



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jun-2003

Version: 3.1

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

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

Material Name: Antivert® (Meclizine hydrochloride) tablets

Trade Name: Antivert®
Synonyms: meclizine hydrochloride tablets
Chemical Family: Benzhydrylpiperazine agent
Intended Use: nausea and vomiting (antiemetic)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*
Sucrose	57-50-1	200-334-9	*
Meclizine hydrochloride	31884-77-2	Not listed	*

Ingredient	CAS Number	EU EINECS List	%
Polyethylene glycol	25322-68-3	Not listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: 12.5 mg: Blue/white tablets 25 mg: White/yellow tablets 50 mg: Blue/yellow tablets
Signal Word: CAUTION

Statement of Hazard: May be harmful if swallowed.
May cause central nervous system effects

Eye Contact: Dust may cause irritation (based on components).
Skin Contact: Dust may cause irritation (based on components).
Inhalation: Dust may cause irritation. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion: May be harmful if swallowed See 'Statements of hazard' and 'Known clinical effects' in this section.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include sleepiness, drowsiness, fatigue, headache, dizziness, and dry mouth

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EU Indication of danger: Not classified

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.
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 contaminated clothing and shoes. Wash 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: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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

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: Wipe up with a damp cloth and place in container for disposal. 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: Spills should be handled by vacuuming or wet mopping. Transfer all waste to a labeled container and move it to a secure holding area.

Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. Use adequate ventilation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes

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

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Storage Temperature 15-30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Starch

OSHA - Final PELs - TWAs	15 mg/m ³ total dust 5 mg/m ³ respirable fraction
ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA

Sucrose

OSHA - Final PELs - TWAs	15 mg/m ³ total dust 5 mg/m ³ respirable fraction
ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA

Meclizine hydrochloride

Pfizer OEL TWA-8 Hr: 0.07 mg/m³
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Meclizine: CAM-KAS-00-015; STP M 2.7 (Contact Pfizer for additional details)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

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:	Tablet	Color:	Blue/white, yellow/white or blue/yellow
Odor:	Odorless	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

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General Information:	There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient, except where noted.
Carcinogenicity:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Sucrose	
Rat Oral LD50	29.7 g/kg
Starch	
Mouse IP LD50	6600 mg/kg
Magnesium stearate	
Rat Oral LD50	> 2000 mg/kg
Rat Inhalation LC50	> 2000 mg/m ³
Meclizine hydrochloride	
Mouse Oral LD50	1600 mg/kg
Rat Oral LD50	1750 (free base)mg/kg
Inhalation Acute Toxicity	No data available
Ingestion Acute Toxicity	See Acute toxicity table.
Polyethylene glycol	
Eye Irritation Rabbit	Mild
Skin Irritation Rabbit	Mild
Eye Irritation / Sensitization	See Acute toxicity table.
Skin Irritation / Sensitization	See Acute toxicity table.
Subchronic Effects	Subchronic toxicity studies in dogs and rats for six months showed no abnormal symptoms or changes.
Chronic Effects/Carcinogenicity	No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.
Teratogenicity	Meclizine was found to cause cleft palate and other abnormalities in rats at doses 25 to 50 times the human therapeutic dose. Meclizine has not been found to be teratogenic in mice, rabbits, pigs, and monkeys. Epidemiological studies in pregnant women revealed no increased risk of abnormalities due to meclizine treatment.
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 with asthma, glaucoma, or enlarged prostate gland and 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

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Disposal Procedures: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Labeling: None required
EU Indication of danger: Not classified

OSHA Label:

CAUTION

May be harmful if swallowed.

May cause central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:

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.

Starch

EU EINECS List	232-679-6
Inventory - United States TSCA - Sect. 8(b)	Listed

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	Listed
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Calcium phosphate dibasic, anhydrous

EU EINECS List	231-826-1
Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed

Sucrose

EU EINECS List	200-334-9
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet