# SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

**Product Identifier**

<table>
<thead>
<tr>
<th>Material Name:</th>
<th>VISTARIL (Hydroxyzine pamoate) oral suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name:</td>
<td>Vistaril(R)</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**

**Intended Use:** Pharmaceutical product used as an antianxiety agent, nausea and vomiting (antiemetic), antihistamine, sedative.

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## 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification**

- Reproductive Toxicity: Category 2

**Label Elements**

- **Signal Word:** Warning
- **Hazard Statements:** H361d - Suspected of damaging the unborn child
- **Precautionary Statements:**
  - P201 - Obtain special instructions before use
  - P281 - Use personal protective equipment as required
  - P308 + P313 - IF exposed or concerned: Get medical attention/advice
  - P405 - Store locked up
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Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxyzine pamoate</td>
<td>10246-75-0</td>
<td>233-582-1</td>
<td>Acute Tox.4 (H302) Repr.2 (H361d)</td>
<td>1-5</td>
</tr>
<tr>
<td>Lemon No. 78 flavor</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sorbic acid</td>
<td>110-44-1</td>
<td>203-768-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitol solution</td>
<td>50-70-4</td>
<td>200-061-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td></td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Hydroxyzine pamoate
Pfizer OEL TWA-8 Hr: 300 µg/m³

Propylene glycol
Australia TWA
150 ppm
474 mg/m³
10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland OEL - TWAs</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>470 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
</tbody>
</table>

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Suspension</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>Pale yellow</td>
</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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<tr>
<td>Water Solubility</td>
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<tr>
<td>pH</td>
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<tr>
<td>Melting/Freezing Point (°C)</td>
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<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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</tr>
<tr>
<td>Propylene glycol</td>
<td>No data available</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>No data available</td>
</tr>
<tr>
<td>Sorbitol solution</td>
<td>No data available</td>
</tr>
<tr>
<td>Sorbic acid</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydroxyzine pamoate</td>
<td>No data available</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Water
No data available

Lemon No. 78 flavor
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Specific Gravity: 1.261 - 1.284

Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: The most commonly reported adverse effects seen with the use of hydroxyzine include drowsiness, somnolence, headache, weakness, depression, and irritability.

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

Propylene glycol
- Rat Oral LD 50 22,000 mg/kg
- Mouse Oral LD 50 24,900mg/kg
- Rabbit Dermal LD 50 20,800mg/kg

Carboxymethylcellulose sodium
- Mouse Oral LD50 > 27,000 mg/kg
- Rat Oral LD50 27,000 mg/kg
11. TOXICOLOGICAL INFORMATION

Rabbit  Dermal  LD50  > 2000 mg/kg

Sorbitol solution
Rat  Oral  LD50  15,900 mg/kg
Mouse  Oral  LD50  17,800 mg/kg

Sorbic acid
Rat  Oral  LD50  7360 mg/kg
Mouse  Oral  LD50  3200 mg/kg

Hydroxyzine pamoate
Rat  Oral  LD50  1740 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)
Propylene glycol
Skin Irritation  Rabbit  Mild
Eye Irritation  Rabbit  Mild

No data available

Skin Irritation / Sensitization  No data available

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
Carboxymethylcellulose sodium
13 Week(s)  Rat  Oral  227 g/kg  LOAEL  Liver, Kidney, Ureter, Bladder

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Teratogenicity  Hydroxyzine when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range. Hydroxyzine has been associated with teratogenesis in beagle puppies. In pregnant monkeys (one per dose group), oral doses of 6, 8, and 12 mg/kg resulted in abortion in all three pregnancies. However, dosing at 5 or 10 mg/kg did not produce abortions, nor were any gross malformations seen in offspring.

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

At increase risk from exposure:  Individuals with a history of hypersensitivity to this material or other materials in its chemical class may be susceptible to the toxicity of overexposure. Individuals taking central nervous system depressants (alcohol, hypnotics, narcotics, barbiturates) should avoid exposure to this material.

Additional Information:  FDA PREGNANCY CATEGORY C.

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:  No data available
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.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Hydroxyzine pamoate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 233-582-1

Lemon No. 78 flavor
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Sorbic acid
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
SAFETY DATA SHEET

Material Name: VISTARIL (Hydroxyzine pamoate) oral suspension
Revision date: 07-Sep-2017

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol solution</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>203-768-7</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>200-338-0</td>
</tr>
<tr>
<td>Water</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-791-2</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

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

Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.
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End of Safety Data Sheet