SAFETY DATA SHEETS

This SDS packet was issued with item:

078935644

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078935642 078937220

1. Chemical Product and Company Identification

Product identifier: - Methocarbamol Tablets USP 500 mg/750 mg
Chemical Name: 1,2-Propanediol, 3-(2-methoxyphenoxy)-, 1-carbamate, (+/-)-
Synonym: Guaiacol glyceryl ether carbamate * Guaiphenesin carbamate
Chemical Formula: C11H15NO5
Manufacturer information and Address: -GRANULES INDIA LIMITED
Sy No. 160/A, 161, 162 & 174, Gagillapur village,
Dundigal - Gandimaisamma Mandal, Medchal-
Malkajgiri District, Telangana, PIN – 500 043,
Ph. No.: 91-8418-306400
Fax: 91-8418-306402

2. Hazard(s) identification

Physical hazards: Not classified.
Health hazards: Acute toxicity, oral Category 4
Specific target organ toxicity, single exposure: Category 3 (Narcotics effects)
OSHA hazard(s): Not classified.
Label Elements:

Pictogram	
Signal word	**Warning**

Hazard statement: Harmful if swallowed. May cause drowsiness or dizziness.
Precautionary statement:
Prevention: Use only outdoors or in a well-ventilated area. Wash thoroughly after handling.
Response: If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked
Disposal: Dispose of contents/container in accordance with local/regional/national/international
Hazard(s) Not Otherwise Classified (HNOC): Not classified.

3. Composition/Information on Ingredients

Composition Name:	Common name and synonyms	CAS No.	% by Weight
Methocarbamol	Guaiacol glyceryl ether carbamate Guaiphenesin carbamate	532-03-6	90

Excipients:
Colloidal Silicon Dioxide, USP NF/Ph.Eur Maize Starch,
USP NF/Ph.Eur

Povidone K-30, USP NF/Ph.Eur
Sodium Starch Glycolate, USP NF/Ph.Eur
Sodium lauryl sulfate, USP NF/Ph.Eur
Stearic acid, USP NF/Ph.Eur

4. First Aid Measures

Inhalation: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists**.**
Eye Contact: Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists**.**

Most important symptoms/effects, acute and delayed: Dizziness, Drowsiness.

Indication of immediate medical attention and special treatment needed:

Treatment of overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as slurry.
2. DO NOT induce vomiting.
3. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine.
4. For seizures, administer intravenous benzodiazepines. If seizures are uncontrollable or recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia.
5. Monitor cardiac and respiratory functions.
6. The usefulness of forced diuresis or hemodialysis has not been determined. [Meditext 2007 and USP DI 2007]

General information:

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-Fighting Measures

Suitable extinguishing media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media: None known.
Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters
Wear suitable protective equipment.
Fire-fighting equipment/instructions
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods: Cool containers exposed to flames with water until well after the fire is out.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and Storage

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities:
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Exposure Limits: No exposure standards allocated.
Biological limit values: No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls:
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment:
Eye/face protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection:
Hand protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other: For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination

Respiratory protection: Where respirators are deemed necessary to reduce or control Occupational exposures use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards: Not available
General hygiene: Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Physical state and appearance	:	Solid (White powder.)
Odor	:	Odorless or slight characteristic odor
Molecular Weight	:	206.29 g/mole
Color	:	White
pH (1% solution/water)	:	Not applicable
Boiling Point	:	Not available
Melting Point	:	197.6 - 201.2 °F (92 - 94 °C)
Critical Temperature	:	Not available
Flammability (solid, gas)	:	Not applicable
Evaporation rate	:	Not available
Specific Gravity	:	Not available
Vapor Pressure	:	0.0000001 kPa at 25 °C
Vapor Density :	:	Not available
Volatility	:	Not available
Odor Threshold	:	Not available
Water/Oil Dist. Coeff.	:	Not available
Ionicity (in Water)	:	Not available
Dispersion Properties :	:	Not available
Solubility	:	Insoluble in cold water, Very soluble in alcohol, in methanol, in acetone, and in chloroform; slightly soluble in ethyl acetate
Viscosity	:	Not available
Auto-ignition temperature	:	Not available
Chemical family	:	Phenol derivative.

10. Stability and Reactivity Data

Reactivity : No reactivity hazards known
Chemical stability : Stable at normal conditions.
Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
Conditions to avoid : None known.
Incompatible materials : Strong oxidizing agents.
Hazardous decomposition products: NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

11. Toxicological Information

Information on likely routes of exposure
Ingestion: Harmful if swallowed.
Inhalation: Due to lack of data the classification is not possible.
Skin contact: Due to lack of data the classification is not possible.
Eye contact: Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics:
Dizziness. Drowsiness. Headache. Confusion. Changes in vision. Uncontrolled eye movements. Insomnia. Nausea. Vomiting. Loss of appetite. Dry mouth. Fever. Skin inflammation. Itching. Red eyes. Nasal congestion.

Delayed and immediate effects of exposure:
Low blood pressure. Central nervous system depression.

Medical conditions aggravated by exposure:
Active alcoholism. Impaired liver function. Impaired kidney function. Myasthenia gravis. Epilepsy, or history of epilepsy..

Acute toxicity: Harmful if swallowed.

Product	Species	**Test Results**
Methocarbamol (CAS 532-03-6)		
Acute		
Oral		
LD50	Mouse	812 mg/kg
	Rat	1320 mg/kg

Skin corrosion/irritation: Due to lack of data the classification is not possible.
Serious eye damage/eye irritation: Due to lack of data the classification is not possible.
Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Due to lack of data the classification is not possible.
Sensitization: There have been reports of allergic reactions including anaphylaxis following therapeutic use of this material.

Germ cell mutagenicity:
Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found. This material was not mutagenic in a standard battery of genetic toxicological tests.

Carcinogenicity:
Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA

Reproductive toxicity:
Due to lack of data the classification is not possible. In humans, there have been rare reports of fetal abnormalities and birth defects following in utero exposure to methocarbamol. The Collaborative Perinatal Project did not find an association between first trimester use of methocarbamol and birth defects in 22 women exposed during pregnancy.

Specific target organ toxicity - single exposure: Narcotic effects.
Specific target organ toxicity - repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity : No ecotoxicity data noted for the ingredient(s).
Persistence and degradability: No data is available on the degradability of this product.
Bioaccumulative potential : Not available.
Mobility in soil : Not available.
Other adverse effects : Not available.

13. Disposal considerations

Disposal instructions:
This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
Local disposal regulations: Not available
Hazardous waste code: Not available.
Waste from residues / unused products:
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging:
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

DOT: Not regulated as a hazardous material by DOT.
IATA: Not regulated as a dangerous good.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
No information available.

15. Regulatory Information

Regulatory information on this product is not available.

16. Other Information

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End of Material Safety Data Sheet