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

Material Name: Haloperidol Injection 5 mg/mL

Trade Name: SERENACE Injection 5 mg/mL
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antipsychotic

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol</td>
<td>52-86-8</td>
<td>200-155-6</td>
<td>0.49</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>200-015-0</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Glucose</td>
<td>50-99-7</td>
<td>200-075-1</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution
Signal Word: DANGER

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

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

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. Can cause effects on central nervous system, gastrointestinal 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:** Not classified

**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.

### 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.

### 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:** 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 spill with absorbent material. 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:** Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
Storage Conditions: Store at controlled room temperature.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Haloperidol
Pfizer OEL TWA-8 Hr: 1 ug/m³
The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
- Hands: Wear protective gloves when working with large quantities.
- Eyes: Wear safety glasses or goggles if eye contact is possible.
- Skin: Wear protective clothing when working with large quantities.
- 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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
<th>Color:</th>
<th>Clear, colorless</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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 LD50 128 mg/kg
- Rat Subcutaneous Minimum Symptomatic Dose 1 mg/kg

Lactic acid
- Rat Oral LD50 3543 mg/kg
- Rabbit Dermal LD50 >2000 mg/kg

Glucose
- Rat Oral LD50 25800 mg/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.
Irritation / Sensitization: (Study Type, Species, Severity)

Lactic acid
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Moderate Severe

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

Lactic acid
Reproductive & Fertility  Rat  Oral  6.25 mg/kg/day  NOEL  Fertility, Not teratogenic

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

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 Indication of danger: Not classified

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

Canada - WHMIS: Classifications

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

Haloperidol
California Proposition 65 development toxicity, initial date 1/29/99
Australia (AICS): female reproductive toxicity, initial date 1/29/99
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 4
EU EINECS List: 200-155-6

Water for Injection
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 231-791-2

Glucose
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List: 200-075-1

Lactic acid
Inventory - United States TSCA - Sect. 8(b): Present
16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet