL

#### SECTION 4 : FIRST AID MEASURES

<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
<b>Ingestion:</b>	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.
<b>Other First Aid:</b>	For Adverse Event Information, please call (800) 551-7176.

#### SECTION 5 : FIRE FIGHTING MEASURES

<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	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.
<b>Extinguishing Media:</b>	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.
<b>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	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

<b>Personal Precautions:</b>	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.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	Contain spills with an inert absorbent material such as soil, sand or oil dry.
<b>Methods for cleanup:</b>	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

<b>Handling:</b>	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.
<b>Storage:</b>	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature]. Protect from light. Do not freeze.
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

#### SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	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.
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<b>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	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 ( <a href="http://www.cdc.gov/niosh/npptl/topics/respirators/">http://www.cdc.gov/niosh/npptl/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
<b>Other Protective:</b>	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

## EXPOSURE GUIDELINES

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid solution.
<b>Color:</b>	Colorless.
<b>Boiling Point:</b>	Not established.
<b>Melting Point:</b>	147 - 152°C
<b>Solubility:</b>	Insoluble. in water.
<b>Vapor Density:</b>	Not established.
<b>Vapor Pressure:</b>	Not established.
<b>Percent Volatile:</b>	Not established.
<b>pH:</b>	3.0 - 3.8
<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	375.86
<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.

## SECTION 10 : STABILITY and REACTIVITY

<b>Chemical Stability:</b>	Stable under normal temperatures and pressures.
<b>Hazardous Polymerization:</b>	Not reported.
<b>Conditions to Avoid:</b>	Protect from light, heat, and freezing.

## SECTION 11 : TOXICOLOGICAL INFORMATION

<b>Acute Toxicity:</b>	Eye, skin, and respiratory irritation.
<b><u>Haloperidol Lactate :</u></b>	
<b>Acute Toxicity:</b>	LD50: IP Rat 27 mg/kg LD50: IP Mouse 30 mg/kg LD50: SC Mouse 41 mg/kg LD50: IV Mouse 15 mg/kg TDLo: Multiple Man 343 mcg/kg LD50: IV Dog 18 mg/kg
<b>Acute Effects:</b>	Eye, skin, and respiratory irritation.
<b>Chronic Effects:</b>	Possible hypersensitization.
<b><u>Haloperidol Lactate :</u></b>	
<b>RTECS Number:</b>	EU1575000
<b>Ingestion:</b>	Oral - Rat LD50: 128 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 71 mg/kg [Details of toxic effects not reported other than lethal dose value]
<b>Other Toxicological Information:</b>	Intravenous. - Human TDLo: 0.02 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - changes in psychophysiological tests] Intravenous. - Guinea pig TDLo: 0.3 mg/kg [Cardiac - EKG changes not diagnostic of specified effects] Intravenous. - Rat LD50: 15 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 13 mg/kg [Behavioral - ataxia Behavioral - rigidity (including catalepsy)] Intravenous. - Rabbit LD50: 8 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 0.001 mg/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum] Intravenous. - Rat TDLo: 50 ug/kg [Brain and Coverings - recordings from specific areas of CNS Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites] Intravenous. - Rat TDLo: 100 ug/kg [Brain and Coverings - recordings from specific areas of CNS Biochemical - Metabolism (Intermediary) - other Biochemical - Neurotransmitters or modulators]

(putative) - dopamine at other sites]  
Intravenous. - Rat TDLo: 0.05 mg/kg [Brain and Coverings - recordings from specific areas of CNS]  
Intravenous. - Rat TDLo: 13 mg/kg [Reproductive - Effects on Newborn - viability index (e.g., number alive at day 4 per number born alive) Reproductive - Effects on Newborn - delayed effects]  
Intravenous. - Rat TDLo: 33600 ug/kg [Reproductive - Fertility - mating performance (e.g. number sperm positive females per number females mated; number copulations per number estrus cycles)  
Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea) Reproductive - Effects on Embryo or Fetus - fetal death]  
Intravenous. - Rat TDLo: 12800 ug/kg [Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]  
Subcutaneous - Rat TDLo: 0.003 mg/kg [Behavioral - alteration of operant conditioning]  
Subcutaneous - Rat TDLo: 0.19 mg/kg [Behavioral - rigidity (including catalepsy)]  
Subcutaneous - Rat TDLo: 0.3 mg/kg [Biochemical - Metabolism (Intermediary) - other Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]  
Subcutaneous - Rat TDLo: 0.01 mg/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]  
Subcutaneous - Rat TDLo: 0.03 mg/kg [Behavioral - changes in motor activity (specific assay)]  
Subcutaneous - Rat TDLo: 0.63 mg/kg [Behavioral - changes in motor activity (specific assay)  
Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]  
Subcutaneous - Mouse TDLo: 0.07 mg/kg [Behavioral - analgesia]  
Subcutaneous - Rat LD50: 60 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Subcutaneous - Mouse LD50: 41 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Subcutaneous - Mouse TDLo: 0.5 mg/kg [Behavioral - changes in motor activity (specific assay)  
Behavioral - rigidity (including catalepsy)]  
Subcutaneous - Rat TDLo: 0.1 mg/kg [Behavioral - changes in motor activity (specific assay)  
Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites]  
Subcutaneous - Mouse TDLo: 0.04 mg/kg [Behavioral - antipsychotic Behavioral - alteration of classical conditioning]  
Subcutaneous - Rat TDLo: 2.78 mg/kg [Biochemical - Neurotransmitters or modulators (putative) - catecholamine levels in CNS Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]  
Subcutaneous - Rat TDLo: 1.01 mg/kg [Endocrine - changes in gonadotropins]  
Subcutaneous - Rat TDLo: 0.033 mg/kg [Behavioral - abuse]  
Subcutaneous - Mouse TDLo: 0.1 mg/kg [Behavioral - changes in psychophysiological tests]  
Subcutaneous - Rat TDLo: 0.025 mg/kg [Behavioral - alteration of classical conditioning]  
Subcutaneous - Rat TDLo: 0.5 mg/kg [Behavioral - rigidity (including catalepsy) Behavioral - alteration of classical conditioning]  
Subcutaneous - Rat TDLo: 1 mg/kg [Biochemical - Metabolism (Intermediary) - other]  
Subcutaneous - Rat TDLo: 0.01 mg/kg [Behavioral - antipsychotic]  
Subcutaneous - Rat TDLo: 0.04 mg/kg [Behavioral - alteration of classical conditioning Behavioral - changes in psychophysiological tests]  
Subcutaneous - Rat TDLo: 0.3 mg/kg [Behavioral - rigidity (including catalepsy) Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]  
Subcutaneous - Rat TDLo: 0.1 mg/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites]  
Subcutaneous - Rat TDLo: 0.1 mg/kg [Behavioral - changes in motor activity (specific assay)  
Behavioral - antipsychotic]  
Subcutaneous - Rat TDLo: 0.02 mg/kg [Behavioral - changes in psychophysiological tests]  
Subcutaneous - Rat TDLo: 0.02 mg/kg [Behavioral - antipsychotic Behavioral - changes in psychophysiological tests]  
Subcutaneous - Mouse TDLo: 0.1 mg/kg [Behavioral - changes in motor activity (specific assay)]  
Subcutaneous - Rat TDLo: 0.02 mg/kg [Brain and Coverings - other degenerative changes]  
Subcutaneous - Rat TDLo: 0.1 mg/kg [Brain and Coverings - other degenerative changes Behavioral - changes in motor activity (specific assay) Behavioral - rigidity (including catalepsy)]  
Subcutaneous - Rat TDLo: 0.05 mg/kg [Brain and Coverings - other degenerative changes Endocrine - other changes]  
Subcutaneous - Mouse TDLo: 0.11 mg/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]  
Subcutaneous - Mouse TDLo: 0.075 mg/kg [Sense Organs and Special Senses (Olfaction) - effect, not otherwise specified]  
Subcutaneous - Rat TDLo: 0.09 mg/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites]  
Subcutaneous - Rat TDLo: 0.03 mg/kg [Behavioral - changes in motor activity (specific assay)  
Behavioral - alteration of operant conditioning]  
Subcutaneous - Rat TDLo: 10.5 mg/kg/3W (intermittent) [Biochemical - Metabolism (Intermediary) - other proteins]  
Subcutaneous - Mouse TDLo: 0.84 mg/kg/21D (intermittent) [Behavioral - antipsychotic Behavioral - alteration of classical conditioning]  
Subcutaneous - Rat TDLo: 26 mg/kg/26D (continuous) [Biochemical - Metabolism (Intermediary) - other proteins Biochemical - Metabolism (Intermediary) - glycolytic]  
Subcutaneous - Rat TDLo: 10 mg/kg/10D (continuous) [Behavioral - changes in psychophysiological tests]  
Subcutaneous - Rat TDLo: 12500 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]  
Subcutaneous - Rat TDLo: 70 mg/kg [Reproductive - Specific Developmental Abnormalities - eye/ear]  
Subcutaneous - Rat TDLo: 7500 ug/kg [Reproductive - Effects on Newborn - behavioral]  
Subcutaneous - Rat TDLo: 10750 ug/kg [Reproductive - Effects on Newborn - growth statistics (e.g.% reduced weight gain)]  
Subcutaneous - Rat TDLo: 6750 ug/kg [Reproductive - Maternal Effects - postpartum]  
Subcutaneous - Mouse TDLo: 3500 ug/kg [Reproductive - Fertility - other measures of fertility]  
Intraperitoneal. - Mouse TDLo: 1 mg/kg [Behavioral - rigidity (including catalepsy) Biochemical - Metabolism (Intermediary) - effect on cyclic nucleotides]  
Intraperitoneal. - Rat TDLo: 0.25 mg/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]  
Intraperitoneal. - Mouse TDLo: 50 ug/kg [Behavioral - alteration of classical conditioning]  
Intraperitoneal. - Mouse TDLo: 1 mg/kg [Behavioral - convulsions or effect on seizure threshold]  
Intraperitoneal. - Rat TDLo: 0.5 mg/kg [Vascular - measurement of regional blood flow]  
Intraperitoneal. - Mouse TDLo: 0.035 mg/kg [Behavioral - changes in motor activity (specific assay)  
Behavioral - antipsychotic]  
Intraperitoneal. - Mouse TDLo: 0.1 mg/kg [Behavioral - changes in motor activity (specific assay)  
Behavioral - rigidity (including catalepsy) Behavioral - antipsychotic]  
Intraperitoneal. - Mouse TDLo: 1 mg/kg [Behavioral - changes in psychophysiological tests]  
Intraperitoneal. - Rat TDLo: 0.5 mg/kg [Brain and Coverings - recordings from specific areas of CNS  
Behavioral - rigidity (including catalepsy)]  
Intraperitoneal. - Rat LD50: 27 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Mouse LD50: 30 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Mouse TDLo: 25 mg/kg [Gastrointestinal - ulceration or bleeding from stomach]  
Intraperitoneal. - Mouse TDLo: 0.1 mg/kg [Nutritional and Gross Metabolic - body temperature decrease]  
Intraperitoneal. - Rat TDLo: 3 mg/kg [Kidney/Ureter/Bladder - urine volume increased]  
Intraperitoneal. - Mouse TDLo: 0.25 mg/kg [Behavioral - changes in motor activity (specific assay)  
Behavioral - rigidity (including catalepsy)]  
Intraperitoneal. - Rat TDLo: 0.16 mg/kg [Behavioral - rigidity (including catalepsy)]  
Intraperitoneal. - Rat TDLo: 0.03 mg/kg [Behavioral - alteration of operant conditioning]  
Intraperitoneal. - Rat TDLo: 0.1 mg/kg [Behavioral - food intake (animal)]  
Intraperitoneal. - Rat TDLo: 0.3 mg/kg [Behavioral - rigidity (including catalepsy) Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]

Intraperitoneal. - Rat TDLo: 0.03 mg/kg [Behavioral - alteration of classical conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 1 mg/kg [Endocrine - other changes Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol)]

Intraperitoneal. - Rat TDLo: 1 mg/kg [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - peptidases]

Intraperitoneal. - Rat TDLo: 0.1 mg/kg [Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 0.5 mg/kg [Biochemical - Metabolism (Intermediary) - other proteins]

Intraperitoneal. - Mouse TDLo: 0.1 mg/kg [Behavioral - rigidity (including catalepsy)]

Intraperitoneal. - Mouse TDLo: 1 mg/kg [Behavioral - rigidity (including catalepsy) Biochemical - Metabolism (Intermediary) - other proteins]

Intraperitoneal. - Rat TDLo: 0.5 mg/kg [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Rat TDLo: 0.2 mg/kg [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Rat TDLo: 0.1 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 0.3 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 1 mg/kg [Brain and Coverings - other degenerative changes]

Intraperitoneal. - Mouse TDLo: 100 ug/kg [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Rat TDLo: 450 ug/kg [Brain and Coverings - other degenerative changes Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]

Intraperitoneal. - Mouse TDLo: 30 mg/kg/10D (intermittent) [Brain and Coverings - changes in brain weight]

Intraperitoneal. - Mouse TDLo: 50 mg/kg/20D (intermittent) [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Rat TDLo: 0.5 mg/kg/2D (intermittent) [Behavioral - alteration of operant conditioning]

Intraperitoneal. - Rat TDLo: 0.7 mg/kg/7D (intermittent) [Behavioral - food intake (animal)]

Intraperitoneal. - Rat TDLo: 2.1 mg/kg/21D (intermittent) [Related to Chronic Data - changes in uterine weight]

Intraperitoneal. - Rat TDLo: 22.5 mg/kg/9D (intermittent) [Behavioral - food intake (animal) Nutritional and Gross Metabolic - weight loss or decreased weight gain]

Intraperitoneal. - Mouse TDLo: 14 mg/kg/14D (intermittent) [Behavioral - rigidity (including catalepsy)]

Intraperitoneal. - Mouse TDLo: 28 mg/kg/14D (intermittent) [Behavioral - tolerance]

Intraperitoneal. - Mouse TDLo: 28 mg/kg/7D (intermittent) [Behavioral - tolerance]

Intraperitoneal. - Mouse TDLo: 56 mg/kg/14D (intermittent) [Brain and Coverings - other degenerative changes]

Intraperitoneal. - Rat TDLo: 3.5 mg/kg/7D (intermittent) [Endocrine - effect on menstrual cycle]

Intraperitoneal. - Rat TDLo: 21 mg/kg/21D (intermittent) [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - catalases Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other oxidoreductases]

Intraperitoneal. - Rat TDLo: 7 mg/kg/7D (intermittent) [Brain and Coverings - other degenerative changes Behavioral - changes in motor activity (specific assay) Biochemical - Metabolism (Intermediary) - other proteins]

Intraperitoneal. - Rat TDLo: 17 mg/kg/17D (intermittent) [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - other proteins Biochemical - Metabolism (Intermediary) - effect on cyclic nucleotides]

Intraperitoneal. - Rat TDLo: 10 mg/kg/10D (intermittent) [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - peptidases]

Intraperitoneal. - Rat TDLo: 7 mg/kg/14D (intermittent) [Behavioral - tremor Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Rat TDLo: 31.5 mg/kg/21D (intermittent) [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - other]

Intraperitoneal. - Rat TDLo: 1.5 mg/kg/3D (intermittent) [Nutritional and Gross Metabolic - other changes]

Intraperitoneal. - Rat TDLo: 10.5 mg/kg/21D (intermittent) [Reproductive - Maternal Effects - menstrual cycle changes or disorders Nutritional and Gross Metabolic - other changes Biochemical - Metabolism (Intermediary) - lipids including transport]

Intraperitoneal. - Rat TDLo: 21 mg/kg/21D (intermittent) [Brain and Coverings - other degenerative changes Behavioral - changes in motor activity (specific assay) Nutritional and Gross Metabolic - weight loss or decreased weight gain]

Intraperitoneal. - Mouse Sister chromatid exchange: 285 ug/kg

Intraperitoneal. - Rat TDLo: 40 mg/kg [Reproductive - Effects on Newborn - behavioral]

Intraperitoneal. - Mouse TDLo: 23 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Effects on Newborn - behavioral]

Intraperitoneal. - Rat TDLo: 50 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]

Intraperitoneal. - Rat TDLo: 50 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]

Intraperitoneal. - Rat TDLo: 22.5 mg/kg [Reproductive - Effects on Newborn - growth statistics (e.g., reduced weight gain) Reproductive - Effects on Newborn - behavioral]

Intraperitoneal. - Rat TDLo: 35 mg/kg [Reproductive - Effects on Newborn - biochemical and metabolic Reproductive - Effects on Newborn - behavioral Reproductive - Effects on Newborn - other postnatal measures or effects]

Intraperitoneal. - Rat TDLo: 35 mg/kg [Reproductive - Effects on Newborn - delayed effects]

Intraperitoneal. - Mouse TDLo: 25 mg/kg/5D (continuous) [Tumorigenic - carcinogenic by RTECS criteria Liver - tumors Blood - leukemia]

Intraperitoneal. - Mouse TD: 50 mg/kg/10D (continuous) [Tumorigenic - carcinogenic by RTECS criteria Gastrointestinal - tumors Blood - leukemia]

#### **Propylparaben :**

**RTECS Number:** DH2800000

**Ingestion:** Oral - Mouse LD50: 6332 mg/kg [Details of toxic effects not reported other than lethal dose value]

**Other Toxicological Information:** Subcutaneous - Mouse LD50: 1650 mg/kg [Details of toxic effects not reported other than lethal dose value]  
 Subcutaneous - Mouse TDLo: 51 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight]  
 Subcutaneous - Rat TDLo: 99 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight]  
 Subcutaneous - Mouse TDLo: 195 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight]  
 Intraperitoneal. - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value]

#### **Methylparaben :**

**RTECS Number:** DH2450000

**Skin:** Administration onto the skin - Rabbit Standard Draize test.: 0.1 mL/24H  
 Administration onto the skin - Rabbit Standard Draize test.: 0.5 mL/21D (Intermittent)  
 Administration onto the skin - Rat TDLo: 374.92 gm/kg/13W (Intermittent) [Nutritional and Gross Metabolic - Weight loss or decreased weight gain Blood - Other changes]

**Ingestion:** Oral - Mouse LD50: >8 gm/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - Ataxia]  
 Oral - Mouse LD50: >8000 mg/kg [Behavioral - Ataxia]  
 Oral - Rat LD50: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value]

**Other Toxicological Information:** Intravenous. - Mouse TDLo: 100 mg/kg [Vascular - shock Lungs, Thorax, or Respiration - respiratory depression]  
Intravenous. - Mouse TDLo: 2.5 mg/kg [Lungs, Thorax, or Respiration - tumors]  
Subcutaneous - Mouse TDLo: 165 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]  
Subcutaneous - Mouse LD50: 1.2 gm/kg [Details of toxic effects not reported other than lethal dose value]  
Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Subcutaneous - Mouse TDLo: 49.5 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight]  
Subcutaneous - Mouse TDLo: 165 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight]  
Intraperitoneal. - Mouse LD50: 960 mg/kg [Peripheral Nerve and Sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - somnolence (general depressed activity) Behavioral - ataxia]  
Intraperitoneal. - Mouse LD50: 125 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Intraperitoneal. - Rat LD50: 960 mg/kg [Details of toxic effects not reported other than lethal dose value]

## 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

### Haloperidol Lactate :

**EINECS Number:** 200-155-6  
**California PROP 65:** Listed: developmental.  
**Canada DSL:** Listed

### Propylparaben :

**TSCA Inventory Status:** Listed  
**EINECS Number:** 202-307-7  
**Canada DSL:** Listed

### Methylparaben :

**TSCA Inventory Status:** Listed  
**EINECS Number:** 202-785-7  
**Canada DSL:** Listed

## SECTION 16 : ADDITIONAL INFORMATION

### HMIS Ratings:

**HMIS Health Hazard:** 2\*  
**HMIS Fire Hazard:** 0  
**HMIS Reactivity:** 0  
**HMIS Personal Protection:** M

**SDS Creation Date:** January 08, 2009  
**SDS Revision Date:** October 30, 2023  
**SDS Revision Notes:** Updated HMIS Ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).

**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.

