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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
<tr>
<td>Meclizine hydrochloride</td>
<td>31884-77-2</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>*</td>
</tr>
</tbody>
</table>

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
EU Indication of danger: Not classified

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11. 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.
Storage Temperature
15-30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Starch
OSHA - Final PELS - TWAs
15 mg/m³ total dust
5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)
10 mg/m³ TWA

Sucrose
OSHA - Final PELS - TWAs
15 mg/m³ total dust
5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)
10 mg/m³ 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 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: 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/m³

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.
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

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
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet