	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Vecuronium Bromide for Injection</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>Jul 25, 2011</b>	MSDS No.: <b>MSDS 024</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>1 of 9</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:** Vecuronium Bromide for Injection (10 mg and 20 mg/vial)  
**Product Code:** 25021-657  
 25021-658  
**Common/Trade Name:** Norcuron®  
**Chemical Name:** Vecuronium Bromide  
**Chemical Family:** Amino-Steroid  
**Product Use:** Pharmaceutical  
**Product Type:** Regulated Prescription Drug  
**Container Information:** Vials


### Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Vecuronium Bromide, USP	7	50700-72-6
Sodium Phosphate, Dibasic Anhydrous	11	7558-79-4
Citric Acid Anhydrous	14	77-92-9
Mannitol, NF	67	69-65-8
Sodium Hydroxide, NF	Trace	1310-73-2
Phosphoric Acid, NF	Trace	7664-44-2

### Section 3 - Hazards Identification

**Primary Physical and Health Hazards:** Vecuronium is a drug product that is a smooth muscle relaxer used in association with general anesthesia when intubating patients. It affects the central nervous system and muscular systems.

**Routes of Entry:** Skin, ingested and inhalation

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**Signs & Symptoms of Exposure:**

Excessive exposure may induce paralysis with risks for respiratory failure and vomiting. It may also cause irritation of eyes, skin and respiratory tract. May cause dizziness, headache, weakness and loss of coordination.

**Chemical Listed as Carcinogen:**

**NTP: No IARC: No OSHA: No**

**Medical Conditions Generally Aggravated by Exposure:**

Conditions aggravated by exposure may include skin and respiratory (asthma-like) disorders.

**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 for 15 minutes; remove contaminated clothing.

**Ingestion:**

If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information

**Injection**


See patient package insert in shipping carton for complete information.

**Inhalation:**

If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

**Notes to Physician:**

See patient package insert in shipping carton for complete information.


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### Section 5 - Fire Fighting Measures

<b>Flash Point:</b>	Not established
<b>Autoignition Temperature:</b>	Not established
<b>Flammable Limits in Air:</b>	Lower %: Not established Upper %: Not established
<b>Flammable Limits:</b>	Not established
<b>Extinguishing Media:</b>	Use water or a type ABC multi-purpose extinguisher.
<b>Special Fire Fighting Procedures:</b>	As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.
<b>Unusual Fire/Explosion Hazards:</b>	None

### Section 6 - Accidental Release Measures

<b>Spill:</b>	Lightly wet Vecuronium Bromide powder and absorb with a damp absorbent cloth. Dispose according to local, state and federal regulations. Wear latex or nitrile gloves.
<b>Release to Air:</b>	If dust enters air, reduce exposures by ventilating the area; clean up the spill immediately.
<b>Release to Water:</b>	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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## Section 7 - Handling and Storage

### General Handling:

As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

### Waste Disposal Method:

Incineration in an approved/permitted incinerator is recommended. Refer to local, state, and federal disposal guidelines.

### Storage Conditions:

Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Protect from light. Keep away from any incompatible materials or conditions (see Section 10). Store at temperatures between 15-30°C (59-86°F).

## Section 8 - Exposure Controls / Personal Protection

### Respiratory Protection:

Under normal use, respirators are not needed.

### Eye Protection:


Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

### Ventilation:

Use with adequate ventilation such as a Class II Type A Biological Safety Cabinet.

### Skin Protection:

Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

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**Other Protective Equipment:** None


**Additional Exposure Precautions:** No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

**Exposure Limits**

<b><u>Compound</u></b>	<b><u>Issuer</u></b>	<b><u>Type</u></b>	<b><u>OEL</u></b>
Vecuronium Bromide	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Citric Acid Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Sodium Phosphate Dibasic Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

**Section 9 - Physical and Chemical Properties**

<b>Physical State:</b>	Solid	<b>Specific Gravity:</b>	Not applicable
<b>Appearance And Odor:</b>	White to off-white powder, odorless	<b>Evaporation Rate:</b>	Not applicable
<b>Boiling Point:</b>	Not applicable	<b>Melting Point</b>	Not applicable
<b>Vapor Pressure:</b>	Not applicable	<b>Solubility in Water:</b>	Soluble
<b>Vapor Density:</b>	Not applicable	<b>pH:</b>	3.5-4.5
		<b>Molecular Weight:</b>	637.73

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### Section 10 - Stability and Reactivity

<b>Stability:</b>	Stable under normal storage handling conditions.
<b>Incompatibility (Materials to avoid):</b>	This product is generally compatible with other common materials in a medical facility. Keep away from strong acids, strong bases and strong oxidizers.
<b>Hazardous Decomposition:</b>	Heat may cause product to decompose, destroying the product or producing toxic fumes.
<b>Hazardous Polymerization:</b>	Will not occur.
<b>Conditions to Avoid:</b>	None


### Section 11 - Toxicological Information

<b>Signs &amp; Symptoms of Exposure:</b>	Excessive exposure may induce paralysis with risks for respiratory failure and vomiting. It may also cause irritation of eyes, skin and respiratory tract. May cause dizziness, headache, weakness and loss of coordination.
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#### Acute Toxicity

Component	Type	Route	Species	Dosage
Vecuronium Bromide	LD <sub>50</sub>	Oral	Rat	455 mg/kg
Vecuronium Bromide	LD <sub>50</sub>	Oral	Mouse	41 mg/kg
Vecuronium Bromide	LD <sub>50</sub>	Interperatoneal	Rat	2630 mcg/kg
Vecuronium Bromide	LD <sub>50</sub>	Intraperatoneal	Mouse	142 mcg/kg
Vecuronium Bromide	TD <sub>LO</sub>	Oral	Woman	130 mcg/kg
Vecuronium Bromide	LD <sub>50</sub>	Subcutaneous	Rat	1730 mcg/kg
Vecuronium Bromide	LD <sub>50</sub>	Intravenous	Rat	200 mcg/kg

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)

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## Section 12 - Ecological Information

Handle in a manner which prevents spills or releases to the environment.

## Section 13 - Disposal Considerations

**Waste Disposal:** Incineration in an approved/permitted incinerator is recommended. Refer to local, state, and federal disposal guidelines.

## Section 14 - Transport Information

**Regulatory Agencies:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** 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**

TSCA - *No*

CERCLA - *Not on this list*


SARA 302 - *Not on this list*

SARA 313 - *Not on this list*


OSHA Substance Specific - *No*

## 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.

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For additional information contact:  
Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195  
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**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)