	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Labetalol Hydrochloride Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>Feb 23, 2009</b>	MSDS No.: <b>MSDS 019</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>1 of 8</b>

### Section 1 - Chemical Product and Company

**Distributor:**

Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700  
Schaumburg, IL 60195  
847-908-1600

**Emergency Telephone:** 866-625-1618

**Product Identifier:** Labetalol Hydrochloride Injection, USP  
**Product Code:** NDC 25021-300-20  
NDC 25021-300-40  
**Common/Trade Name:** Labetalol Hydrochloride  
**Chemical Name:** 2-hydroxy-5-[1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl]benzamide monohydrochloride  
**Chemical Family:** Adrenergic Receptor Blocking Agent  
**Product Use:** Pharmaceutical  
**Product Type:** Regulated Prescription Drug  
**Container Information:** Vial


### Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	OSHA PEL	ACGGIH TLV	Other Limits Recommended	CAS No.
Labetalol Hydrochloride	0.5	None	None	None	32780-64-6
Dextrose, anhydrous	4.5	None	None	None	50-99-7
EDTA Disodium	0.01	None	None	None	60-00-4
Mehylparaben	0.08	None	None	None	99-76-3
Propylparaben	0.01	None	None	None	59593-07-6
Water for Injection	94.9	None	None	None	7732-18-5

### Section 3 - Hazards Identification

**Primary Physical and Health Hazards:** Labetalol is a drug used for the treatment of severe high blood pressure. It is a beta-blocker and affects the circulatory system by slowing heart rate and decreasing blood pressure. Product is irritating and may cause rashes on chronic exposure.

**Routes of Entry:** Labetalol may be absorbed by inhalation, absorption, ingestion and injection.

	<b>Sagent Pharmaceuticals, Inc.</b>				
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	Issue Date: <b>Feb 23, 2009</b>	MSDS No.: <b>MSDS 019</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>2 of 8</b>

**Signs & Symptoms of Exposure:** May cause irritation to eyes, skin, respiratory tract, dizziness, nausea, fatigue, vomiting, and difficulty of breathing.

**Chemical Listed as Carcinogen:** **NTP:** No **IARC:** No **OSHA:** No

**Medical Conditions Generally Aggravated by Exposure:** Diseases that cause low blood pressure, bronchial asthma, cardiac problems such as cardiac failure, cardiogenic shock and bradycardia.

#### Section 4 - First Aid Measures

**Eye Exposure:** Flush eyes with large volumes of water for 15 minutes.

**Skin Exposure:** Wash skin with cool, soapy water.

**Ingestion:** If ingestion occurs, flush mouth out with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

**Injection:** Overdose causes excessive hypotension (low blood pressure) that is posture sensitive, and sometimes excessive bradycardia (low heart rate). Refer to package insert for complete listing of warnings and adverse reactions.

**Inhalation:** If difficulty breathing, administer oxygen. Seek the attention of a physician immediately. If necessary, provide artificial respiration.

**Notes to Physician:** See patient package insert in shipping carton for complete information.


#### Section 5 - Fire Fighting Measures

**Flash Point** Not established

**Autoignition Temperature:** Not established

**Flammable Limits in Air** Lower %: Not established  
Upper %: Not established

**Flammable Limits:** Not established

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**Extinguishing Media** Use a multi-purpose ABC fire extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

**Unusual Fire/Explosion Hazards:** None

### Section 6 - Accidental Release Measures

**Spill:** Absorb Labetalol with absorbent pads or wipes and dispose of according to local, state, and federal regulations.

**Release to Air:** If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.


**Release to Water:** Refer to local water authority. Do not dispose of down the drain; refer to local, state, and federal disposal guidelines.

### Section 7 - Handling and Storage

**General Handling:** Wash hands following use. No eating, drinking or smoking while handling this product.

**Waste Disposal Method:** Incinerate in an approved incinerator for flammable liquids according to local guidelines.

**Storage Conditions:** Store at 20° to 25° C (68° to 77° F) [See USP Controlled Room Temperature]. Protect from light. Do not freeze.

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Labetalol Hydrochloride Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>Feb 23, 2009</b>	MSDS No.: <b>MSDS 019</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>4 of 8</b>

**Section 8 - Exposure Controls / Personal Protection**

**Respiratory Protection:** Under normal use, respirators are not required. If aerosols/vapors are generated, a disposable dust mist respirator (N95) may be worn. Personnel wearing respirators should be fit tested and approved for respirator use under OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Eye Protection:** Safety glasses

**Ventilation:** Handle product in a well-ventilated area.


**Skin Protection:** Lab coat and gloves.

**Other Protective Equipment:** None

**Additional Exposure Precautions:** Wash hands following use. No eating, drinking or smoking while handling this product.

**Exposure Limits**

<b><u>Compound</u></b>	<b><u>Issuer</u></b>	<b><u>Type</u></b>	<b><u>OEL</u></b>
Labetalol Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Dextrose	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
EDTA Disodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Methylparaben	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Labetalol Hydrochloride Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>Feb 23, 2009</b>	MSDS No.: <b>MSDS 019</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>5 of 8</b>


Propylparaben	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

### Section 9 - Physical and Chemical Properties

<b>Physical State:</b>	Liquid	<b>Specific Gravity:</b>	Not determined
<b>Appearance and Odor:</b>	Clear, colorless to light yellow with no odor	<b>Evaporation Rate:</b>	Not determined
<b>Boiling Point:</b>	Not determined	<b>Solubility in Water:</b>	Soluble
<b>Vapor Pressure:</b>	Not determined	<b>pH:</b>	3.0 to 4.0
<b>Vapor Density:</b>	Not determined	<b>Molecular Weight:</b>	364.9

### Section 10 - Stability and Reactivity

<b>Stability:</b>	Stable
<b>Incompatibility (Materials to avoid):</b>	Strong bases and oxidizers
<b>Hazardous Decomposition:</b>	Decomposition of Labetalol may include potentially Hazardous byproducts of combustion such as nitrogen oxides, carbon monoxide and carbon dioxide.
<b>Hazardous Polymerization:</b>	Will not occur
<b>Conditions to Avoid:</b>	None

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	Issue Date: <b>Feb 23, 2009</b>	MSDS No.: <b>MSDS 019</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>6 of 8</b>

### Section 11 - Toxicological Information

**Signs & Symptoms of Exposure & Overexposure:**

No evidence of carcinogenicity was observed after oral administration to mice for 18 months or rats for 2 years.

No evidence of mutagenicity was seen in dominant lethal assays in mice and rats and a modified ames test.

Pregnancy Class C. Teratology experiments in rats and rabbits have been negative with oral Labetalol HCl doses of up to 300 mg/kg (rats) and 200 mg/kg (rabbits).


Doses greater than 1,00 mg/kg produced fetotoxicity. No teratogenic effects have been reported in limited human data.

**Acute Toxicity**

Component	Type	Route	Species	Dosage
Labetalol Hydrochloride	TD <sub>LO</sub>	Oral	Human, man	8571 mg/kg/D
Labetalol Hydrochloride	LD <sub>50</sub>	Oral	Rat	>2 gm/kg
Labetalol Hydrochloride	LD <sub>50</sub>	Intravenous	Rat	>50 mg/kg
Labetalol Hydrochloride	LD <sub>50</sub>	Oral	Mouse	660 mg/kg
Labetalol Hydrochloride	LD <sub>50</sub>	Intravenous	Mouse	97 mg/kg

### Section 12 - Ecological Information

Information is currently not available on the environmental impact of Labetalol Hydrochloride. Handle in a manner to prevent spills or releases to the environment.

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	Issue Date: <b>Feb 23, 2009</b>	MSDS No.: <b>MSDS 019</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>7 of 8</b>

### Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

### Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations**

CERCLA - *Not on this list*


SARA 313 - *Not on this list*

### Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.  
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	Issue Date: <b>Feb 23, 2009</b>	MSDS No.: <b>MSDS 019</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>8 of 8</b>

**Glossary:** This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)