



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.7

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

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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Vistaril® (Hydroxyzine pamoate) oral suspension

Trade Name: Vistaril(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antianxiety agent, nausea and vomiting (antiemetic), antihistamine, sedative.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS List | % |
|---------------------|--------------|----------------|------|
| Hydroxyzine pamoate | 10246-75-0 | 233-582-1 | <1.0 |
| Lemon No. 78 flavor | NOT ASSIGNED | Not listed | * |

| Ingredient | CAS Number | EU EINECS List | % |
|-------------------------------|------------|----------------|---|
| Sorbic acid | 110-44-1 | 203-768-7 | * |
| Carboxymethylcellulose sodium | 9004-32-4 | Not listed | * |
| Sorbitol solution | 50-70-4 | 200-061-5 | * |
| Propylene glycol | 57-55-6 | 200-338-0 | * |

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

3. HAZARDS IDENTIFICATION

Appearance: Homogeneous pale yellow suspension

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

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.
EU Indication of danger: Not classified

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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.

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: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get 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 carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

Fire / Explosion Hazards: Not available

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. Avoid breathing dust.

Storage Conditions: Store in a cool, dry, well-ventilated area. Keep container tightly closed when not in use.

Storage Temperature: Store as directed by product packaging.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydroxyzine pamoate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Propylene glycol

Australia TWA
= 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA

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. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
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: | Suspension | Color: | Pale yellow |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| pH: | 4.5-5.5 | | |
| Specific Gravity: | 1.261 - 1.284 | | |

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: Strong oxidizers
Polymerization: Will not occur

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)

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg

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Rabbit Dermal LD50 20,800 mg/kg

Carboxymethylcellulose sodium

Mouse Oral LD50 > 27,000 mg/kg

Rat Oral LD50 27,000 mg/kg

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.

Inhalation Acute Toxicity

No data available

Ingestion Acute Toxicity

See Acute toxicity table.

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

Propylene glycol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Eye Irritation / Sensitization

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

Chronic Effects/Carcinogenicity

No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.

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.

Mutagenicity

No data available

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

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Environmental Overview: The environmental characteristics of this mixture 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:

Non-hazardous in accordance with international standards for workplace safety.

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.

Hydroxyzine pamoate

| | |
|-------------------|-----------|
| Australia (AICS): | Present |
| EU EINECS List | 233-582-1 |

Sorbic acid

| | |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | T |
| Australia (AICS): | Present |
| EU EINECS List | 203-768-7 |

Carboxymethylcellulose sodium

| | |
|---|---------|
| Inventory - United States TSCA - Sect. 8(b) | XU |
| Australia (AICS): | Present |

Sorbitol solution

| | |
|---|---------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |

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| | |
|----------------|-----------|
| EU EINECS List | 200-061-5 |
|----------------|-----------|

Propylene glycol

| | |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 200-338-0 |

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet