

SAFETY DATA SHEET

SECTION 1: Identification of the substance

Identification of the product

Product Name : Haloperidol Tablets USP, 0.5 mg, 1 mg, 2 mg, 5 mg, 10 mg, 20 mg
Chemical Family : Mixture
Therapeutic Category : Pharmaceutical product used as antipsychotic
Marketed by : Creekwood Pharmaceuticals LLC 1130, Route 46 W, Suite 21,
Parsippany, New Jersey 07054
Contact Information : 1-732-344-0220

SECTION 2 : HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: DANGER

Statement of Hazard: May be harmful if swallowed.
May cause nervous system, cardiovascular system and reproductive effects May damage the unborn child.

Additional Hazard Information:

Short Term: Overdose: Seizure and/or coma may occur.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. Animal studies have shown a potential to cause adverse effects on the fetus. Can cause effects on central nervous system, gastrointestinal, cardiovascular system and respiratory system.

Known Clinical Effects: Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.

EU Indication of danger: Toxic to Reproduction: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R60 - May impair fertility.
 R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	%
Haloperidol	52-86-8	3.85
Sodium starch Glycolate	9063-38-1	*
Magnesium stearate	557-04-0	*
Lactose Monohydrate	64044-51-5	*
Hypromellose	9004-65-3	*
Colloidal Silicon dioxide	112945-52-5	*
Microcrystalline Cellulose	9004-34-6	*

Additional Information: * Proprietary
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4 : FIRST AID MEASURES

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Section 5 : FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	May burn emitting oxides of: chlorine nitrogen and hydrogen fluoride
Fire Fighting Procedures:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
Storage Conditions:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Haloperidol OEL TWA-8 Hr:	=1 ug/m ³
Sodium starch Glycolate US OSHA -TWAs: ACGIH Threshold Limit Value (TWA)	= 15 mg/m ³ TWA = 10 mg/m ³ TWA
Magnesium stearate ACGIH Threshold Limit Value (TWA) Australia TWA	= 10 mg/m ³ TWA except stearates of toxic metals = 10 mg/m ³ TWA
The exposure limit(s) listed for solid components are only relevant if dust may be generated.	
Lactose Monohydrate Observe general threshold limit for dust.	
Hypromellose Threshold Limit Value (TWA)	= 10 mg/m ³ TWA

Colloidal Silicon dioxide

UK. EH40 (WELs)Threshold Limit Value (TWA)

= 10 mg/m³ TWA for inhalable dust

UK. EH40 (WELs)Threshold Limit Value (TWA)

= 4 mg/m³ TWA for respirable dust**Microcrystalline Cellulose**

Respiratory protection is required when dusts are generated. Eye protection is required.

Analytical Method: Analytical method available for haloperidol. Contact Creekwood for further information.**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.**Personal Protective Equipment:****Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.**Respiratory protection:** Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.**9. PHYSICAL AND CHEMICAL PROPERTIES:**

Physical State:	Tablets	Color:	White, Yellow & Pale Pink
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability:	Stable at normal conditions
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION**General Information:** The information included in this section describes the potential hazards of the individual ingredients.**Acute Toxicity: (Species, Route, End Point, Dose)****Haloperidol**

Rat	Oral	LD 50	128 mg/kg	
Rat	Subcutaneous	Minimum Symptomatic Dose	1 mg/kg	

Sodium starch Glycolate

Rat	Oral	LD 50	>2000 mg/kg	
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Magnesium stearate

Not classified (based on available data)

Lactose Monohydrate

Not classified (based on available data)

Hypromellose

Rabbit Skin LD 50 >5000 mg/kg

Collidal Silicon dioxide

Rat Oral LD 50 >5000 mg/kg

Microcrystalline Cellulose

No toxic effects

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Haloperidol

13 Week(s)	Rat	Oral	10 mg/kg	NOAEL	None identified
6 Month(s)	Dog		2 mg/kg	LOEL	Central Nervous System
1 Year(s)	Rat		10 mg/kg	LOEL	Central Nervous System
80 Week(s)	Rat	Oral	0.34-1.11 mg/kg	LOEL	Central Nervous System

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Haloperidol

Reproductive & Fertility	Rat	Oral	0.5-5 mg/kg	LOAEL	Developmental toxicity, Fetotoxicity, Fertility
Reproductive & Fertility	Mouse	Intraperitoneal	0.5-5 mg/kg	LOAEL	Developmental toxicity, Fetotoxicity, Fertility
Reproductive & Fertility	Rat	Oral	30 mg/kg/day	LOAEL	Fertility
Embryo / Fetal Development	Rat	Oral	15 mg/kg	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rat	Oral	0.5-5 mg/kg	LOAEL	Teratogenic, Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Haloperidol

Bacterial Mutagenicity (Ames)	Bacteria	Positive
Sister Chromatid Exchange	Rat	Positive
Mammalian Cell Mutagenicity	Rat	Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Haloperidol

2 Year(s)	Rat	Oral	5 mg/kg/day	NOEL	Not carcinogenic
2 Year(s)	Female Mouse	Oral	1.25 mg/kg/day	LOEL	Tumors, Mammary gland
2 Year(s)	Female Mouse	Oral	5	LOEL	Tumors, Endocrine system, Mammary gland

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to Reproduction: Category 2

EU Risk Phrases:
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
DANGER
May be harmful if swallowed.
May cause nervous system, cardiovascular system and reproductive effects
May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Haloperidol**California Proposition 65**developmental toxicity, initial date 1/29/99
female reproductive toxicity, initial date 1/29/99**Australia (AICS):
Standard for the Uniform Scheduling
for Drugs and Poisons:**Present
Schedule 4**EU EINECS List**

200-155-6

16. OTHER INFORMATION

Creekwood Pharmaceutical LLC believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

End of Safety Data Sheet