

SDS Title: Methocarbamol Injection USP Safety Data Sheet	SDS Number: SDS-000009	Page Number: Page 1 of 10
Function: Regulatory Affairs	Effective Date: November 09, 2020	Version Number: 2.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Methocarbamol Injection, USP (100mg/mL)

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Medical Treatment: Analgesic

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631  
224-443-4617

[www.meithealpharma.com](http://www.meithealpharma.com)

### 1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

Resp. Sens. 1 H334  
Skin Sens. 1 H317  
STOT SE 3 H335

Full text of hazard classes and H-statements: see section 16

### 2.2. Label Elements

#### GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) :

Danger

Hazard Statements (GHS-US) :

H317 - May cause an allergic skin reaction.  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H335 - May cause respiratory irritation.

Precautionary Statements (GHS-US) :

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.



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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.

**2.3. Other Hazards**

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

**2.4. Unknown Acute Toxicity (GHS-US)**

No data available

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1. Substance**

Not applicable

**3.2. Mixture**

Name	Product Identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	39.96	Not classified
Polyethylene glycol	(CAS-No.) 25322-68-3	50	STOT SE 3, H335
1,2-Propanediol, 3-(2-methoxyphenoxy)-, 1-carbamate	(CAS-No.) 532-03-6	10	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT SE 3, H336
Hydrochloric acid	(CAS-No.) 7647-01-0	0.017	Press. Gas (Comp.), H280 Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400
Sodium hydroxide	(CAS-No.) 1310-73-2	0.024	Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-phrases: see section 16



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## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** May cause respiratory irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization. Common clinical side effects include: headache, dizziness, light-headedness, drowsiness, and sedation.

**Symptoms/Injuries After Inhalation:** Irritation of the respiratory tract and the other mucous membranes. Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

**Symptoms/Injuries After Skin Contact:** May cause an allergic skin reaction.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects. Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** None known.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, dry chemical, foam, carbon dioxide. Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers. Remove containers from fire area if this can be done without risk. Do not breathe fumes from fires or vapors from decomposition.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Thermal decomposition generates: Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides.

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## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing.

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Contains substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, and spray. Avoid contact with skin, eyes and clothing. Use appropriate personal protective equipment (PPE).

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures. Wash contaminated clothing before reuse.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Containers which are opened should be properly resealed and kept upright to prevent leakage. Store locked up.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Reducing agents. Water reactive materials.

### 7.3. Specific End Use(s)

Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions.

Medical Treatment: Analgesic

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## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters


For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> (MW>200, aerosol)

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>

### 8.2. Exposure Controls

- |  |   |
|--|---|
| <p>Appropriate Engineering Controls</p> <p>Personal Protective Equipment</p>   | <p>: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.</p> <p>: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.</p> |
|    |   |
| <p>Materials for Protective Clothing</p> <p>Hand Protection</p> <p>Eye and Face Protection</p> <p>Skin and Body Protection</p> | <p>: Chemically resistant materials and fabrics.</p> <p>: Wear protective gloves.</p> <p>: Chemical safety goggles.</p> <p>: Wear suitable protective clothing. In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.</p>                            |
| <p>Respiratory Protection</p>  | <p>: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.</p>   |
| <p>Other Information</p>   | <p>: When using, do not eat, drink or smoke.</p>  |

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## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Colorless
Odor	: No data available
Odor Threshold	: No data available
pH	: 3.5 - 6
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
<b>Flammability (solid, gas)</b>	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
<b>Solubility</b>	: No data available
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
<b>Viscosity</b>	: No data available

### 9.2. Other Information No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Reducing agents. Water reactive materials.
- 10.6. Hazardous Decomposition Products:** Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

<b>Hydrochloric acid (7647-01-0)</b>	
LD50 Oral Rat	238 (238 - 277) mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	1411 ppm
LC50 Inhalation Rat	0.42 mg/l/4h
ATE (Gases)	700.00 ppmV/4h

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ATE (Vapors)	1.68 mg/l/4h
<b>Sodium hydroxide (1310-73-2)</b>	
LD50 Oral Rat	140 - 340 mg/kg
ATE (Oral)	140.00 mg/kg body weight

<b>Polyethylene glycol (25322-68-3)</b>	
LD50 Oral Rat	22 g/kg
LD50 Dermal Rabbit	> 20 ml/kg

<b>1,2-Propanediol, 3-(2-methoxyphenoxy)-, 1-carbamate (532-03-6)</b>	
LD50 Oral Rat	1320 mg/kg

**Skin Corrosion/Irritation:** Not classified.

**pH:** 3.5 - 6

**Serious Eye Damage/Irritation:** Not classified.

**pH:** 3.5 - 6

**Respiratory or Skin Sensitization:** May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

<b>Hydrochloric acid (7647-01-0)</b>	
IARC group	3

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** May cause respiratory irritation.

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Irritation of the respiratory tract and the other mucous membranes. Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

**Symptoms/Injuries After Skin Contact:** May cause an allergic skin reaction.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects. Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

<b>Hydrochloric acid (7647-01-0)</b>	
EC50 Daphnia 1	0.492 mg/l
<b>Sodium hydroxide (1310-73-2)</b>	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

### 12.2. Persistence and Degradability

<b>Methocarbamol Injection USP, 100 mg/mL</b>
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<b>Persistence and Degradability</b>	Not established.
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**12.3. Bioaccumulative Potential**

<b>Methocarbamol Injection USP, 100 mg/mL</b>	
<b>Bioaccumulative Potential</b>	Not established.

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects**

**Other Information** : Avoid release to the environment.

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1. Waste Treatment Methods**

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions.

**Ecology - Waste Materials:** Avoid release to the environment.

**SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

- 14.1. In Accordance with DOT** Not regulated for transport
- 14.2. In Accordance with IMDG** Not regulated for transport
- 14.3. In Accordance with IATA** Not regulated for transport

**SECTION 15: REGULATORY INFORMATION**

**15.1. US Federal Regulations**

<b>Methocarbamol Injection USP, 100 mg/mL</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Immediate (acute) health hazard
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
<b>CERCLA RQ</b>	5000 lb
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	500 lb (gas only)
<b>SARA Section 313 - Emission Reporting</b>	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
<b>Sodium hydroxide (1310-73-2)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>CERCLA RQ</b>	1000 lb
<b>Polyethylene glycol (25322-68-3)</b>	





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Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)).

<b>1,2-Propanediol, 3-(2-methoxyphenoxy)-, 1-carbamate (532-03-6)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory

### 15.2. US State Regulations

<b>Hydrochloric acid (7647-01-0)</b>
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List
<b>Sodium hydroxide (1310-73-2)</b>
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

### SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

<b>Date of Preparation or Latest Revision</b>	: 11/09/2020
<b>Other Information</b>	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

#### GHS Full Text Phrases:

Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Press. Gas (Comp.)	Gases under pressure Compressed gas
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H280	Contains gas under pressure; may explode if heated
H290	May be corrosive to metals

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H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H400	Very toxic to aquatic life
H402	Harmful to aquatic life

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

Effective