



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 2.4

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**

**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

**Material Name: Meclizine hydrochloride chewable tablets**

**Trade Name:** Bonine(R); Bonamine(TM)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product for the treatment of nausea and vomiting (antiemetic).

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

| Ingredient                | CAS Number | EU EINECS List | %    |
|---------------------------|------------|----------------|------|
| Meclizine hydrochloride   | 31884-77-2 | Not listed     | 12.5 |
| Colloidal silicon dioxide | 7631-86-9  | 231-545-4      | *    |
| Starch                    | 9005-25-8  | 232-679-6      | *    |
| Sodium saccharin USP      | 128-44-9   | 204-886-1      | *    |
| Magnesium stearate        | 557-04-0   | 209-150-3      | *    |
| Talc (non-asbestiform)    | 14807-96-6 | 238-877-9      | *    |

| Ingredient              | CAS Number   | EU EINECS List | % |
|-------------------------|--------------|----------------|---|
| FD & C Red No. 40       | 25956-17-6   | 247-368-0      | * |
| Lactose NF, monohydrate | 64044-51-5   | Not listed     | * |
| Raspberry flavor        | NOT ASSIGNED | Not listed     | * |

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Pink tablets  
**Signal Word:** WARNING

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

**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

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**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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:** 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.

**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:** 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 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.

**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:** 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.

**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:** 15-30°C

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Meclizine hydrochloride

Pfizer OEL TWA-8 Hr: 0.07 mg/m<sup>3</sup>

#### Colloidal silicon dioxide

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO<sub>2</sub>) mg/m<sup>3</sup> TWA  
= 20 mppcf TWA  
Australia TWA = 2 mg/m<sup>3</sup> TWA

#### Starch

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA  
ACGIH Threshold Limit Value (TWA) = 2 mg/m<sup>3</sup> TWA  
Australia TWA = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers  
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Analytical Method:** Analytical method available for Meclizine. Contact Pfizer Inc for further information.

**Engineering Controls:** Good general ventilation should be sufficient to control airborne levels.

#### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.  
**Eyes:** Not required under normal conditions of use. 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:** None required under normal conditions of use. 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>   | Tablet   | <b>Color:</b>             | Pink    |
| <b>Odor:</b>             | Odorless | <b>Molecular Formula:</b> | Mixture |
| <b>Molecular Weight:</b> | Mixture  |                           |         |

### 10. STABILITY AND REACTIVITY

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**Stability:** Stable  
**Conditions to Avoid:** None known  
**Incompatible Materials:** Strong oxidizers

**Hazardous Decomposition Products:** No data available See Section 5 - under Hazardous combustion products.  
**Polymerization:** Will not occur

## 11. TOXICOLOGICAL INFORMATION

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

#### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

#### Starch

Mouse IP LD50 6600 mg/kg

#### Sodium saccharin USP

Mouse Oral LD50 17.5 g/kg

Rat Oral LD50 14.2 - 17 g/kg

#### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### Meclizine hydrochloride

Mouse Oral LD50 1600 mg/kg

Rat Oral LD50 1750 mg/kg (free base)

**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.

**Ingestion Acute Toxicity** The acute oral LD50 for the active ingredient is listed in the table, above. While this formulation has not been tested as a whole, it would not be expected to be toxic orally based on the amount of active ingredient it contains.

**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.

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

#### Meclizine hydrochloride

Embryo / Fetal Development Rat Oral 625-2500 mg/kg/day LOEL Teratogenic

Embryo / Fetal Development Rabbit No route specified Not Teratogenic

Embryo / Fetal Development Rabbit No route specified Not Teratogenic

Embryo / Fetal Development Monkey No route specified Not Teratogenic

**Teratogenicity** Epidemiological studies in pregnant women revealed no increased risk of abnormalities due to meclizine treatment. However, animal studies in mice, rats, and rabbits showed specific developmental abnormalities at maternally toxic doses.

**Mutagenicity** No data available

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Talc (non-asbestiform)

**IARC:** Group 3

#### Sodium saccharin USP

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**IARC:** Group 3

**Colloidal silicon dioxide**

**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 with asthma, glaucoma, or enlarged prostate gland and individuals taking central nervous system depressants (alcohol, hypnotics, narcotics, barbiturates) should avoid exposure to this material.

**Additional Information:** Phrase does not exist! Reproduction studies in rats have shown cleft palates. Epidemiological studies in pregnant women, however, do not indicate that meclizine increases the risk of abnormalities when administered during pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.

### 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 central nervous system effects.

**Canada - WHMIS: Classifications**

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## 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.

## Meclizine hydrochloride

Australia (AICS): Present

## Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 231-545-4

## Starch

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present  
EU EINECS List 232-679-6

## Sodium saccharin USP

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 204-886-1

## FD & C Red No. 40

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 247-368-0

## Lactose NF, monohydrate

Australia (AICS): Present

## Magnesium stearate

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 209-150-3

## Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 238-877-9

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. 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 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

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

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