



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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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: Meclizine Hydrochloride and Pyridoxine Hydrochloride Drops (Syrup)

Trade Name: BONADOXINE, BONADOXINA
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for nausea and vomiting (antiemetic)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Glycerin, USP	56-81-5	200-289-5	*
Citric acid	77-92-9	201-069-1	*
Meclizine hydrochloride	31884-77-2	Not listed	0.25

Ingredient	CAS Number	EU EINECS List	%
Sodium saccharin	128-44-9	204-886-1	*
Sugar	57-50-1	200-334-9	*
Propylene glycol	57-55-6	200-338-0	*
FD&C Green No. 3	2353-45-9	219-091-5	*
Butylparaben	94-26-8	202-318-7	*
Cherry flavor blend	NOT ASSIGNED	Not listed	*
Pyridoxine Hydrochloride (Vitamin B6)	58-56-0	200-386-2	0.5
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	*

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

3. HAZARDS IDENTIFICATION

Appearance: Light green syrup

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

Additional Hazard Information:

Short Term: May cause eye irritation (based on components) .
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 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: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek 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 applicable

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: Avoid contact with eyes. Wash thoroughly after handling.

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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)

Meclizine hydrochloride

Mouse Oral LD50 1600 mg/kg
Rat Oral LD50 1750 mg/kg (free base)

Pyridoxine Hydrochloride (Vitamin B6)

Rat Oral LD 50 4 g/kg

Citric acid

Rat Oral LD50 3000 mg/kg

Glycerin, USP

Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m³
Rat Dermal LD 50 >21.9 g/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Sodium saccharin

Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17 g/kg
Rat Intraperitoneal LD50 7100 mg/kg

Sugar

Rat Oral LD 50 29700 mg/kg
Mouse Oral LD 50 14000 mg/kg

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.

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

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Glycerin, USP

Eye Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Sodium saccharin

36 Week(s)	Rat	Oral	756 g/kg	LOAEL	Kidney, Ureter, Bladder
54 Day(s)	Rat	Oral	32400 mg/kg	LOAEL	Immune system

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

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

Sodium saccharin

IARC: Group 3

FD&C Green No. 3

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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

Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC-50	96 Hours	50 mg/L
<i>Daphnia Magna</i> (Water Flea)	EC-50	24 Hours	>500 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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.

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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.

Sodium saccharin

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

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

Citric acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1

Sugar

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

Meclizine hydrochloride

Australia (AICS):	Present
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FD&C Green No. 3

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	219-091-5

Butylparaben

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-318-7
Pyridoxine Hydrochloride (Vitamin B6)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-386-2
FD&C yellow No.6 aluminum lake	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	239-888-1

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations.

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