



# SAFETY DATA SHEET

Revision date: 20-Apr-2015

Version: 4.0

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

### Product Identifier

**Material Name:** Vistaril® (Hydroxyzine pamoate) capsules

**Trade Name:** Vistaril(R)

**Chemical Family:** Mixture

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

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

### Details of the Supplier of the Safety Data Sheet

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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**+00 44 (0)1304 616161**

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

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 2

#### EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3

#### EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

### 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**  
**Australian Hazard Classification (NOHSC):**

No data available  
Hazardous Substance. Non-Dangerous Goods.

**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

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Hydroxyzine pamoate	10246-75-0	233-582-1	Xn;R22 Repr. Cat.3;R63	Acute Tox.4 (H302) Repr.2 (H361d)	1-10
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Hard gelatin capsules	MIXTURE	Not Listed	Not Listed	Not Listed	*

**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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Description of 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.

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**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get 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

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

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

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

## 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 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.

**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

### Precautions for Safe Handling

Minimize dust generation and accumulation. Use appropriate ventilation. 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 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:** Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature. Protect from freezing.

**Storage Temperature:** 15-30°C (59-86°F)

**Incompatible Materials:** Strong oxidizers

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**Specific end use(s):** Pharmaceutical product used as antianxiety agent, nausea and vomiting (antiemetic), antihistamine, sedative

### 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/m<sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m<sup>3</sup>

#### Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Australia TWA 10 mg/m<sup>3</sup>

Belgium OEL - TWA 10 mg/m<sup>3</sup>

Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>

Czech Republic OEL - TWA 4.0 mg/m<sup>3</sup>

Greece OEL - TWA 10 mg/m<sup>3</sup>

5 mg/m<sup>3</sup>

Ireland OEL - TWAs 10 mg/m<sup>3</sup>

4 mg/m<sup>3</sup>

OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>

Portugal OEL - TWA 10 mg/m<sup>3</sup>

Slovakia OEL - TWA 4 mg/m<sup>3</sup>

Spain OEL - TWA 10 mg/m<sup>3</sup>

Switzerland OEL - TWAs 3 mg/m<sup>3</sup>

#### Sucrose

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Australia TWA 10 mg/m<sup>3</sup>

Belgium OEL - TWA 10 mg/m<sup>3</sup>

Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>

Estonia OEL - TWA 10 mg/m<sup>3</sup>

France OEL - TWA 10 mg/m<sup>3</sup>

Ireland OEL - TWAs 10 mg/m<sup>3</sup>

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 10 mg/m<sup>3</sup>

OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>

Portugal OEL - TWA 10 mg/m<sup>3</sup>

Slovakia OEL - TWA 6 mg/m<sup>3</sup>

Spain OEL - TWA 10 mg/m<sup>3</sup>

#### 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves as minimum protection.
<b>Eyes:</b>	Wear safety glasses as minimum protection.
<b>Skin:</b>	Wear impervious protective clothing when handling this compound.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Capsule	<b>Color:</b>	Dark green/light green; green/white; green/gray
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Hydroxyzine pamoate</b>			
No data available			
<b>Hard gelatin capsules</b>			
No data available			
<b>Magnesium stearate</b>			
No data available			
<b>Sodium lauryl sulfate</b>			
No data available			
<b>Corn Starch</b>			
No data available			
<b>Sucrose</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Polymerization:</b>		Will not occur	

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

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### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
<b>Incompatible Materials:</b>	Strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
<b>Short Term:</b>	May be harmful if swallowed. Accidental ingestion may cause effects similar to those seen in clinical use.
<b>Long Term:</b>	Animal studies have shown a potential to cause adverse effects on the fetus.
<b>Known Clinical Effects:</b>	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)

##### Hydroxyzine pamoate

Rat Oral LD50 1740 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

##### Sucrose

Rat Oral LD50 29.7 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.

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

##### Sodium lauryl sulfate

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild Moderate  
Skin Sensitization - GPMT Guinea Pig Negative  
Skin Sensitization - LLNA Mouse Negative

#### 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.

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

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### 11. TOXICOLOGICAL INFORMATION

#### Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### 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:

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Sodium lauryl sulfate

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 3.6 mg/L

#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

No data available

#### Mobility in Soil:

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.

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### 15. REGULATORY INFORMATION

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

##### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 2, Subdivision A



##### Hydroxyzine pamoate

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

##### Hard gelatin capsules

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

##### Magnesium stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

##### Sodium lauryl sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1

##### Corn Starch

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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



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### 15. REGULATORY INFORMATION

#### Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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	200-334-9

### 16. OTHER INFORMATION

#### Text of R phrases and 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

Xn - Harmful  
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.  
R63 - Possible risk of harm to 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 16 - Other Information.

**Revision date:** 20-Apr-2015  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**