

SAFETY DATA SHEET

1. Identification

Product identifier	CLONAZEPAM TABLETS USP 0.5 mg, 1 mg and 2 mg
Other means of identification	
Synonyms	CLONAZEPAM TABLETS USP 0.5 mg * CLONAZEPAM TABLETS USP 1 mg * CLONAZEPAM TABLETS USP 2 mg
Recommended use	Not available.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Distributor	
Company name	Accord Healthcare, Inc.
Address	1009 Slater Road Suite 210-B Durham, NC 27703, USA.
Telephone number	1-919-941-7880
Fax	1-919-941-7881
Contact Name	Technical Representative
Website	www.accord-healthcare.com
Emergency telephone number	1-800-424-9300 Call CHEMTREC Day or Night
Manufacturer	
Company name	Intas Pharmaceuticals Limited,
Address	Plot No.: 457 – 458, Village: Matoda, Taluka: Sanand, Sarkhej - Bavla Highway, District: Ahmedabad Gujarat, India. 382 210

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 2
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2 (respiratory system, immune system, central nervous system, blood)
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	Suspected of damaging fertility or the unborn child. May cause drowsiness or dizziness. May cause damage to organs (respiratory system, immune system, central nervous system, blood) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If exposed or concerned: Get medical advice/attention.

Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Finished Pharmaceutical products in their final packages are not subject to OSHA labeling requirements. Handling pharmaceutical products in workplace is subject to OSHA requirements for labeling.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
CLONAZEPAM	1622-61-3	Proprietary
Cellulose	9004-34-6	Proprietary
D-LACTOSE	63-42-3	Proprietary
FD AND C BLUE NO. 2, ALUMINUM LAKE	16521-38-3	Proprietary
FD&C Yellow #6 aluminum lake	15790-07-5	Proprietary
Lactose monohydrate	64044-51-5	Proprietary
Magnesium distearate	557-04-0	Proprietary
Starch	9005-25-8	Proprietary

Composition comments	All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. Active: Clonazepam. Inactive: Anhydrous lactose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and starch (corn), with the following colorants: 0.5 mg-FD&C Yellow No. 6 Lake and 1 mg-FD&C Blue No.2 Lake.
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4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content does not get into the lungs. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	May cause drowsiness and dizziness. Narcosis. Headache. Nausea, vomiting. Behavioral changes. Decrease in motor functions. Swallowing may cause gastrointestinal irritation. Dusts may irritate the respiratory tract, skin and eyes. Prolonged exposure may cause chronic effects. Adverse effects of benzodiazepines may include memory loss, confusion, false sense of well-being, drowsiness, dizziness, weakness, unsteadiness, headache, blurred or double vision, slurred speech, nausea, diarrhea, and constipation. Clonazepam may also cause weight gain, abnormal eye movements, chest congestion, and dry mouth or hypersalivation. Possible allergic reaction to material if inhaled, ingested, or in contact with skin. Overdose effects include the adverse effects listed above and fast or slow heartbeat; low blood pressure; troubled breathing; cold, clammy skin; coma; and death.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. PRE-EXISTING MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED BY EXPOSURE: Hypersensitivity to material, alcohol or drug abuse, laucoma, myasthenia gravis, lung disease, sleep apnea, kidney or liver impairment, porphyria, seizure disorders, and mental disorders such as depression.

General information IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media Water spray. Dry chemical. Carbon dioxide (CO₂). Foam.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical The product may form dust and can accumulate electrostatic charges, which may cause an electrical spark (ignition source). Use proper grounding procedures. During fire, gases hazardous to health may be formed. Crushed and broken tablets can cause a dust combustion / explosion hazards.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Evacuate personnel to safe area. Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Minimize dust generation and accumulation. The product may form dust and can accumulate electrostatic charges, which may cause an electrical spark (ignition source). Use proper grounding procedures. Provide appropriate exhaust ventilation at places where dust is formed. Do not breathe dust. Avoid prolonged exposure. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Store in a dry place. Store in a well-ventilated place. Store at room temperature. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Cellulose (CAS 9004-34-6)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
Starch (CAS 9005-25-8)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Cellulose (CAS 9004-34-6)	TWA	10 mg/m ³

US. ACGIH Threshold Limit Values

Components	Type	Value
Magnesium distearate (CAS 557-04-0)	TWA	10 mg/m ³
Starch (CAS 9005-25-8)	TWA	10 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Cellulose (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total
Starch (CAS 9005-25-8)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Skin protection	
Other	Wear appropriate chemical resistant clothing.
Respiratory protection	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Observe any medical surveillance requirements.

9. Physical and chemical properties

Appearance	0.5 mg tablet: orange, round, flat faced, beveled edge, scored, debossed with "1" and "2" on one side and plain on the other. 1 mg tablet: blue, round, flat faced, beveled edge, debossed with "C 1" on one side and plain on the other. 2 mg tablet: white to off white, round, flat faced, beveled edge tablets debossed with "C 2" on one side and plain on the other.
Physical state	Solid.
Form	Tablet.
Color	Various colors.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions Hazardous polymerization will not occur.

Conditions to avoid Light. Avoid heat, flames, sparks, and other sources of ignition. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents. Fluorine.

Hazardous decomposition products Hydrogen Chloride (HCl). Nitrogen oxides (NOx).

11. Toxicological information**Information on likely routes of exposure**

Inhalation May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dust may irritate respiratory system.

Skin contact Dust or powder may irritate the skin.

Eye contact Dust may irritate the eyes.

Ingestion Swallowing may cause gastrointestinal irritation.

Symptoms related to the physical, chemical and toxicological characteristics May cause drowsiness and dizziness. Narcosis. Headache. Nausea, vomiting. Behavioral changes. Decrease in motor functions. Swallowing may cause gastrointestinal irritation. Dusts may irritate the respiratory tract, skin and eyes.

Adverse effects of benzodiazepines may include memory loss, confusion, false sense of well-being, drowsiness, dizziness, weakness, unsteadiness, headache, blurred or double vision, slurred speech, nausea, diarrhea, and constipation. Clonazepam may also cause weight gain, abnormal eye movements, chest congestion, and dry mouth or hypersalivation. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose effects include the adverse effects listed above and fast or slow heartbeat; low blood pressure; troubled breathing; cold, clammy skin; coma; and death.

Information on toxicological effects

Acute toxicity Swallowing may cause gastrointestinal irritation. Narcotic effects.

Components	Species	Test Results
CLONAZEPAM (CAS 1622-61-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	2 g/kg
	Rat	> 15 g/kg
Skin corrosion/irritation	Dust or powder may irritate the skin.	
Serious eye damage/eye irritation	Dust may irritate the eyes.	
Respiratory or skin sensitization		
Respiratory sensitization	May cause inhalation hypersensitivity (occupational asthma) in sensitive individuals.	
Skin sensitization	Risk of sensitization or allergic reactions among sensitive individuals.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. The data currently available are not sufficient to determine the genotoxic potential of clonazepam.	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
NTP Report on Carcinogens		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not regulated.		
Reproductive toxicity	Suspected of damaging fertility or the unborn child.	
	In a two-generation fertility study in which clonazepam was given orally to rats at 10 and 100 mg/kg/day (low dose approximately 5 times and 24 times the maximum recommended human dose of 20 mg/day for seizure disorder and 4 mg/day for panic disorder, respectively, on a mg/m ² basis), there was a decrease in the number of pregnancies and in the number of offspring surviving until weaning.	
	Results were mixed in a meta-analysis of studies that tracked the occurrence of major malformations in infants of mothers who used a benzodiazepine in early pregnancy. There have been reports of newborns exhibiting flaccidity, breathing and feeding problems, and hypothermia after maternal use of benzodiazepines in late pregnancy, and withdrawal symptoms, e.g. tremor and irritability, have been seen in newborns exposed to benzodiazepines in utero.	
	In rabbits given oral doses of 0.2 to 10 mg/kg/day during gestation, there was a non-dose-related incidence of cleft palate, open eyelid, fused sternebrae, and limb defects. In mice and rats, oral doses up to 15 and 40 mg/kg/day, respectively, did not cause birth defects.	
Specific target organ toxicity - single exposure	May cause drowsiness and dizziness.	
Specific target organ toxicity - repeated exposure	May cause damage to organs (respiratory system, immune system, central nervous system, blood) through prolonged or repeated exposure.	
Aspiration hazard	Not available.	
Chronic effects	Possible hypersensitization, tolerance, and dependence. Withdrawal symptoms may include restlessness, hallucinations, delirium, seizures, fast heartbeat, high blood pressure, flu-like aches, nausea, vomiting, and unsteadiness.	
Further information	Individuals sensitive to one of the benzodiazepines may be sensitive to this material also.	
12. Ecological information		
Ecotoxicity	No ecotoxicity testing has been conducted on this product.	
Persistence and degradability	Not inherently biodegradable.	
Bioaccumulative potential	No data available.	
Mobility in soil	No data available.	
Other adverse effects	None known.	

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations. This is a controlled substance. Contact local DEA office for appropriate disposal procedures.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. 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	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	Yes
SARA 313 (TRI reporting)	Not regulated.
Other federal regulations	
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List	Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)	Not regulated.
Safe Drinking Water Act (SDWA)	Not regulated.
	Drug Enforcement Administration (DEA): This product is a Schedule IV Controlled Substance (21 CFR 1308.14)

US state regulations

US. Massachusetts RTK - Substance List

Cellulose (CAS 9004-34-6)

Starch (CAS 9005-25-8)

US. New Jersey Worker and Community Right-to-Know Act

Cellulose (CAS 9004-34-6)

US. Pennsylvania Worker and Community Right-to-Know Law

Cellulose (CAS 9004-34-6)

Starch (CAS 9005-25-8)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

CLONAZEPAM (CAS 1622-61-3)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 18-October-2015

Revision date -

Version # 01

NFPA ratings



Disclaimer

Accord Healthcare, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.