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

Material Name: Benadryl® (Diphenhydramine hydrochloride) for Injection
Trade Name: Benadryl (R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antihistamine sedative

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>Diphenhydramine hydrochloride</td>
<td>147-24-0</td>
<td>205-687-2</td>
<td>5</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>**</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</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>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: Colorless, odorless solution
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information:
Short Term: Not an eye irritant, Not a skin irritant, Not a skin sensitizer (based on components). May cause central nervous system effects.

Known Clinical Effects: The most common adverse effects seen with the therapeutic use of diphenhydramine HCl include drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.

EU Indication of danger: Not classified
4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and shoes. Wash skin with soap and water. If irritation occurs or persists, get 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May emit toxic fumes of nitrogen oxides and hydrogen chloride.

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: Use appropriate ventilation. Avoid breathing vapor or mist. Avoid contact with skin and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Diphenhydramine hydrochloride
Pfizer OEL TWA-8 Hr: 0.15 mg/m³, (as free base)
Material Name: Benadryl® (Diphenhydramine hydrochloride) for Injection
Revision date: 05-Jan-2007

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Analytical Method:
Analytical method available for Diphenhydramine. Contact Pfizer Inc for further information.

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

- Hands: Rubber gloves
- Eyes: Safety glasses or goggles
- 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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Sterile solution</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Soluble: Water</td>
</tr>
<tr>
<td>pH</td>
<td>5.0-6.0</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>100</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>2.3 (20 °C)</td>
</tr>
<tr>
<td>Relative Density</td>
<td>1.05</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>&gt;61</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

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

Hazardous Decomposition Products: None known
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.
MATERIAL SAFETY DATA SHEET

Material Name: Benadryl® (Diphenhydramine hydrochloride) for Injection
Revision date: 05-Jan-2007
Version: 2.4

Acute Toxicity: (Species, Route, End Point, Dose)

Hydrogen chloride
Rat  Inhalation  LC50 1H  3,124 ppm
Mouse  Inhalation  LC50 1H  1,108 ppm
Mouse  Oral  LD50 900 mg/kg

Sodium hydroxide
Mouse  IP  LD50  40 mg/kg

Diphenhydramine hydrochloride
Rat  Oral  LD50  500 mg/kg
Mouse  Oral  LD50  114 mg/kg
Guinea Pig  Oral  LD50  284 mg/kg
Human  Oral  LDmin.  10.1 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

Diphenhydramine hydrochloride
Eye Irritation  Rabbit  Non-irritating
Skin Sensitization - Beuhler  Guinea Pig  Negative
Skin Sensitization - LLNA  Mouse  Negative

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

Diphenhydramine hydrochloride
13 Week(s)  Rat  Oral  310 mg/kg/day  LOAEL  Liver
2 Year(s)  Rat  Oral  15 mg/kg/day  NOAEL  Liver
2 Year(s)  Mouse  Oral  21 mg/kg/day  NOAEL  Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Diphenhydramine hydrochloride
Embryo / Fetal Development  Rat  Oral  100 mg/kg/day  NOAEL  Not teratogenic, Maternal toxicity, Fetotoxicity
Embryo / Fetal Development  Mouse  Oral  80 mg/kg/day  NOAEL  Not Teratogenic, Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development  Rat  Oral  50 mg/kg/day  NOAEL  Not Teratogenic, Maternal Toxicity, Fetotoxicity
Liver  Central nervous system

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

Diphenhydramine hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vitro Mammalian Cell Mutagenicity  Mouse Lymphoma  Negative
In Vitro Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Positive without activation
In Vitro Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Negative
In Vitro Unscheduled DNA Synthesis  Rat Hepatocyte  Negative

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

Diphenhydramine hydrochloride
2 Year(s)  Rat  Oral  15 mg/kg/day  NOAEL  Not carcinogenic
12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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:
WARNING
Harmful if swallowed.

Canada - WHMIS: Classifications

WHMIS hazard class: None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Diphenhydramine hydrochloride
Australia (AICS): Present
16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet