MATERIAL SAFETY DATA SHEET

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

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

Material Name: Vistaril® (Hydroxyzine hydrochloride) intramuscular solution

Trade Name: Vistaril(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as sedative, anxiolytic, Antipruritic.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Hydroxyzine hydrochloride	2192-20-3	218-586-3	2.4 - 4.9
Benzyl Alcohol	100-51-6	202-859-9	<1.0
Sodium hydroxide	1310-73-2	215-185-5	<1.0

Ingredient	CAS Number	EU EINECS List	%
Water for injection	7732-18-5	231-791-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution in multiple-dose vials
Signal Word: WARNING

Statement of Hazard:
May be harmful if swallowed.
May cause harm to the unborn child.
May cause central nervous system effects

Additional Hazard Information:
Short Term: May cause eye irritation (based on components) . Not expected to cause skin irritation . May be harmful if swallowed. Accidental ingestion may cause effects similar to those seen in clinical use.
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

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: Remove clothing and wash affected skin with soap and water. 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 only in a well-ventilated area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature: Store at or below 30°C (86°F).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydroxyzine hydrochloride

Pfizer OEL TWA-8 Hr:	0.3 mg/m³

Sodium hydroxide

OSHA - Final PELS - TWAs:	2 mg/m³
ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak

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. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands:	Rubber gloves
Eyes:	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:	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:	Liquid	**Color:**	Colorless
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

pH:	3.5 - 5.5
Specific Gravity:	0.990 - 1.020

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	None known
Incompatible Materials:	Strong oxidizers
Hazardous Decomposition Products:	No data available
Polymerization:	Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Benzyl Alcohol

Rat	Oral	LD50	1.23 g/kg
Rat	Intravenous	LD50	53 mg/kg

Hydroxyzine hydrochloride
Rat Oral LD50 840 mg/kg
Mouse IP LD50 81 mg/kg
Rat IP LD50 160 mg/kg
Mouse IV LD50 137 mg/kg
Rat IV LD50 45 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Inhalation Acute Toxicity No data available
Ingestion Acute Toxicity See Acute toxicity table

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

Benzyl Alcohol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate
Skin Irritation Guinea Pig Moderate

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Eye Irritation / Sensitization May cause eye irritation based on components.
Chronic Effects/Carcinogenicity No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Hydroxyzine hydrochloride
Reproductive & Fertility Rat Oral 400 mg/kg LOAEL Developmental toxicity, Reproductive toxicity

Reproductive Effects No data available
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.

12. ECOLOGICAL INFORMATION

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:
WARNING
May be harmful if swallowed.
May cause harm to the unborn child.
May cause central nervous system effects

Canada - WHMIS: Classifications

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

Hydroxyzine hydrochloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	218-586-3

Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-859-9

Water for injection

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

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet