MATERIAL SAFETY DATA SHEET

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: Atarax® (Hydroxyzine hydrochloride) syrup

Trade Name: Atarax (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	<1
Spearmint oil	8008-79-5	Not listed	*
L-Menthol	2216-51-5	218-690-9	*
Ethanol	64-17-5	200-578-6	<1
Hydrogen chloride	7647-01-0	231-595-7	*

Ingredient	CAS Number	EU EINECS List	%
Sugar syrup no. 1	NOT ASSIGNED	Not listed	*
Peppermint oil	8006-90-4	Not listed	*
Purified water	7732-18-5	231-791-2	*
Sodium benzoate	532-32-1	208-534-8	*

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

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid

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

Additional Hazard Information:
Short Term: 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. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

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: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

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.

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

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydroxyzine hydrochloride

Pfizer OEL TWA-8 Hr:	0.3 mg/m³

Ethanol

OSHA - Final PELS - TWAs:	= 1000 ppm TWA = 1900 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA = 1880 mg/m^3 TWA

Hydrogen chloride

ACGIH Ceiling Threshold Limit:	= 2 ppm Ceiling
Australia PEAK	= 5 ppm Peak = 7.5 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. Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands:	Rubber gloves
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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:	Syrup	**Color:**	Colorless
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: Strong oxidizers

Hazardous Decomposition Products: No data available
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)

Peppermint oil
Rat Oral LD 50 2426 mg/kg
Mouse Oral LD 50 2490 mg/kg

Sodium benzoate
Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600 mg/kg

L-Menthol
Rat Oral LD50 3300 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

Ethanol
Mouse Oral LD50 3,450 g/m^3
Rat Oral LD50 7,060 mg/kg
Mouse Inhalation LC50 4h 39 g/m^3
Rat Inhalation LC50 10h 20,000 ppm

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

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

L-Menthol
Eye Irritation Rabbit Severe

Ethanol
Eye Irritation Rabbit Severe

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

Sodium benzoate
10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

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

Sodium benzoate
Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

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

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.

Hydrogen chloride
IARC: Group 3

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. See aquatic toxicity data, below:

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

L-Menthol
Fathead minnow LC50 96 Hours 18.9 mg/L

Ethanol
Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L
Rainbow Trout NPDES LC50 96 Hours 12,900 mg/L
Fathead minnow NPDES LC50 96 Hours 14,200 mg/L

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 hydrochloride

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

Peppermint oil

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

Spearmint oil

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

L-Menthol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	218-690-9

Ethanol

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-578-6

Purified water

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

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	208-534-8

Hydrogen chloride

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only

Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
EU EINECS List	231-595-7

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