



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Section 1, Identification	
GHS Product identifier	Clobazam Tablets 10mg and 20mg
Trade Name	Not applicable
Other means of identification Synonyms	Clobazam, Finished product
Recommended use	Pharmaceutical product for the treatment of Antihistamine
Manufacturer	Hetero Labs Limited , Unit III, 22-110, Part-II, Industrial Development Area, Jeedimetla, Hyderabad, Telangana, India - 500055
Distributor	Camber Pharmaceuticals, Inc , Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Section 2, Hazard(s)identification	
Classified hazards	Non-Hazardous Substance. Non-Dangerous Goods. Exempt from requirements
Label elements	
Hazard statement Environment	Harmful if swallowed or in contact with skin and Harmful if inhaled.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Clobazam, IH	22316-47-8
Lactose monohydrate	64044-51-5
Granulated corn starch	9005-25-8
Colloidal Silicon Dioxide, (Aerosil 200)	7631-86-9 or 112926-00-8
Talc	14807-96-6
Magnesium stearate	557-04-0



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Section 4: First-Aid Measures

Inhalation	Immediately wash skin with soap and copious Amount of water for at least 15 minutes. If Irritation persists seek medical attention.
Skin Contact	Remove any contaminated clothing. Wash exposed area thoroughly with soap and wate. If irritation occurs or persisits, seek Medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Ingestion	Never give anything by mouth to an unconscious person.Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Suitable Extinguishing Media	Use carbon dioxide, dry chemical.
Unsuitable Extinguishing Media	No data Available
Specific hazards arising from During fire, gases hazardous to health may be formed. the chemical	Not expected for the product, although the packaging is combustible.
Special protective equipment and precautions for firefighters	No data Available
special firefighting procedures	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
Specific methods	No data Available



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Section 6: Accidental Release Measures

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Personal precautions, protective equipment and emergency procedures	No additional information
Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Methods and materials for containment and cleaning up	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions. Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Additional Consideration for Large Spills	Wash clothing and equipment after handling.

Section 7: Handling and Storage

Section 7, Handling and storage

Handling	Precautions for safe handling No special precautions are necessary if used correctly.
Conditions for safe storage, including any incompatibilities	Store clobazam Tablets Store at 20 to 25°C (68 to 77° F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Components	Type	
	ACGIH TLV	OSHA PEL
Lactose monohydrate	Not available	Not available
Granulated corn starch	10 mg/m ³	15 mg/m ³
Colloidal Silicon Dioxide, (Aerosil 200)	10 mg/m ³	6 mg/m ³
Talc	2 mg/m ³	2 mg/m ³
Magnesium stearate	10	Not available
Appropriate engineering Control	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.	



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Individual protection measures, such as personal protective equipment	
Eye/face protection	Protective goggles.
Skin protection Hand protection	Protective clothing.
Respiratory protection	Gas mask with filter type A.
Hygiene considerations	The present safety data sheet is consistent with the specific conditions relied on to justify the registration of the substance as isolated intermediate.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties	
Physical State	Tablet
Form	Tablets
Colour	White-Clobazam Tablets 10mg and 20 mg
Odor	Not available
Description	<p>Clobazam Tablets 10mg</p> <p>White to off white, oval tablets debossed 'C' and '9' along with functional score on one side and 'H' on the other side.</p> <p>Bottle of 100 Tablets (NDC 31722-639-01) 10 X10's unit dose pack (NDC 31722-639-31)</p> <p>Clobazam Tablets 20mg</p> <p>White to off white, oval tablets debossed 'C' and '13' along with functional score on one side and 'H' on the other side.</p> <p>Bottle of 100 Tablets (NDC 31722-640-01) 10 X10's unit dose pack (NDC 31722-640-31)</p>

Section 10: Stability and Reactivity

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Reactivity	Product is not explosive.
Chemical stability	Stable under normal conditions of use.
Reactions	No additional information available



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Conditions to avoid	No additional information available
Incompatible materials	As a precautionary measure. Keep away from strong oxidizers.
Hazardous decomposition	Not available

Section 11: Toxicological Information

Information on likely routes of exposure	
Inhalation	No data available
Skin contact	No data available
Eye contact	No data available
Ingestion	No data available

Acute toxicity :

Components	LD50 oral	LD50 dermal	LD50 inhalation
Lactose monohydrate	10,000 mg/kg-Rat	Not available	Not available
Granulated corn starch	Not available	Not available	Not available
Colloidal Silicon Dioxide, (Aerosil 200)	>10000 mg/kg-Rat	>5000 mg/kg (Rabbit)	Not available
Talc	Not available	Not available	Not available
Magnesium stearate	Not available	Not available	Not available

Skin corrosion/irritation	No data available
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
Effects on Fertility:	No data available
Specific target organ toxicity - single exposure (GHS)	No data available
Specific target organ toxicity - repeated exposure (GHS)	No data available
Aspiration hazard	No data available

Section 12: Ecological Information

Toxicity : Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

Components	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Daphnia Magna(Water flea)
Lactose monohydrate	Not available	Not available	Not available	Not available
Granulated corn starch	Not available	Not available	Not available	Not available



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Components	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Daphnia Magna(Water flea)
Colloidal Silicon Dioxide, (Aerosil 200)	Not available	Not available	Not available	Not available
Talc	Not available	Not available	Not available	Not available
Magnesium stearate	Not available	Not available	Not available	Not available
Section 13: Disposal Considerations				
Waste treatment methods				
Disposal instructions		Dispose in accordance with local, state, and federal regulations.		
Local disposal regulations		No data available		
Hazardous waste code		No data available		
Waste from residues I unused		No data available		
Contaminated packaging		No data available		
Section 14: Transport Information				
DOT				
UN-Number Proper shipping name Hazard class Reportable quantity Description Emergency response guide Number		Not applicable		
IATA				
UN-Number Proper shipping name Hazard class Description		Not applicable		
IMDG				
UN-Number Proper shipping name Hazard class Reportable quantity Description Emergency response guide Number		Not applicable		
Section 15: Regulatory Information				
U.S State regulations				
California Proposition 65: This product does not content any proposition 65 chemicals				



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Section 16: Other Information

Section 16, Other information

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Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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