 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 24JAN2019	SDS No.: SDS029	Revision No: 01	Page 1 of 11


### Section 1 - Identification


- (a) **Product Identifier:** Methocarbamol Injection, USP
- (b) **Product Code:** 70860-653
- Common/Trade Name:** robaxin®
- Chemical Name:** 3-(2-methoxyphenoxy)-1,2-propanediol 1-carbamate
- Chemical Family:** Analgesic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Single Dose Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:**
- US OSHA:**
- Resp. Sens. 1 H334  
 Skin Sens. 1 H317  
 STOT SE 3 H335


**(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**

<b>GHS Signal Word:</b>	Danger
<b>GHS Hazard Statement:</b>	H317 - May cause an allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 - May cause respiratory irritation.
<b>GHS Symbols:</b>	

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>2 of 11</b>

<b>GHS Precautionary Statements:</b>	<p>P261 - Avoid breathing vapors, mist, or spray.  P271 - Use only outdoors or in a well-ventilated area.  P272 - Contaminated work clothing must not be allowed out of the workplace.  P280 - Wear protective gloves, protective clothing, and eye protection.  P284 - [In case of inadequate ventilation] wear respiratory protection .  P302+P352 - If on skin: Wash with plenty of water.  P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.  P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.  P312 - Call a poison center or doctor if you feel unwell.  P321 - Specific treatment (see section 4 on this SDS).  P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.  P363 - Wash contaminated clothing before reuse.  P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  P405 - Store locked up.  P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.</p>
<b>Other Hazards</b>	<p>Exposure may aggravate pre-existing eye, skin, or respiratory conditions.</p>

**(d) Unknown Acute Toxicity** N/A

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>3 of 11</b>


### Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure*	(c) CAS No.	(d) Impurities / Stabilizing Additives
3-(2-methoxyphenoxy)-1,2-propanediol 1-carbamate	Methocarbamol, USP	1000 mg	532-03-6	N/A
Polyethylene glycol 300, USP-NF	Polyethylene glycol 300, USP-NF	5.0 mL	25322-68-3	N/A
Hydrochloric Acid, NF	Hydrochloric Acid, NF	q.s. for pH adjustment	7647-01-0	N/A
Sodium Hydroxide, NF	Sodium Hydroxide	q.s. for pH adjustment	1310-73-2	N/A
Water for Injection, USP	Water for Injection	q.s. to 10 mL	7732-18-5	N/A
Nitrogen, NF	Nitrogen	As required	7727-37-9	N/A

\*Composition of Drug product: Methocarbamol Injection USP, 1 gm/10 mL (100 mg/mL)  
q.s. – Quantity Sufficient

### Section 4 – First Aid Measures


- Eye Exposure:** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.
- Skin Exposure:** Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>4 of 11</b>

- Ingestion:** Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Injection:** In cases of accidental injection, wash and disinfect area, seek emergency medical attention.
- Inhalation:** Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. In the event of any complaints or symptoms, avoid further exposure.
- Notes to Physician:** Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

### Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** As with any fire, use extinguishing media appropriate for primary cause of fire.
- (b) **Hazardous Combustion Products:** None.
- (c) **Special Protective Equipment / Precautions:** Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>5 of 11</b>

### Section 6 - Accidental Release Measures

- Spill:** Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.
- Release to Air:** Not available.
- Release to Water:** Not available. Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.


### Section 7 - Handling and Storage

- General Handling:** Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]
- Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

### Section 8 - Exposure Controls / Personal Protection

#### (a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Dexmedetomidine Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	AIHA	WEEL	NE

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>6 of 11</b>

**Notes:**

OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit

ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

AIHA WEEL: Workplace Environmental Exposure Level

**(b) Engineering Controls**


Local exhaust and general ventilation must be adequate to meet exposure standards.

**(c) Individual Protection Measures**

Respiratory Protection:	Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Eye Protection:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side shields.
Skin Protection:	Wear suitable working clothes
Other Protective Equipment:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

**Section 9 - Physical and Chemical Properties**

<b>(a) Appearance</b>	clear, colorless liquid
<b>(b) Odor</b>	Not available
<b>(c) Odor Threshold</b>	Not available
<b>(d) pH</b>	3.5 to 6.0
<b>(e) Melting Point:</b>	Not available
<b>(f) Initial Boiling Point:</b>	Not available
<b>(g) Flash Point</b>	Not available
<b>(h) Evaporation Rate:</b>	Not available
<b>(i) Flammability</b>	Not available

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 24JAN2019	SDS No.: SDS029	Revision No: 01	Page 7 of 11


<b>(j)</b>	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
<b>(k)</b>	<b>Vapor Pressure:</b>	Not available
<b>(l)</b>	<b>Vapor Density:</b>	Not available
<b>(m)</b>	<b>Relative Density</b>	Not available
<b>(n)</b>	<b>Solubility(ies)</b>	Not available
<b>(o)</b>	<b>Partition Coefficient: n-octanol/water</b>	Not available
<b>(p)</b>	<b>Auto-ignition Temperature</b>	Not available
<b>(q)</b>	<b>Decomposition Temperature</b>	Not available
<b>(r)</b>	<b>Viscosity</b>	Not available

### Section 10 - Stability and Reactivity

<b>(a)</b>	<b>Reactivity</b>	Not determined
<b>(b)</b>	<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	Will not occur.
<b>(d)</b>	<b>Conditions to Avoid</b>	Not determined
<b>(e)</b>	<b>Incompatible Materials</b>	Oxidizing materials, acids and alkalis
<b>(f)</b>	<b>Hazardous Decomposition Products</b>	None known.

### Section 11 - Toxicological Information

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Possibly skin, eyes, mouth
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	<p>Skin corrosion/irritation: Causes skin irritation.</p> <p>Serious eye damage/irritation: Causes serious eye irritation.</p> <p>Respiratory or skin sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.</p> <p>Germ cell mutagenicity: Not classified</p> <p>Carcinogenicity: Not classified</p>

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>8 of 11</b>

<b>(c)</b>	<b>Delayed and immediate effects and chronic effects from short and long term exposure</b>	<p>Symptoms/injuries after inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>Symptoms/injuries after skin contact: May cause an allergic skin reaction.</p> <p>Symptoms/injuries after eye contact: Causes serious eye irritation.</p> <p>Symptoms/injuries after ingestion: May be harmful if swallowed.</p>
------------	--	---

**(d) Acute Toxicity**  
Not determined

Component	Type	Route	Species	Dosage
1,2-Propanediol, 3-(2-methoxyphenoxy)- -, 1-carbamate	LD <sub>50</sub> ATE US	Oral Oral	Rat -	1320 mg/kg 1320.000 mg/kg body weight
Polyethylene glycol	LD <sub>50</sub> LD <sub>50</sub> ATE US	Oral Dermal Oral	Rat Rat -	22 g/kg >20 ml/kg 28000000.000 mg/kg
Water	LD <sub>50</sub>	Oral	Rat	>90 ml/kg
Hydrochloric Acid	LD <sub>50</sub> LD <sub>50</sub> LC <sub>50</sub>  ATE US	Oral Dermal Inhalation  Gases	Rat Rabbit Rat (mg/l)  -	238-277 mg/kg >5010 mg/kg 1.68 mg/l (Exposure time: 1 hour) 781.000 ppmV/4h
Sodium Hydroxide	LD <sub>50</sub> ATE US	Dermal Dermal	Rabbit -	1350 mg/kg 1350.00 mg/kg


**(e) Hazardous Chemical Listings**

NTP: Not Listed      IARC: Not Listed      OSHA: Not Listed

**Section 12 - Ecological Information**

<b>(a)</b>	<b>Ecotoxicity</b>	LC <sub>50</sub> fish 1: 45.4 mg/l (Exposure time: 96 h - Species: <i>Oncorhynchus mykiss</i> [static])
------------	--------------------	---



 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>9 of 11</b>

<b>(b)</b>	<b>Persistence and degradability</b>	No applicable ecological information found.
<b>(c)</b>	<b>Bioaccumulative potential</b>	No applicable ecological information found.
<b>(d)</b>	<b>Mobility in soil</b>	No applicable ecological information found.
<b>(e)</b>	<b>Other Adverse Effects</b>	No applicable ecological information found.

**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**

**DOT:** Not regulated as a dangerous good.  
**IATA:** Not regulated as a dangerous good.  
**IMDG:** Not regulated as a dangerous good.


<b>(a)</b>	<b>UN Number</b>	N/A
<b>(b)</b>	<b>UN Proper Shipping Name</b>	N/A
<b>(c)</b>	<b>Transport Hazard Class(es)</b>	N/A
<b>(d)</b>	<b>Packing Group</b>	N/A
<b>(e)</b>	<b>Environmental Hazards</b>	N/A
<b>(f)</b>	<b>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	N/A
<b>(g)</b>	<b>Special Precautions</b>	N/A

**Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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 – Listed
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 311/312: Immediate (acute) health hazard
- SARA 313 - Not on this list
- OSHA – Not on this list

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>10 of 11</b>

### Section 16 - Other Information


As of the date of effectiveness, 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 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:

Athenex Pharmaceutical Division  
 10 N. Martingale Road, Suite 230  
 Schaumburg, IL 60173  
 847-886-9515

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
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

 <b>Pharmaceutical Division</b>	<b>Methocarbamol Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: <b>24JAN2019</b>	SDS No.: <b>SDS029</b>	Revision No: <b>01</b>	Page <b>11 of 11</b>

NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
SDS	Safety Data Sheet
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)
WHMIS	Workplace Hazardous Materials Information System

## Signature Manifest

**Document Number:** SDS029

**Revision:** 01

**Title:** Methocarbamol Injection, USP

All dates and times are in Eastern Standard Time.

### Methocarbamol Injection, USP

#### Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Corporate Quality	21 Jan 2019, 12:47:44 PM	Approved

#### Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	24 Jan 2019, 09:08:37 AM	Approved

#### Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	25 Jan 2019, 11:21:35 AM	Approved