



MATERIAL SAFETY DATA SHEET

Revision date: 25-Aug-2011

Version: 2.0

Page 1 of 7

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Haloperidol Tablets

Trade Name:	SERENACE Tablets
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antipsychotic

2. HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: DANGER

Statement of Hazard: May damage fertility or 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.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Haloperidol Tablets
Revision date: 25-Aug-2011

Page 2 of 7
Version: 2.0

2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Haloperidol	52-86-8	200-155-6	T;R25 Repr.Cat2;R60 Repr.Cat2;R61	0.5-1.4
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Dibasic calcium phosphate, dihydrate USP	7789-77-7	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose	63-42-3	200-559-2	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

MATERIAL SAFETY DATA SHEET

Material Name: Haloperidol Tablets
Revision date: 25-Aug-2011

Page 3 of 7
Version: 2.0

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:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Haloperidol

Pfizer OEL TWA-8 Hr: 1 µg/m³

Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Haloperidol Tablets
Revision date: 25-Aug-2011

Page 4 of 7
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Analytical Method: Analytical method available for haloperidol. Contact Pfizer Inc for further information.
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: 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
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical 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

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Lactose

Rat Oral LD50 > 10 g/kg

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)

MATERIAL SAFETY DATA SHEET

Material Name: Haloperidol Tablets
Revision date: 25-Aug-2011

Page 5 of 7
Version: 2.0

11. TOXICOLOGICAL INFORMATION

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

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

MATERIAL SAFETY DATA SHEET

Material Name: Haloperidol Tablets
Revision date: 25-Aug-2011

Page 6 of 7
Version: 2.0

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 damage fertility or 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 1/29/99
Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:	Present Schedule 4
EU EINECS/ELINCS List	200-155-6

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

MATERIAL SAFETY DATA SHEET

Material Name: Haloperidol Tablets
Revision date: 25-Aug-2011

Page 7 of 7
Version: 2.0

15. REGULATORY INFORMATION

Dibasic calcium phosphate, dihydrate USP

Australia (AICS): Present

Lactose

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

REACH - Annex IV - Exemptions from the obligations of Register: Present

EU EINECS/ELINCS List 200-559-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25 - Toxic if swallowed.

R61 - May cause harm to the unborn child.

R60 - May impair fertility.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet