

Methocarbamol Tablets, 500 mg and 750 mg

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Date of Issue: 12/04/2019

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Methocarbamol Tablets, 500 mg and 750 mg

1.2. Intended Use of the Product

Use of the Substance/Mixture: Regulated prescription drug

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

Company

Oxford Pharmaceuticals, LLC

301 Leaf Lake Parkway

Birmingham, AL 35211

T 205-434-9649

www.oxford-rx.com

1.4. Emergency Telephone Number

Emergency Number : ChemTel Inc.
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Acute Tox. 4 (Oral) H302

Resp. Sens. 1 H334

Skin Sens. 1 H317

STOT SE 3 H336

Comb. Dust

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)

: H302 - Harmful if swallowed.
H317 - May cause an allergic skin reaction.
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
H336 - May cause drowsiness or dizziness.

If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
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.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
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).
P330 - Rinse mouth.

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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	Synonyms	Product Identifier	%	GHS US classification
1,2-Propanediol, 3-(2-methoxyphenoxy)-, 1-carbamate	Carbamic acid, 2-hydroxy-3-(o-methoxyphenoxy)propyl ester / 1-Carbamoyloxy-2-hydroxy-3-(2'-methoxyphenoxy)-propane / 3-(o-Methoxyphenoxy)-1, 2-propanediol-1-carbamate / Methocarbamol / 1,2-Propanediol, 3-(o-methoxyphenoxy)-, 1-carbamate / 3-2-(Formylphenoxy)-2-hydroxypropyl carbamate	(CAS-No.) 532-03-6	85 - 95	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT SE 3, H336
Starch	High amylose cornstarch / Starch, edible / Corn starch / AVENA SATIVA STARCH / Starches	(CAS-No.) 9005-25-8	3 - 9	Comb. Dust
2-Pyrrolidinone, 1-ethenyl-, homopolymer	Polyvinylpyrrolidone / PVP / Poly(vinylpyrrolidone) / Poly(1-vinyl-2-pyrrolidinone) / Poly(1-ethenyl-2-pyrrolidinone) / N-Vinylpyrrolidone polymer / Sokalan HP 80 / Tolpovidone I 131 / Providone / Poly(1-ethenylpyrrolid-2-one) / Crospovidone / Povidone	(CAS-No.) 9003-39-8	1 - 3	Comb. Dust
Starch, carboxymethyl ether, sodium salt	Starch carboxymethyl ether sodium salt / Starch, carboxymethyl ether, monosodium salt / Starch, carboxymethyl, sodium salt / Sodium starch glycolate / Sodium Carboxymethyl Starch / Sodium carboxymethoxystarch / Sodium carboxymethylstarch / SODIUM CARBOXYMETHYL STARCH / Sodium carboxymethyl starch	(CAS-No.) 9063-38-1	0.5 - 2	Comb. Dust
Stearic acid	1-Heptadecanecarboxylic acid / Neo-fat 18 / n-Octadecanoic acid / Octadecanoic acid / STEARIC ACID	(CAS-No.) 57-11-4	0.2 - 1	Comb. Dust
Silica, amorphous, fumed, crystalline-free	Colloidal silica / Silica, amorphous, fumed / Pyrogenic colloidal silica / Synthetic amorphous silica / Pyrogenic, fumed, amorphous silica / Silica, amorphous, crystalline-free / SILICA / Aquafil / Amorphous silicon dioxide / Silica, amorphous, fumed, crystalline free / Fumed silica	(CAS-No.) 112945-52-5	0.1 - 0.5	Not classified
Magnesium stearate	Octadecanoic acid, magnesium salt / Stearate, magnesium / Stearic acid, magnesium salt / Octadecanoic acid, magnesium salt (2:1) / Magnesium distearate / MAGNESIUM STEARATE / Salts of stearic acids with magnesium bases / Magnesium octadecanoate / Bis(octadecanoic acid)magnesium salt / Salt of stearic acid with magnesium base / Dioctadecanoate magnesium	(CAS-No.) 557-04-0	0.1 - 0.5	Comb. Dust

Full text of H-phrases: see section 16

The specific chemical identity and/or exact percentage of composition have been withheld as a trade secret [29 CFR 1910.1200].

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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: Immediately remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

First-aid Measures After Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. 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: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk. . May cause drowsiness and dizziness. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization. Harmful if swallowed.

Symptoms/Injuries After Inhalation: High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headache, and similar narcotic symptoms. 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: Skin contact with large amounts of dust may cause mechanical irritation. May cause an allergic skin reaction.

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

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects. This material is harmful orally and can cause adverse health effects or death in significant amounts.

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, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

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: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Explosion Hazard: Dust generated from processing may present a dust explosion hazard.

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.

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

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust.

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: 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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

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6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. 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: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Precautions for Safe Handling: Avoid breathing dust. Do not get in eyes, on skin, or on clothing. Handle empty containers with care because they may still present a hazard. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

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 place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Strong oxidizers.

7.3. Specific End Use(s)

Regulated prescription drug

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).

Stearic acid (57-11-4)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³ (inhalable particulate matter (Stearates)) 3 mg/m ³ (respirable particulate matter (Stearates))
Magnesium stearate (557-04-0)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³ (inhalable particulate matter (Stearates)) 3 mg/m ³ (respirable particulate matter (Stearates))
Starch (9005-25-8)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear protective gloves.

Eye and Face Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : 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.

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Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Tablet
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
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
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: 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. Dust accumulation (to minimize explosion hazard)
- 10.5. **Incompatible Materials:** Strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Harmful if swallowed.

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

Methocarbamol Tablets, 500 mg and 750 mg	
ATE (Oral)	1,466.67 mg/kg body weight
1,2-Propanediol, 3-(2-methoxyphenoxy)-, 1-carbamate (532-03-6)	
LD50 Oral Rat	1320 mg/kg
2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)	
LD50 Oral Rat	100000 mg/kg
Silica, amorphous, fumed, crystalline-free (112945-52-5)	
LD50 Oral Rat	3160 mg/kg
Stearic acid (57-11-4)	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
Magnesium stearate (557-04-0)	
LD50 Oral Rat	> 2000 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

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

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)	
IARC group	3
Silica, amorphous, fumed, crystalline-free (112945-52-5)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): May cause drowsiness or dizziness.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headache, and similar narcotic symptoms. 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: Skin contact with large amounts of dust may cause mechanical irritation. May cause an allergic skin reaction.

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

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects. This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

Methocarbamol Tablets, 500 mg and 750 mg	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Methocarbamol Tablets, 500 mg and 750 mg	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil

Stearic acid (57-11-4)	
Log Koc	51.05

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

Methocarbamol Tablets, 500 mg and 750 mg	
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Respiratory or skin sensitization Health hazard - Acute toxicity (any route of exposure) Physical hazard - Combustible dust

1,2-Propanediol, 3-(2-methoxyphenoxy)-, 1-carbamate (532-03-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Starch, carboxymethyl ether, sodium salt (9063-38-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

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EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Stearic acid (57-11-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Magnesium stearate (557-04-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Starch (9005-25-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

15.2. US State Regulations

Starch (9005-25-8)
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List

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

Date of Preparation or Latest Revision : 12/04/2019

Other Information : 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. 4 (Oral)	Acute toxicity (oral) Category 4
Comb. Dust	Combustible Dust
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H336	May cause drowsiness or dizziness

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.

SDS US (GHS HazCom)