

# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Mestinon® Syrup</b>
<b>Other means of identification</b>	
<b>Product Code</b>	NDC 0187-3012-20
<b>Synonyms</b>	Pyridostigmine bromide syrup
<b>Recommended use</b>	Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

<b>Recommended restrictions</b>	No other uses are advised.
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### Manufacturer/Importer/Supplier/Distributor information

<b>Company name</b>	Valeant Pharmaceuticals International, Inc.	
<b>Address</b>	2150 St. Elzéar Blvd. West Laval, Quebec H7L 4AB Canada	
<b>Telephone</b>	Customer Support	1-800-321-4576
<b>E-mail</b>	Not available.	
<b>Emergency phone number</b>	For Emergency - US	1-800-535-5053
	For Emergency - International	1-352-323-3500

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
ETHANOL		64-17-5	5
PYRIDOSTIGMINE BROMIDE		101-26-8	1
FD&C BLUE 1		3844-45-9	*
FD&C RED NO. 40		25956-17-6	*
GLYCERIN		56-81-5	*
LACTIC ACID		79-33-4	*
RASPBERRY FLAVOR, IMITATION		N/A	*
SODIUM BENZOATE		532-32-1	*
SORBITOL		50-70-4	*
SUCROSE		57-50-1	*
WATER		7732-18-5	*

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Rash. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Upper respiratory tract irritation. Coughing. Difficulty in breathing. Prolonged exposure may cause chronic effects. Severe eye irritation.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	<p>Large Spills: Stop the flow of material, if this is without risk. Use water spray to reduce vapors or divert vapor cloud drift. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.</p>
<b>Environmental precautions</b>	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Do not breathe mist or vapor. Do not get in eyes, on skin, or on clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Consumer storage: Store upright at room temperature up to 25°C (77°F). Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm	
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.

#### US. ACGIH Threshold Limit Values

Components	Type	Value
ETHANOL (CAS 64-17-5)	STEL	1000 ppm
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm	
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3 10 mg/m3	Respirable. Total

**Biological limit values** No biological exposure limits noted for the ingredient(s).

### Exposure guidelines

**Appropriate engineering controls** No special controls required during normal clinical use.  
When handling bulk product Provide adequate general and local exhaust ventilation.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** No eye protection required under conditions of intended use.  
When handling bulk product: If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

**Hand protection** No hand protection required under conditions of intended use.  
When handling bulk product: For prolonged or repeated skin contact use suitable protective gloves.

#### Other

No special precautions needed under conditions of intended use.  
When handling bulk product: Wear suitable protective clothing as protection against splashing or contamination.

#### Respiratory protection

No respiratory protection required under conditions of intended use.  
When handling bulk product: Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

**Physical state** Liquid.  
**Form** Reddish, clear solution.  
**Color** Red.

**Odor** Raspberry

**Odor threshold** Not available.

**pH** 4.2 - 4.8

**Melting point/freezing point** Not available.

<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Specific gravity</b>	1.48 estimated

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Rash. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Upper respiratory tract irritation. Coughing. Difficulty in breathing.
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### Information on toxicological effects

<b>Acute toxicity</b>	Harmful if swallowed. May cause an allergic skin reaction.
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<b>Product</b>	<b>Species</b>	<b>Test Results</b>
Mestinson® Syrup (CAS Mixture)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 500 mg/kg

Components	Species	Test Results
ETHANOL (CAS 64-17-5)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Mouse	39 mg/l, 4 Hours
	Rat	20000 ppm, 10 Hours
<i>Oral</i>		
LD50	Dog	5.5 g/kg
	Guinea pig	5.6 g/kg
	Mouse	3450 mg/kg
	Rat	6.2 g/kg
<i>Other</i>		
LD50	Mouse	933 mg/kg
	Rat	1440 mg/kg
FD&C RED NO. 40 (CAS 25956-17-6)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	10000 mg/kg
<i>Oral</i>		
LD50	Dog	5000 mg/kg
	Rat	10000 mg/kg
LACTIC ACID (CAS 79-33-4)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	7.94 mg/l, 4 Hours
<i>Oral</i>		
LD50	Guinea pig	1810 mg/kg
	Mouse	4875 mg/kg
	Rat	3730 mg/kg
<i>Other</i>		
LD50	Mouse	4500 mg/kg
PYRIDOSTIGMINE BROMIDE (CAS 101-26-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	37.5 mg/kg
SORBITOL (CAS 50-70-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	17800 mg/kg
<i>Other</i>		
LD50	Mouse	9480 mg/kg
	Rat	7100 mg/kg
SUCROSE (CAS 57-50-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	29700 mg/kg

\* Estimates for product may be based on additional component data not shown.

<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.
<b>Serious eye damage/eye irritation</b>	Not available.

**Respiratory or skin sensitization****Respiratory sensitization** May cause allergy or asthma symptoms or breathing difficulties if inhaled.**Skin sensitization** May cause an allergic skin reaction.**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.**Carcinogenicity** Carcinogenic effects are not expected as a result of occupational exposure.**IARC Monographs. Overall Evaluation of Carcinogenicity**

FD&amp;C BLUE 1 (CAS 3844-45-9)

3 Not classifiable as to carcinogenicity to humans.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.**Specific target organ toxicity - single exposure** Not classified.**Specific target organ toxicity - repeated exposure** May cause damage to organs through prolonged or repeated exposure.**Aspiration hazard** Not available.**Chronic effects** Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.**Further information** Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.**12. Ecological information****Ecotoxicity** Harmful to aquatic life with long lasting effects.

Components		Species	Test Results
ETHANOL (CAS 64-17-5)			
<b>Aquatic</b>			
Crustacea	EC50	Water flea (Daphnia magna)	7.7 - 11.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	> 100 mg/l, 96 hours
FD&C BLUE 1 (CAS 3844-45-9)			
<b>Aquatic</b>			
Fish	LC50	Coho salmon,silver salmon (Oncorhynchus kisutch)	332 mg/l, 96 hours
GLYCERIN (CAS 56-81-5)			
<b>Aquatic</b>			
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	51000 - 57000 mg/l, 96 hours
LACTIC ACID (CAS 79-33-4)			
<b>Aquatic</b>			
Crustacea	EC50	Water flea (Daphnia magna)	180 - 320 mg/l, 48 hours
SODIUM BENZOATE (CAS 532-32-1)			
<b>Aquatic</b>			
Fish	LC50	Fathead minnow (Pimephales promelas)	> 100 mg/l, 96 hours

\* Estimates for product may be based on additional component data not shown.

**Persistence and degradability****Bioaccumulative potential****Partition coefficient n-octanol / water (log Kow)**

ETHANOL	-0.31
GLYCERIN	-1.76
LACTIC ACID	-0.72
SORBITOL	-2.2
SUCROSE	-3.7

**Mobility in soil****Mobility in general**

**Other adverse effects** Not available.

### 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### DOT

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not established.

### 15. Regulatory information

#### US federal regulations

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

ETHANOL (CAS 64-17-5) Listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**  
Not regulated.

#### Other federal regulations

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

#### US state regulations

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**  
Not listed.

ETHANOL (CAS 64-17-5)  
FD&C BLUE 1 (CAS 3844-45-9)  
GLYCERIN (CAS 56-81-5)  
SUCROSE (CAS 57-50-1)

ETHANOL (CAS 64-17-5)  
GLYCERIN (CAS 56-81-5)

ETHANOL (CAS 64-17-5)  
GLYCERIN (CAS 56-81-5)  
SUCROSE (CAS 57-50-1)

Not regulated.

**WARNING:** This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

ETHANOL (CAS 64-17-5)	Listed: April 29, 2011
	Listed: July 1, 1988

ETHANOL (CAS 64-17-5) Listed: October 1, 1987

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

<b>Issue date</b>	11-25-2014
<b>Version #</b>	01

Valeant cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.