

MATERIAL SAFETY DATA SHEET
according to regulation (EC) No. 1907/2006

ACENOCOUMAROL

Revision date:
22.01.2009

Page: 1 of 3

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE MANUFACTURER

Product common name: ACENOCOUMAROL
Synonyms: ACENOCOUMARIN, NICOUMALONE
Application: Pharmaceutical industry
Manufacturer: IPOCHEM Ltd, 03-236 Warszawa, ul Annopol 6, POLAND
Person qualified: dr Jerzy Goliński, Tel: 0-22 519 47 51, e-mail: j.golinski@ipochem.com.pl
Emergency call No: Mo-Fr 7.00–15.00: 0-22 519 47 40, 24h: 988, 112

2. HAZARDS IDENTIFICATION

Hazard symbols:
X Harmful

R-phrases:
R20/22 Harmful by inhalation and if swallowed.
R61 May cause harm to unborn child

S-phrases:
S35 This material and its container must be disposed of in a safe way
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
S53 Avoid exposure – obtain special instructions before use

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name:	4-hydroksy-3[1-(4-nitrofenylo)-3oksobutylo]-2H-1benzopiran-2-on
CAS No:	152-72-7
EINECS No:	205-807-3
Formula:	C ₁₉ H ₁₅ NO ₆
Molecular weight:	353,32

4. FIRST AID MEASURES

General advice

Consult a physician, show this safety data sheet. Remarks for a physician: haemorrhages, inhibition on the hepatic gamma-carboxylation of the vitamin.

If inhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration. Consult a physician.

In case of skin contact

Take off contaminated garment immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with plenty of water.

Remarks on symptoms for a physician: vomiting, nausea, peripheral circulatory troubles, colicky pains in the abdomen, diarrhea, hypotension, sickness.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media

High volume water jet.

Special protective equipment for fire-fighters

Wear self-contained breathing apparatus for fire fighting.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

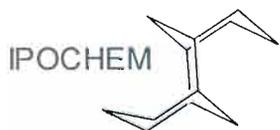
Provide full protective clothing and equipment for personnel. Avoid any direct or indirect contact with skin and eyes. Avoid breathing dust. Ensure adequate ventilation.

Environmental precautions

Avoid contamination of the soil. Do not let product enter sewage system and watercourses.

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal. Dampen with water before removing with appropriate utensils.



7. HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation in places where dust is formed. Take precautionary measures against static discharges.

Conditions for safe storage

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment

Wear suitable respiratory equipment, clean working garment, rubber or plastic gloves, safety glasses.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Handle with gloves.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Eye protection

Safety glasses with side-shields conforming to EN166

Skin and body protection

Choose body protection according to the amount and concentration of the substance in the working area.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke while working. Wash hands before breaks and at the end of a workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

White to off-white crystalline powder, odourless or almost odourless

Safety data

pH: neutral

Melting point: 196 to 199°C

Boiling point: n.a.

Flash point: n.a.

Ignition point: 390°C, method: whirled dust

Self-ignition: no self-ignition up to 190°C

Lower explosion limit: no data available

Upper explosion limit: no data available

Combustibility: brief ignition and rapid extinction

Water solubility: 0,0078 g/l at 25°C

Remarks: hazard class for milling: SKM 1, hazard class

for drying: SKT 1, dust explosion class: ST 2H

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions.

Thermal stability

Decomposition takes place at approx. 210°C

Conditions to avoid

None known

Materials to be avoided

None known

Hazardous decomposition products

Hazardous decomposition products formed during combustion: carbon oxides, nitrogen oxides, other irritant and toxic gases and vapours

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Acute oral toxicity: LD₅₀: 513 mg/kg, species: rat

Acute dermal, inhalation toxicity: no data available

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

NTP / IARC / OSHA: not listed

Reproductive toxicity

Like other coumarin derivatives may be associated with congenital malformation of the embryo.

In women taking acenocoumarol the substance passes

into the breast milk, but in quantities so small that no undesirable effects on the infant are expected.

Specific target organ toxicity - single exposure

Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation Harmful if inhaled. Respiratory tract irritation

Ingestion Harmful if swallowed.

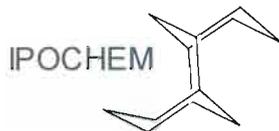
Skin Harmful if absorbed through skin.

Eyes Causes eye irritation.

Signs and Symptoms of Exposure

vomiting, nausea, peripheral circulatory troubles, colicky pains in the abdomen, diarrhea, hypotension, sickness.

Additional Information none



MATERIAL SAFETY DATA SHEET
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12. ECOLOGICAL INFORMATION

Toxicity

LC₅₀: > 100 mg/l, species: Rainbow trout, test duration: 96 hours

Persistence and degradability

Not biodegradable

Bioaccumulative potential

no data available

Mobility in soil

no data available

PBT and vPvB assessment

no data available

Other adverse effects

no data available

Other

Because of the n-octanol/water distribution coefficient (log p_{OW}) accumulation in organisms is not likely

13. DISPOSAL CONSIDERATIONS

Product

Observe all state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Where possible recycling is preferred to disposal or incineration.

Contaminated packaging

Dispose of as unused product. Contact a licensed professional waste disposal service to dispose of this material.

14. TRANSPORT INFORMATION

ADR/RID

NOT DANGEROUS GOODS

IMDG

NOT DANGEROUS GOODS

IATA

NOT DANGEROUS GOODS

15. REGULATORY INFORMATION

This substance is not classified in the Annex I of Directive 67/548/EEC nor in the Annex I of Regulation (EC) No 689/2008.

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

The information in this document is based on the present state of our knowledge and is applicable to the substance with regard to appropriate safety precautions. The document does not represent any guarantee of the properties of the product and shall be used only as a guide. Producer shall not be held liable for any damage resulting from handling or contact with the product.

MATERIAL SAFETY DATA SHEET ATORVASTATIN CALCIUM

1. Information of the substance / preparation and of the company

Commercial product name Atorvastatin Calcium
Company: Farmabase Pharmaceutical Raw Materials
Campiello del Trivio, 12
38068 Rovereto
Italy
Phone: 0464/421996
Fax: 0464/421985
CAS nr. 134523-03-8

2. Chemical Characterisation & physical form

Chemical formula $C_{66}H_{68}CaF_2N_4O_{10}$
Molecular weight 1153.6
Physical form Atorvastatin Calcium is a white powder

3. Hazards Identification

Not considered hazardous when handled under normal conditions with good house keeping.

4. First aid measures

Eye contact: immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

Skin contact: immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Ingestion: if swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

Inhalation: remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Remove and wash/dispose of contaminated clothing promptly.

5. Fire fighting measures

Extinguishing media: carbon dioxide, dry chemical powder or appropriate foam. Water spray.

Unusual fire and explosion hazards:

Emits toxic fumes under fire conditions.

Special fire fighting procedures:

Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

6. Accidental release measures

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Turn leaking containers up to prevent further evacuate area.

Wear self-contained breathing apparatus, rubber boots & heavy rubber gloves. Sweep-

F A R M A B A S E
PHARMACEUTICAL RAW MATERIALS

up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up is complete.

7. Handling and storage

Store under the following conditions: store cool, dark and dry.

8. Exposure controls / personal protection

Respiratory protection: required when dusts are generated.

Eye protection: required.

Hand protection: required.

Industrial hygiene: immediately change contaminated clothing. Wash hands and face after working with substance.

9. Physical and chemical properties

Physical state	powder
Colour	white
Melting point	not available
Solubility	not available

10. Stability and reactivity

Conditions to be avoided: unknown

Substances to be avoided: unknown

Hazardous decomposition products: unknown

11. Toxicological information

No data available.

12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.

13. Disposal considerations

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in keeping with all local and national legislation.

Packaging should be disposed of in keeping with all local and national legislation.

Handle contaminated containers as product.

14. Transport information

The material is non hazardous according to current regulations for transportation of hazardous goods. These codes are not applicable as the material is not hazardous.

15. Other regulatory information

DSCL (EEC):

R20/21/22-harmful by inhalation, in contact with skin and if swallowed

S36/37-wear suitable protective clothing and gloves.

Campiello del Trivio, 12
38068 Rovereto (Italy)
P.O.Box 120

Phone: 0464 421996 - 424246
Fax: 0464 421985
Email: fabioec@tin.it

VAT/P.I.: IT 01285580229
C.F.: CCH FBA 62T18 H6121E
C.C.I.A.A.: 127370
Pos.Mecc.: TN 011775

F A R M A B A S E
PHARMACEUTICAL RAW MATERIALS

16. Other information

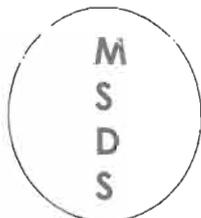
The information herein is believed to be correct as of the date but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws & guidelines as applicable.

FARMABASE Pharmaceutical
Raw Materials

Campello del Trivio, 12
38068 Rovereto (Italy)
P.O.Box 120

Phone: 0464 421996 - 424246
Fax: 0464 421985
Email: fabioec@tin.it

VAT/P.I.: IT 01285580229
C.F.: CCH FBA 62T18 H612E
C.C.I.A.A.: 127370
Pos.Mec.: TN 011775



Material Safety Data Sheet

1. Identification of Substance

- Product details

Name : BISOPROLOL FUMARATE

- Chemical Names :
 BISOPROLOL HEMIFUMARATE ; 2-PROPANOL,
 1-(4-((2-(1-METHYLETHOXY)ETHOXY)METHYL)PHENOXY)-3-((1-METHYLETHYL)AMINO)-, (+/-)-, (E)-2-BUTENEDIOATE (2:1) (SALT);
 (+/-)-1-(4-((2-(1-METHYLETHOXY)ETHOXY)METYL)PHENOXY)-3-((1-METHYLETHYL)AMINO)-2-PROPANOL (E)-2-BUTENEDIOATE (2:1) (SALT);
 (+/-)-1-(PARA-((2-ISOPROPOXYETHOXY)METHYL)PHENOXY)-3-ISOPROPYLAMINO-2-PROPANOL HEMIFUMARATE; CONCOR; DETENSIEL; EMCONCOR; EMCOR;
 EURADAL; ISOTEN; MONOCOR; SOPROL; C40H66N2O12; OHS34051; RTECS UB8390000
- Manufacturer / Supplier
 Unichem Laboratories Ltd.
 99, MIDC Area, Dhatav,
 Roha – Raigad. 402 116
- Emergency information :
 Unichem Laboratories Ltd.
 99, MIDC Area, Dhatav,
 Roha – Raigad. 402 116
 India.
 Telephone No. :- 091-02194-63561
 091-02194-63562
 Fax No. :- 091-02194-63545

2. Composition / data on components

- Chemical formula :
 C40H66N2O12; OHS34051
CAS No.
 104344-23-2

3. Hazards identification

- NEPA RatingS(0-4)
 HEALTH=1 FIRE = 1 REACTIVITY=0

[Handwritten Signature]
 Pharmachem sa India
 67, P. ... Towers
 10-75/1 1. to 6. ...
 Hyderabad 500 018
 18. 2009

- **EMERGENCY OVERVIEW**
 Color : White
 Physical description : Crystalline powder
 Major Health Hazards : No significant target effects reported
 Physical Hazards : Dust/air mixtures may ignite or explode
- **POTENTIAL HEALTH EFFECTS**
Eye contact (long term exposure) : irregular heartbeat, visual disturbances

Ingestion (short term exposure) : irregular heartbeat, drowsiness, dizziness, disorientation, dilated pupils, lung congestion, convulsions, coma
Ingestion (long term exposure) : allergic reactions, sore throat, rash, hair loss, ringing in the ears, nausea, vomiting, diarrhea, stomach pain, chest pain, difficulty breathing, headache, fainting, tingling sensation, joint pain, hearing loss, visual disturbances, impotence, lung damage, blood disorders, kidney damage, liver enlargement.

4. First aid measures

- **Inhalation**
 Remove from exposure immediately. Use a bag valve mask or similar device to perform artificial respiration (rescue breathing) if needed. Get medical attention.
- **Skin contact :**
 Remove contaminated clothing, jewelry and shoes immediately. Wash with soap or mild detergent and large amounts of water until no evidence of chemical remains (at least 15-20 minutes). Get medical attention, if need.
- **Eye contact:**
 Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains. Get medical attention immediately.
- **Ingestion :**
 If vomiting occurs, keep head lower than hips to help prevent aspiration. Get medical attention, if needed.

5. Fire fighting measures

- **Hazards**
 Slight fire hazard. Dust/air mixtures may ignite or explode
- **Extinguishing Media**
 Regular dry chemical, carbon dioxide, water, regular foam
 Long fires : use regular foam or flood with fine water spray.


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 607, Sree Jagiri Towers
 10-75/1 1, to 6, Bagurapat
 Hyderabad-500 016, India.

- **Fire Fighting :**
Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of materials or combustion by-products. Stay upwind and keep out of flow areas.

6. Accidental release measures

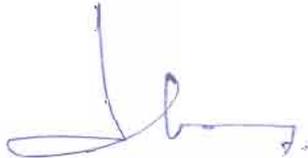
Collect spilled material in appropriate container for disposal. Keep out of water suppliers and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

7. Handling and storage

- Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances.

8. Exposure controls and personal protection

- **Exposure Limits:**
No occupational exposure limits established
- **Ventilation :**
Provide local exhaust ventilation system. Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Ensure compliance with applicable exposure limits.
- **Eye protection:**
Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.
- **Clothing :**
Wear appropriate chemical resistant clothing.
- **Gloves :**
Wear appropriate chemical resistant gloves.
- **Respirator :**
Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.
Any chemical cartridge respirator with organic vapor cartridge(s) and dust and mist filter(s)
Any chemical cartridge respirator with organic vapor cartridge(s) and high-efficiency particulate filter(s).
Any air-purifying respirator with a full face piece, an organic vapor canister and a dust, mist, and fume filter.


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607, Shaktigiri Towers
10-75/1 1, to 6, Bagunpatt
Hyderabad-500 016, India

For unknown concentrations or immediately dangerous to Life or Health-

Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.

Any self-contained breathing apparatus with a full face piece.

9. Physical and chemical properties

- Physical state : solid
- Color: White
- Molecular weight : 766.97
- Molecular Formula : (C18-H31-N-O4)2.C4-H4-O4
- Melting point : 212 F (100 C)
- Density : Not determined.
- Solvent solubility : Soluble : ethanol, methanol, chloroform
- Solubility : Soluble in water.

10. Stability and reactivity

- Reactivity : Stable at normal temperature and pressure
- Conditions to Avoid : Avoid heat, flames, sparks and other sources of ignition.
Avoid contact with incompatible materials.
- Incompatibilities : Oxidizing materials.

11. Toxicological information

Toxicity data :

940 mg/kg oral-rat LD50; 39 mg/kg intravenous-rat LD50; 678 mg/kg oral-mouse LD50; 111 mg/kg intravenous-mouse LD50; 40 mg/kg oral-dog LDL0; 27300 mg/kg/26 week(s) continuous oral-rat TDLo; 16380 mg/kg/13 Week(s) intermittent oral-rat TDLo; 1820 mg/kg/13 week(s) intermittent Oral-dog TDLo

Eye contact (Acute exposure)

BETA-ADRENERGIC BLOCKING AGENTS : Sufficient absorption beta-adrenergic blocking agents through the eye may result in a reduction of intraocular pressure and systemic toxicity as described in chronic exposure.

Eye contact (Chronic exposure)

BETA-ADRENERGIC BLOCKING AGENTS : Repeated or prolonged exposure may cause effects of bradycardia, hypo tension, bronchospasm and congestive heart failure, depression, visual disturbances, anxiety and confusion have also been reported.

Ingestion (Acute exposure)

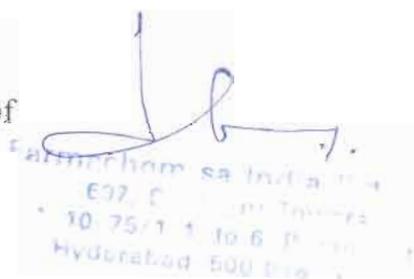
BETA-ADRENERGIC BLOCKING AGENTS : An overdose may produce cardiovascular effects of profound hypotension and bradycardia, or less commonly hypertension and tachycardia;


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Hyderabad 500 016, India

myocardial disease; and cardiorespiratory arrest due to asystole or rarely, ventricular fibrillation. Some beta-blockers act on the central nervous system producing dizziness, drowsiness, decreased alertness, respiratory depression and apnea, delirium, convulsions, catatonia, and coma. Amnesia, dilated pupils, hypoglycemia, hyperkalemia, and bronchospasm may also occur. Allergic reactions may occur in previously exposed persons. Other effects may occur as detailed in chronic ingestion. Most of the critical signs of an overdose appear in above 1-2 hours. Fatalities have been reported.

Chronic Exposure :

BETA-ADRENERGIC BLOCKING AGENTS : In addition to the effects of acute exposure, continued therapeutic use has produced dry mouth, taste distortion, heartburn, gastric pain, nausea, vomiting, anorexia, bloating, flatulence and diarrhea or constipation. Nervous system effects may include fatigue, headache, lightheadedness, lethargy, mental depression, weakness, paresthesias, hypoesthesia, hyperesthesia, anxiety, nervousness, diminished concentration, insomnia, nightmares and bizarre, vivid and numerous dreams. Changes in behavior, hallucinations, disorientation of time and place, short-term memory loss, emotional lability, decreased performance on neuropsychometrics, slurred speech, tinnitus and hearing loss may also occur. The eyes may be affected by irritation, discomfort, drying, burning, conjunctivitis, visual disturbances, and decreased intraocular pressure. Myasthenia gravis may be aggravated. Cardiovascular effects which may be produced or exacerbated, and which may depend on underlying disease, include angina, arterial insufficiency usually of the Raynaud type, vasodilation, claudication, congestive heart failure, first and third degree heart block, and cerebral vascular accident. Symptoms may include chest pain, shortness of breath, cold extremities, edema, flushing, pallor and syncope. Respiratory effects may include nasal stuffiness, cough, rhonchi, bronchial obstruction, rales, wheezing and pulmonary fibrosis. Renal and mesenteric arterial thrombosis, renal failure ischemic colitis, retroperitoneal fibrosis, acute pancreatitis, hepatomegaly, elevated liver enzymes, altered blood lipid levels and hyperglycemia have been reported. Impotence or decreased libido, dysuria nocturia and urinary retention or frequency may occur. Arthritis, arthralgia, muscle cramps and pain, and back pain are possible. Allergic reactions may include fever, pharyngitis, sore throat, numerous erythematous skin reactions, laryngospasm, respiratory distress, and anaphylaxis which may be fatal. Other skin reactions may include pruritus, increased pigmentation, sweating, reversible alopecia, dry skin, psoriasiform eruptions, onycholysis and rarely, necrotic reactions. Hematologic reactions may include agranulocytosis and thrombocytopenic or nonthrombocytopenic purpura. Induction or exacerbation of lupus erythematosus has been reported rarely. Miscellaneous effects may include facial swelling, weight gain or loss, decreased exercise tolerance, peyronie's disease, and rigors. Hypertensive crisis, myocardial infarction, exacerbation of angina and hyperthyroidism, ventricular arrhythmias and death may occur after abrupt withdrawal.



Handwritten signature and a stamp. The stamp contains the following text: "Karnataka Veterinary, Animal and Fisheries Sciences University", "E97, C", "10-75/1-1 to 6", and "Hydrated 500 mg".

12. Ecological information

Not available.

13. Disposal considerations

Dispose in accordance with all applicable regulations.

14. Transport information

Data not available.

15. Regulatory information

European Regulations

EC Number : Not assigned

EC Risk and Safety phrases :

R 22 Harmful if swallowed

R 64 May cause harm to breastfed babies.

S 2 Keep out of reach of children

S 13 Keep away from food, drink and animal feeding stuffs.

S 24 Avoid contact with skin.

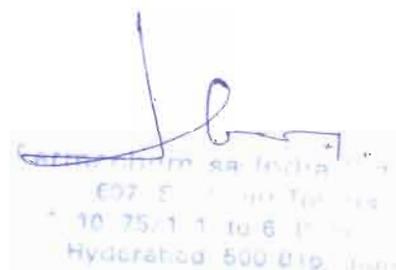
S 36 Wear suitable protective clothing

S 46 If swallowed, seek medical advice immediately and show this container or label.

16. Other information:

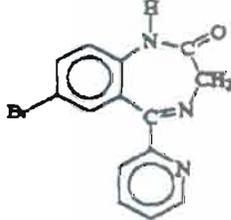
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide Unichem (I) Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product.

- Department of Issuing MSDS :
Safety Department
Unichem Laboratories Ltd.
99, MIDC, Area, Dhatav,
Roha – Raigad.



Handwritten signature and stamp. The stamp contains the following text:
Unichem Laboratories Ltd.
99, MIDC, Area, Dhatav,
Roha - Raigad.
Hydrated: 500 g/l, 100 g/l

MATERIAL SAFETY DATA SHEET

F.I.S. FABBRICA ITALIANA SINTETICI S.p.A. 36041 ALTE DI MONTECCHIO MAGGIORE - VIALE MILANO 26 (V. CENZA) ITALY Telephone (444) 708011 fax (444) 608094 telex 480300 FISVI	
Compilation date: September 11, 2000	Performed by: F.I.S. S.p.A. - Montecchio Maggiore (Vicenza)
1 CHEMICAL IDENTIFICATION AND COMPANY IDENTIFICATION	
Trade Name:	BROMAZEPAM
Chemical name/IUPAC:	7-Bromo-1,3-dihydro-5-(2-pyridinyl)-2H-1,4-benzodiazepin-2-one
	
CAS number	CAS-1812-30-2
EEC number	
EINECS number	2173224
Molecular formula	C ₁₄ H ₁₀ BrN ₂ O
Chemical family	Benzodiazepines
Molecular weight	316.17
COMPANY IDENTIFICATION	
Company name	F.I.S. FABBRICA ITALIANA SINTETICI S.p.A.
Address	Viale Milano 26
City	36041 ALTE DI MONTECCHIO MAGGIORE
Phone number	0444-708011
Note	
2 COMPOSITION / INFORMATION ON THE INGREDIENTS	
Therapeutic category: minor tranquilizer For manufacturing processing or repackaging in the preparation of a drug	
Bromazepam	September 11, 2000 page 1/7

F.I.S. FABBRICA ITALIANA SINTETICI S.P.A.
 36041 ALTE DI MONTECCHIO MAGGIORE - VIALE MILANO 26 (VICENZA) ITALY
 Telephone (444) 708011 fax (444) 608094 telex 48030 FISVI

3 IDENTIFICATION OF THE DANGER

Symbol of danger	Xn
Indication of danger	Harmful
R Phrases	R 22 : Harmful if swallowed R 33 : Danger of cumulative effects

4 FIRST AID ASSISTANCE

First aid:	
eyes contact	wash plentifully with water for at least 15 minutes. Contact a hospital
skin contact	removes clothing and wash plentifully with water and soap
swallowing	if the patient is conscious, cause vomit after administration of water with activated carbon. Contact a hospital
inhalation	in case of poisoning maintain free the respiratory tract. Leave contaminated area immediately. Contact a hospital

5 FIRE FIGHTING POLICY

Combustion and decomposition products	When heated to decomposition or under fire conditions it emits toxic fumes of NOx, COx and HBr
Fire-fighting	Fire fighters should use self-contained breathing equipment and protective clothing
Extinguishing means	Water spray, powder, foam

6 ACTION TO BE TAKEN IN CASE OF ACCIDENTAL LEAKS

Carefully sweep up and place material in a suitable container for disposal, avoid dust generation

F.I.S. FABBRICA ITALIANA SINTETICI S.P.A.
 36041 ALTE DI MONTECCHIO MAGGIORE - VIALE MILANO 26 (VICENZA) ITALY
 Telephone (444) 708011 fax (444) 608094 telex 48030 FISVI

7 HANDLING PROCEDURES / STOCKS

Packaging	Store the substance in well-closed containers, protected from light and moisture avoiding extreme conditions of temperature
Storage Common use	Handle the product in well ventilated areas Used in pharmaceutical chemical industry

8 CONTROL TO EXPOSURE / HANDLING PROTECTIONS

TLV/TLW Note	(ppm)	NA
TLV/STEL Note	(ppm)	NA
TLV/CEILING Note	(ppm)	NA
IDLH		NA
Identification methods		Chromatographic and spectrophotometric methods
Specific protection for breathing		Dust filter mask
eyes		Safety glasses
hands		Rubber gloves
other		Wear protective overalls and cap
Warning		

F.I.S. FABBRICA ITALIANA SINTETICI S.P.A.
 36041 ALTE DI MONTECCHIO MAGGIORE - VIALE MILANO 26 (V. CENZA) ITALY
 Telephone (444) 708011 fax (444) 608094 telex 48030x PISVI

9 SIGNIFICANT PHYSICAL / CHEMICAL PROPERTIES

Physical state		crystalline powder				
Color		White to slightly yellow				
Odor		odorless				
Taste		NA				
Water solubility		practically insoluble (20°C)				
Organic solvent solubility		soluble in DMF (20°C)				
Specific gravity D20/4		NA				
Relative vapor density		NA				
Odor threshold		NA				
Melting point (°C)		NA				
Boiling point (°C)		NA		Note		
Flash point (°C)		NA		Note		
L.E.L. (%)		NA		U.E.L. (%)		
Autoignition temperature (°C)		NA				
Vapour pressure	(a)	n.a.	mmHg	n.a.	n.a.	°C
	(b)	n.a.	mmHg	n.a.	n.a.	°C
	(c)	n.a.	mmHg	n.a.	n.a.	°C

10 STABILITY AND REACTIONS

Material is stable when kept in normal storage conditions

11	TOXICITY DATA
----	---------------

LD50 ori-rat (mg/kg) note	1950 SAX'S 9 ^a Edition: BMN750 page 505
LD50 skin (mg/kg) note	
LC50 ihl. (mg/1/4H) note	ppm:
Toxicity effects (SAX'S 9 ^a Edition: BMN750 page 505)	Poison by intraperitoneal route. Moderately toxic by ingestion.
Skin contact	Moderately irritant
Eyes contact	Moderately irritant
Sensitization property	NA
Carcinogenic effects	NA
Mutagenic effects	NA
Reproductive effects (SAX'S 9 ^a Edition: BMN750 page 505)	oral rat TDLo 35 mg/kg (7-13D post)

12	INFORMATION ON ECOLOGY
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Not known	
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13 HANDLING OF THE DISPOSABLE MATERIAL

Suitable incineration plant

14 TRANSPORT INFORMATION

Transportation by road/railway
 RID/ADR: Class: NA Cat. CT/FS: Cl. Car.

Sea transport IMDG CODE: ONU n.
 Class: NA Page Abbr.

Air transport ICAO/AITA: ONU n.: Class: NA

15 MEDICAL RULES

Symbol of danger	Xn
Indication of danger	Harmful
R phrases	R 22 : Harmful if swallowed R 33 : Danger of cumulative effects
S phrases	S 1/2 : Keep locked up and out of reach of children S 40 : If you feel unwell, seek medical advice (show th : label where possible)
Note	
Periodic and prevent medical examinations according to Italian regulations (Table annexed (DPR 303/56)	
Compulsory insurance (Table annexed DPR 336/94)	
NOTE	

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 Telephone (444) 708011 fax (444) 608094 telex 480308 FISVI

16 OTHER INFORMATION

The information contained here are based on the present state of our knowledge and describe our product under aspect of safety. The data do not signify any warranty with regard to the product properties.

Bibliography

SAX'S Dangerous Properties of Industrial Materials 9th Edition: BMN750
 page 505

Extra bibliography

Internal Material Safety Data Sheet

Compilation date

May 6, 1998

Updating n.

n° 1

Updating date:

September 11, 2000

**** LEGEND

n.s./NA → not applicable - not available
 n.c./NC → not communicated

Safety data sheet

Page: 1/10

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

Date / Revised: 10.05.2011

Version: 4.0

Product: **Caffeine Anhydrous Powder**

(ID no. 30057897/SDS_GEN_GB/EN)

Date of print 11.05.2011

1. Identification of the substance/mixture and of the company/undertaking

Product identifier

Caffeine Anhydrous Powder

Chemical name: caffeine

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Pharmaceutical agent

Details of the supplier of the safety data sheet

Company:
BASF SE
67056 Ludwigshafen
GERMANY

Contact address:
BASF plc
PO Box 4, Earl Road, Cheadle Hulme,
Cheadle, Cheshire
SK8 6QG, UNITED KINGDOM

Telephone: +44 161 485-6222
E-mail address: product-safety-north@basf.com

Emergency telephone number

International emergency number:
Telephone: +49 180 2273-112

2. Hazards Identification

Label elements

According to Regulation (EC) No 1272/2008 [CLP]

| Globally Harmonized System, EU (GHS)

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

Date / Revised: 10.05.2011

Version: 4.0

Product: **Caffeine Anhydrous Powder**

(ID no. 30057897/SDS_GEN_GB/EN)

Date of print 11.05.2011

Pictogram:



Signal Word:

Warning

Hazard Statement:

H302 Harmful if swallowed.

Precautionary Statements (Prevention):

P270 Do not eat, drink or smoke when using this product.

P264 Wash with plenty of water and soap thoroughly after handling.

Precautionary Statements (Response):

P312 Call a POISON CENTER or doctor/physician if you feel unwell.

P301 + P330 IF SWALLOWED: rinse mouth.

Precautionary Statements (Disposal):

P501 Dispose of contents/container to hazardous or special waste collection point.

According to Directive 67/548/EEC or 1999/45/EC

Regulation 1272/2008/EC on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation 1907/2006/EC

Hazard symbol(s)

Xn Harmful.



R-phrase(s)

R22 Harmful if swallowed.

S-phrase(s)

S2 Keep out of the reach of children.

Classification of the substance or mixtureAccording to Regulation (EC) No 1272/2008 [CLP]

Acute tox. 4 (oral)

According to Directive 67/548/EEC or 1999/45/EC

Xn

Possible Hazards:

Harmful if swallowed.

The product is under certain conditions capable of dust explosion.

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

Date / Revised: 10.05.2011

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Product: **Caffeine Anhydrous Powder**

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For the classifications not written out in full in this section the full text can be found in section 16.

Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

Other Hazards (GHS):

The product is under certain conditions capable of dust explosion.

3. Composition/Information on Ingredients

Substances

Chemical nature

caffeine

CAS Number: 58-08-2

EC-Number: 200-362-1

INDEX-Number: 613-086-00-5

4. First-Aid Measures

Description of first aid measures

Remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air, seek medical attention.

On skin contact:

Wash thoroughly with soap and water.

On contact with eyes:

Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

On ingestion:

Rinse mouth immediately and then drink plenty of water, seek medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: vomiting, gastrointestinal complaints, CNS irritability

Indication of any immediate medical attention and special treatment needed

Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

5. Fire-Fighting Measures

Extinguishing media

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

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Product: **Caffeine Anhydrous Powder**

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Suitable extinguishing media:
water spray, dry powder, carbon dioxide, foam

Unsuitable extinguishing media for safety reasons:
water jet

Special hazards arising from the substance or mixture

Burning produces harmful and toxic fumes.

Advice for fire-fighters

Special protective equipment:
Wear a self-contained breathing apparatus.

Further information:

Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Ensure adequate ventilation.

Environmental precautions

Do not discharge into drains/surface waters/groundwater. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up

For small amounts: Pick up with suitable appliance and dispose of.
For large amounts: Pick up with suitable appliance and dispose of.
Dispose of absorbed material in accordance with regulations.

Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

7. Handling and Storage

Precautions for safe handling

Avoid the formation and deposition of dust.

Protection against fire and explosion:

The product is capable of dust explosion. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

Conditions for safe storage, including any incompatibilities

Further information on storage conditions: Keep container tightly closed. Protect contents from the effects of light.

8. Exposure Controls/Personal Protection

Control parameters

Components with workplace control parameters

none

Exposure controls

Personal protective equipment

Respiratory protection:

Breathing protection if breathable aerosols/dust are formed. Particle filter with medium efficiency for solid and liquid particles (e.g. EN 143 or 149, Type P2 or FFP2)

Hand protection:

Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other
Supplementary note: The specifications are based on tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the permeation time determined through testing.

Eye protection:

Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Body protection:

Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).

General safety and hygiene measures

Wearing of closed work clothing is recommended. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Hands and/or face should be washed before breaks and at the end of the shift.

9. Physical and Chemical Properties

Information on basic physical and chemical properties

Form:	powder
Colour:	white
Odour:	almost odourless
Odour threshold:	not determined
pH value:	5.5 - 6.5 (10 g/l, 20 °C)
melting range:	approx. 235 - 239 °C
Boiling point:	not applicable
Flash point:	not applicable
Flammability:	not readily ignited

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

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Version: 4.0

Product: **Caffeine Anhydrous Powder**

(ID no. 30057897/SDS_GEN_GB/EN)

Date of print 11.05.2011

Lower explosion limit:	not determined	
Upper explosion limit:	No data available., not determined	
Ignition temperature:	> 600 °C	(DIN 51794)
Vapour pressure:	dropped	
Relative density:	Study does not need to be conducted.	
Relative vapour density (air):	not relevant	
Solubility in water:	20 g/l (20 °C)	
Partitioning coefficient n-octanol/water (log Kow):	-0.091 (23 °C)	(Directive 92/69/EEC, A.8)
Self ignition:	not self-igniting	
Thermal decomposition:	No decomposition if stored and handled as prescribed/indicated.	
Viscosity, dynamic:	not applicable	
Fire promoting properties:	not fire-propagating	(other)

Other information

Bulk density:	approx. 360 kg/m ³	
pKA:	10.4 (40 °C)	(other)
Molar mass:	194.19 g/mol	

10. Stability and Reactivity**Reactivity**

Formation of flammable gases:	Remarks:	Forms no flammable gases in the presence of water.
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Chemical stability

The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions

No hazardous reactions if stored and handled as prescribed/indicated.

Conditions to avoid

Avoid dust formation. Avoid all sources of ignition: heat, sparks, open flame. Avoid electro-static charge. Avoid light.

Incompatible materials

Substances to avoid:
No substances known that should be avoided.

Hazardous decomposition products

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

Date / Revised: 10.05.2011

Version: 4.0

Product: **Caffeine Anhydrous Powder**

(ID no. 30057897/SDS_GEN_GB/EN)

Date of print 11.05.2011

Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed/indicated.

11. Toxicological Information

Information on toxicological effects

Acute toxicity

Experimental/calculated data:

LD50 rat (oral): 367 mg/kg (BASF-Test)

LC50 rat (by inhalation): approx. 4.94 mg/l 4 h (OECD Guideline 403)

LD50 rat (dermal): > 2,000 mg/kg (BASF-Test)

Irritation

Assessment of irritating effects:

Not irritating to the skin. Not irritating to the eyes.

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)

Serious eye damage/irritation rabbit: non-irritant (OECD Guideline 405)

Respiratory/Skin sensitization

Assessment of sensitization:

Skin sensitizing effects were not observed in animal studies.

Experimental/calculated data:

Mouse Local Lymph Node Assay (LLNA) : Non-sensitizing. (OECD Guideline 429)

Germ cell mutagenicity

Assessment of mutagenicity:

In the majority of tests performed (bacteria/microorganisms/cell cultures) a mutagenic effect was not found. A mutagenic effect was also not observed in in-vivo assays.

Carcinogenicity

Assessment of carcinogenicity:

In long-term animal studies in which the substance was given in the drinking water in high doses, a carcinogenic effect was not observed.

Reproductive toxicity

Assessment of reproduction toxicity:

In high doses a potential to impair fertility cannot be fully excluded.

Developmental toxicity

Assessment of teratogenicity:

In animal studies the substance did not cause malformations.

12. Ecological Information

Toxicity

Assessment of aquatic toxicity:

Acutely harmful for aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish:

LC50 (96 h) 87 mg/l, *Leuciscus idus* (DIN 38412 Part 15, static)

The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates:

EC50 (48 h) 182 mg/l, *Daphnia magna* (Directive 79/831/EEC, static)

The details of the toxic effect relate to the nominal concentration.

Aquatic plants:

EC50 (72 h) > 100 mg/l (growth rate), *Scenedesmus subspicatus* (OECD Guideline 201, static)

The details of the toxic effect relate to the nominal concentration.

Microorganisms/Effect on activated sludge:

EC50 (17 h) 3,490 mg/l, *Pseudomonas putida* (DIN 38412 Part 8, aerobic)

EC20 (180 min) approx. 900 mg/l, activated sludge (OECD Guideline 209, aerobic)

The product has not been tested. The statement has been derived from products of a similar structure or composition.

Persistence and degradability

Assessment biodegradation and elimination (H₂O):

Readily biodegradable (according to OECD criteria). The product has not been tested. The statement has been derived from products of a similar structure or composition.

Elimination information:

90 - 100 % DOC reduction (22 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)

Analogous: Assessment derived from products with similar chemical character.

Bioaccumulative potential

Bioaccumulation potential:

Accumulation in organisms is not to be expected.

Mobility in soil (and other compartments if available)

Assessment transport between environmental compartments:

Adsorption to solid soil phase is not expected.

Results of PBT and vPvB assessment

According to Annex XIV of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not contain a substance

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

Date / Revised: 10.05.2011

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Product: **Caffeine Anhydrous Powder**

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Date of print 11.05.2011

fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Self classification

13. Disposal Considerations

Waste treatment methods

Observe national and local legal requirements.

The UK Environmental Protection (Duty of Care) Regulations (EP) and amendments should be noted (United Kingdom).

This product and any uncleaned containers must be disposed of as hazardous waste in accordance with the 2005 Hazardous Waste Regulations and amendments (United Kingdom)

14. Transport Information

Land transport

ADR

Not classified as a dangerous good under transport regulations

RID

Not classified as a dangerous good under transport regulations

Inland waterway transport

ADN

Not classified as a dangerous good under transport regulations

Sea transport

IMDG

Not classified as a dangerous good under transport regulations

Air transport

IATA/ICAO

Not classified as a dangerous good under transport regulations

15. Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

This product is classified under the Chemicals (Hazard Information and Packaging) Regulations, (CHIP) (United Kingdom).

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

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The data should be considered when making any assessment under the Control of Substances Hazardous to Health Regulations (COSHH), and related guidance, for example, 'COSHH Essentials' (United Kingdom).

16. Other Information

Any other intended applications should be discussed with the manufacturer. Corresponding occupational protection measurements must be followed.

Full text of the classifications, including the indication of danger, the hazard symbols, the R phrases, and the hazard statements, if mentioned in section 2 or 3:

Xn Harmful.

Vertical lines in the left hand margin indicate an amendment from the previous version.

If you have any queries relating to this MSDS, it's contents or any other product safety related questions, please write to the following e-mail address: product-safety-north@basf.com

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

**MATERIAL SAFETY DATA SHEET**

1907/2006/EG

Print date: 17.06.2008

Version of: 31.01.2007

Page 1 of 5

Trade name Calcium Carbonate, heavy

1. Name of company**Manufacturer/supplier**

Manufacturer/supplier: Dr. Paul Lohmann GmbH KG
Hauptstr. 2
D-31860 Emmerthal / Germany

Tel: (49) 5155 - 630
Fax: (49) 5155 - 63134
email: Service@Lohmann-Chemikalien.de

2. Hazard risks**Specific information on human and environmental hazards**

Not classified as hazardous when used in accordance with good manufacturing practices.

3. Composition/information on ingredients

Name of substance
Calcium Carbonate, heavy

CAS-No.	EINECS-No.	Hazard	R-phrases	Code No.
471-34-1	207-439-9			L06

Chemical characterisation (preparation)
CaCO₃ (M = 100.09 g/mol)

4. First aid measures**General informations**

Immediately change all contaminated clothing.

After inhalation

Provide fresh air.

After skin contact

Wash with soap and plenty of water.

Dr. Paul Lohmann GmbH D-31860 Emmerthal

MATERIAL SAFETY DATA SHEET 1907/2006/EG

Print date: 17.06.2008

Version of: 31.01.2007

page 2 of 5

Trade name

Calcium Carbonate, heavy

4. First aid measures

After contact with eyes

Rinse immediately with plenty of water and seek medical advice.

After ingestion

Seek medical advice.

Advice for physicians

5. Fire-fighting measures

Suitable extinguishing media

Product itself is non-combustible; use any means suitable for extinguishing.

6. Accidental spillage measures

Personal precautions

Wear suitable protective clothing (see under section 8).

Clean up and disposal measures

Collect in a suitable container for proper disposal. Rinse area with sufficient water.

Avoid development of dust.

7. Handling and storage

Advice on safe handling

Usual safety precautions should be observed to ensure safe handling.

Provide adequate exhausting system in working areas.

Advices on storage compatibility

Keep away from acids.

Further information on storage conditions

To be kept in well-closed containers in a cool (below 30°C) and dry place.

8. Exposure controls/personal protection

Requirements for technical facilities

Provide adequate exhausting system in working areas.

General protective and hygienic measures

Wash thoroughly after handling.

Respiratory protection

Wear dust mask.

Dr. Paul Lohmann GmbH D-31860 Emmerthal

MATERIAL SAFETY DATA SHEET 1907/2006/EG

Print date: 17.06.2008

Version of: 31.01.2007

page 3 of 5

Trade name

Calcium Carbonate, heavy

8. Exposure controls/personal protection**Hand protection**

Protective gloves (acc. to EN 374)

Eye protection

Wear eye protection.

Body protection

Wear rubber or plastic apron.

9. Physical and chemical properties

Form	Powder
Colour	White
Odour	Odourless
Flash point	n.a. °C
Ignition temperature	n.a. °C
Upper explosion limit	n.a. Vol %
Lower explosion limit	n.a. Vol %
pH value	ca. 10 / 20 °C 10 g/l(susp.)

Further information

Practically insoluble in water.

The product is non-combustible.

n.a. = not applicable

10. Stability and reactivity**Conditions to avoid**

Temperatures above 825°C (decomposition).

Materials to avoid

Acids (liberating carbon dioxide)

11. Toxicological information**Acute toxicity**

For classification relevant values

Subacute / chronic toxicity

Longterm tests

Human experience

12. Ecological information**Information on elimination (persistence and biodegradability)**

The product is inorganic and does not draw on oxygen.

Environmental effects

Dr. Paul Lohmann GmbH D-31860 Emmerthal

MATERIAL SAFETY DATA SHEET 1907/2006/EG

Print date: 17.06.2008

Version of: 31.01.2007

page 4 of 5

Trade name

Calcium Carbonate, heavy

12. Ecological information

Water hazard class: 0 (see section 15)

Ecotoxicological effects

Aquatic toxicity

Effect on water treatment process

see additional remarks

Additional remarks

When low concentrations are discharged correctly into adapted biological sewage treatment plants, interference with the degradation activity of activated sludge is not likely.

Further information

13. Disposal considerations

Product disposal

Disposal according to local regulations.

Contaminated packaging

Disposal according to local regulations.

Recommended cleansing agent

Water

14. Transport information

ADR/RID-GGVS/E class	Packin gr.	Hazard-No.	Substance-No.
ADR class	Figure	Categorie	
IMDG/GGVS class	UN-No.	EMS-No.	MFAG-No.
ICAO/IATA class	UN-No.		

Further information

Not classified for conveyance.

15. Regulatory information

Labelling according to EEC Directives

National regulations

Water hazard class (Germany)

not hazardous to water (Germany)

Dr. Paul Lohmann GmbH D-31860 Emmerthal

MATERIAL SAFETY DATA SHEET 1907/2006/EG

Print date: 17.06.2008

Version of: 31.01.2007

page 5 of 5

Trade name

Calcium Carbonate, heavy

15. Regulatory information

16. Other information

The product is a permitted food additive (E 170).

The data provided herein are based upon information believed to be reliable. This information is not to be considered as a warranty or quality specification and we do not assume any responsibility, including injury or damage, resulting from its use as such or in combination with other materials.

MATERIAL SAFETY DATA SHEET CLOPIDOGREL BISULPHATE

1. Information of the substance / preparation and of the company

Commercial product name Clopidogrel Bisulphate
Company: Farmabase Pharmaceutical Raw Materials
Campiello del Trivio, 12
38068 Rovereto
Italy
Phone: 0464/421996
Fax: 0464/421985
CAS nr. 113665-84-2

2. Chemical Characterisation & physical form

Chemical formula $C_{16}H_{16}ClNO_2S$
Molecular weight 321.8
Physical form Clopidogrel Bisulphate is a white to off white crystalline powder

3. Hazards Identification

Not considered hazardous when handled under normal conditions with good house keeping.

4. First aid measures

Eye contact: immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

Skin contact: immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Ingestion: if swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

Inhalation: remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Remove and wash/dispose of contaminated clothing promptly.

5. Fire fighting measures

Extinguishing media: carbon dioxide, dry chemical powder or appropriate foam. Water spray.

Unusual fire and explosion hazards:

Emits toxic fumes under fire conditions.

Special fire fighting procedures:

Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

6. Accidental release measures

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Turn leaking containers up to prevent further evacuate area. Wear self-contained breathing apparatus, rubber boots & heavy rubber gloves. Sweep-

F A R M A B A S E

PHARMACEUTICAL RAW MATERIALS

up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up is complete.

7. Handling and storage

Store in original container in a cool dark place.

8. Exposure controls / personal protection

Respiratory protection: required when dusts are generated.

Eye protection: required.

Hand protection: required.

Industrial hygiene: immediately change contaminated clothing. Wash hands and face after working with substance.

9. Physical and chemical properties

Physical state crystalline powder

Colour white to off white

Melting point 181 °C – 187 °C

Solubility not available

10. Stability and reactivity

Conditions to be avoided: unknown

Substances to be avoided: unknown

Hazardous decomposition products: unknown

11. Toxicological information

No data available.

12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.

13. Disposal considerations

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in keeping with all local and national legislation.

Packaging should be disposed of in keeping with all local and national legislation.

Handle contaminated containers as product.

14. Transport information

The material is non hazardous according to current regulations for transportation of hazardous goods. These codes are not applicable as the material is not hazardous.

15. Other information

The information herein is believed to be correct as of the date but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws & guidelines as applicable.

FARMABASE Pharmaceutical
Raw Materials

Campiello del Trivio, 12
38068 Rovereto (Italy)
P.O.Box 120

Phone: 0464 421996 - 424246
Fax: 0464 421985
Email: fabioecc@tin.it

VAT/P.I.: IT 01285580229
C.F.: CCH FBA 62T18 H612E
C.C.I.A.A.: 127370
Pos.Mec.: TN 011775

MATERIAL SAFETY DATA SHEET

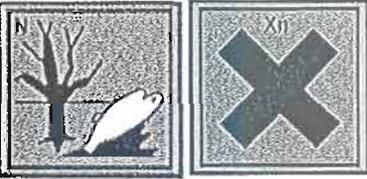
F.I.S. FABBRICA ITALIANA SINTETICI S.p.A. VIALE MILANO 26 - 36075 ALTE DI MONTECCHIO MAGGIORE - (VICENZA) ITALY Telephone (444) 708011 fax (444) 698094	
revision date: October 20, 2009	
1	CHEMICAL IDENTIFICATION AND COMPANY IDENTIFICATION
Trade Name: Chemical name/IUPAC : CAS number EINECS number Molecular formula Chemical family Molecular weight <u>COMPANY IDENTIFICATION</u> Company name Address City Phone number e-mail address of the competent person responsible for the Safety Data Sheet	DIAZEPAM 7-Chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one 439-14-5 2071225 $C_{16}H_{13}ClN_2O$ Benzodiazepines 284.75 F.I.S. FABBRICA ITALIANA SINTETICI S.p.A. Viale Milano 26 36075 ALTE DI MONTECCHIO MAGGIORE 0444-708011 hsedept@fisvi .com
2	IDENTIFICATION OF THE DANGER
Potential health effects	Harmful if swallowed, danger of cumulative effects (details in Section 11)
Different effects	Avoid dust and mist generation
Environmental effects	Toxic to aquatic organisms,

3	COMPOSITION / INFORMATION ON THE INGREDIENTS											
Therapeutic category: sedative For manufacturing processing or repackaging in the preparation of a drug.												
4	FIRST AID ASSISTANCE											
<table border="1"> <tr> <td data-bbox="239 656 640 712">First aid:</td> <td data-bbox="640 656 1433 712"></td> </tr> <tr> <td data-bbox="239 712 640 801">eyes contact</td> <td data-bbox="640 712 1433 801">wash plentifully with water for at least 15 minutes. Seek medical attention.</td> </tr> <tr> <td data-bbox="239 801 640 925">skin contact</td> <td data-bbox="640 801 1433 925">remove contaminated clothing and wash the skin plentifully with water. If necessary seek medical attention.</td> </tr> <tr> <td data-bbox="239 925 640 1014">swallowing</td> <td data-bbox="640 925 1433 1014">if the patient is conscious, cause vomit after administration of water with activated carbon. Seek medical attention.</td> </tr> <tr> <td data-bbox="239 1014 640 1088">inhalation</td> <td data-bbox="640 1014 1433 1088">in case of poisoning maintain free the respiratory tract. Leave contaminated area immediately. Seek medical attention.</td> </tr> </table>			First aid:		eyes contact	wash plentifully with water for at least 15 minutes. Seek medical attention.	skin contact	remove contaminated clothing and wash the skin plentifully with water. If necessary seek medical attention.	swallowing	if the patient is conscious, cause vomit after administration of water with activated carbon. Seek medical attention.	inhalation	in case of poisoning maintain free the respiratory tract. Leave contaminated area immediately. Seek medical attention.
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5	FIRE FIGHTING POLICY											
<table border="1"> <tr> <td data-bbox="239 1180 640 1292">Combustion and decomposition products</td> <td data-bbox="640 1180 1433 1292">When heated to decomposition or under fire conditions it emits very toxic fumes</td> </tr> <tr> <td data-bbox="239 1292 640 1393">Fire-fighting</td> <td data-bbox="640 1292 1433 1393">Fire fighters should use self-contained breathing apparatus and complete protective equipment.</td> </tr> <tr> <td data-bbox="239 1393 640 1458">Extinguishing means</td> <td data-bbox="640 1393 1433 1458">Water spray, powder, foam, CO₂.</td> </tr> </table>			Combustion and decomposition products	When heated to decomposition or under fire conditions it emits very toxic fumes	Fire-fighting	Fire fighters should use self-contained breathing apparatus and complete protective equipment.	Extinguishing means	Water spray, powder, foam, CO ₂ .				
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Fire-fighting	Fire fighters should use self-contained breathing apparatus and complete protective equipment.											
Extinguishing means	Water spray, powder, foam, CO ₂ .											
6	ACTION TO BE TAKEN IN CASE OF ACCIDENTAL LEAKS											
Carefully sweep up and place material in a suitable container for disposal, avoid dust generation												

7	HANDLING AND STORAGE PROCEDURES	
Storage	Store the substance in well-closed containers, protected from light and moisture avoiding extreme conditions of temperature	
Handling	Handle the product in well ventilated area	
Common use	Used in pharmaceutical chemical industry	
8	CONTROL TO EXPOSURE / HANDLING PROTECTIONS	
TLV/TLW Note	(ppm)	NA
TLV /STEL Note	(ppm)	NA
TLV/CEILING Note	(ppm)	NA
IDLH		NA
Identification methods	Chromatographic and spectrophotometric methods	
Specific protection for breathing	Dust filter mask	
eyes	Safety glasses	
hands	Rubber gloves	
other	Wear protective overalls and cap	
Warning		

9	SIGNIFICANT PHYSICAL / CHEMICAL PROPERTIES		
Physical state Color Odor Taste Water solubility Organic solvent solubility Specific gravity D20/4 Relative vapor density Odor threshold Melting point (°C) Boiling point (°C) Flash point (°C) L.E.L. (%) Autoignition temperature (°C)	crystalline powder white odorless NA slightly soluble soluble in ethanol ; very soluble in chloroform NA NA NA 131-135°C NA NA NA NA	Note Note U.E.L. (%)	
10	STABILITY AND REACTIONS		
Material is stable when kept in normal storage conditions			

11	TOXICITY-DATA
LD50 oral - rat (mg/kg)	249 (Drugs in Japan 1995) 352 (SAX's) 710 (Merck index) 1517 (IARC – average)
LD50 skin - mouse (mg/kg)	800 mg/kg (SAX'S 10 th Edition: DCK 759)
LC50 ihl. (mg/l/4H)	NA
Toxicity effects (SAX'S 10 th Edition: DCK 759)	Poison by ingestion, parenteral, subcutaneous, intravenous, and intraperitoneal routes. Moderately toxic by skin contact. Human systemic effects: dermatitis, change in cardiac rate, somnolence, respiratory changes, visual field changes, change in motor activity, muscle contraction, ataxia.
Skin contact	NA
Eyes contact	NA
Sensitization property	Positive individual
Cancerogenic effects	Data reported in literature (SAX'S 10 th Edition: DCK 759)
Mutagenic effects	Data reported in literature (SAX'S 10 th Edition: DCK 759)
Reproductive effects (SAX'S 10 th Edition: DCK 759)	Oral-Woman TDL ₀ : 22,800 µg/kg (25-36W preg): Reproductive effects Intravenous-Woman TDL ₀ : 400 µg/kg (female 39W post): Teratogenic effects
12	INFORMATION ON ECOLOGY
<p>Biodegradabilità: not inherently biodegradable partial primary degradation evidenced by HPLC: < 5 % BOD/ThOD, 28 d ; < 5 % BOD/ThOD, 84 d (MITI Test II, OECD No. 302 C)</p> <p>Ecotoxicity:</p> <ul style="list-style-type: none"> - -strongly toxic for algae (<i>Scenedesmus (=Desmodesmus) nsubspicatus</i>): ErC50 (72 h) 3.11 mg/l (average measured concentration) NOEC (72 h) 0.035 mg/l (average measured concentration) - strongly toxic for planktonic crustaceans (<i>Daphnia magna</i>): EC50 (24 h) 4.3 mg/l - moderately toxic for fish (rainbow trout): LC50 (96 h) 84 mg/l ;NOEC (96 h) 50 mg/l - barely toxic for microorganisms (activated sludge) NOEC > 100 mg/l 	

13	HANDLING OF THE DISPOSABLE MATERIAL	
Dispose according to actual regulation in a suitable incineration plant.		
14	TRANSPORT INFORMATION	
<p>Transportation by road/railway RID/ADR TOXIC SOLID, ORGANIC N.O.S.. (DIAZEPAM) 2/(E) ONU2811 PG. III Class 6.1</p> <p>Sea transport IMDG CODE: TOXIC SOLID, ORGANIC N.O.S.. (DIAZEPAM) ONU2811 PG. III Class 6.1</p> <p>Air transport ICAO/IATA: TOXIC SOLID, ORGANIC N.O.S.. (DIAZEPAM) ONU2811 PG. III Class 6.1</p>		
15	REGULATION INFORMATION	
Symbol of danger	Xn N	
R phrases	R 22 Harmful if swallowed R 48 Danger of serious damage to health by prolonged exposure 51/53 Toxic to aquatic organisms, may cause long-term adverse effects on the aquatic environment.	
S phrases	36/37/39 Wear suitable protective clothing, gloves and eye/face protection 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) 61 Avoid release to the environment. Refer to special instructions/Safety data sheets.	
Note	Labelling in compliance with EU Directives. Classification and labelling are in accordance with information available at present state.	

16	OTHER INFORMATION	
<p>The information contained here are based on the present state of our knowledge and describe our under aspect of safety. The data do not signify any warranty with regard to the product</p>		
<p>Bibliography</p> <p>Extra bibliography</p> <p>Compilation date</p> <p>Updating n.</p> <p>Updating date</p> <p>Updating sections</p> <p>**** LEGEND</p>	<p>Drugs in Japan 1995 SAX'S Dangerous Properties of Industrial Materials - 10^A Edizione: DCK759 Merck Index IARC Monography n°66/1996, point 4.2.2.</p> <p>Internal Material Safety Data Sheet</p> <p>February 8, 2000</p> <p>n°8</p> <p>October 23, 2009</p> <p>11, 12, 14, 15</p>	<p>n.a./NA – not applicable – not available n.c./NC – not communicated</p>
<p>Note: This document is in compliance with EU Regulation 2006/1907</p>		

MATERIAL SAFETY DATA SHEET ENALAPRIL MALEATE

1. Information of the substance / preparation and of the company

Commercial product name Enalapril Maleate
Company: Farmabase Pharmaceutical Raw Materials
Campiello del Trivio, 12
38068 Rovereto
Italy
Phone: 0464/421996
Fax: 0464/421985
CAS nr. 76095-16-4

2. Chemical Characterisation & physical form

Chemical formula $C_{20}H_{28}N_2O_5, C_4H_4O_4$
Molecular weight 492.5
Physical form Enalapril Maleate is an off-white crystalline powder

3. First aid measures

Eye contact if symptoms develop, immediately move individual away from exposure and into fresh air. Flush eyes gently with water for at least 15 minutes while holding eyelids apart; seek immediate medical attention.

Skin contact remove contaminated clothing. Wash exposed area with soap and water. If symptoms persist, seek medical attention. Launder clothing before reuse.

Ingestion seek medical attention. If individual is drowsy or unconscious, do not give anything by mouth; place individual on the left side with the head down. Contact a physician, medical facility, or poison control center for advice about whether to induce vomiting. If possible, do not leave individual unattended.

Inhalation if symptoms develop, move individual away from exposure and into fresh air. If symptoms persist, seek medical attention. If breathing is difficult, administer oxygen. Keep person warm and quiet; seek immediate medical attention.

4. Fire fighting measures

Wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Use agent most appropriate to extinguish fire.

F A R M A B A S E

PHARMACEUTICAL RAW MATERIALS

5. Accidental release measures

Evacuate area and ventilate. Wear protective equipment. If required, use an inert absorbent. Sweep up and place in an appropriate container for disposal. Wash contaminated surfaces.

6. Handling and storage

Keep in a cool, dry, dark location in a tightly sealed container or cylinder. Keep away from incompatible materials, ignition sources and untrained individuals. Secure and label area. Protect containers/cylinders from physical damage.

All chemicals should be considered hazardous. Avoid direct physical contact. Use appropriate, approved safety equipment. Untrained individuals should not handle his chemical or its container. Handling should occur in a chemicals fume hood.

7. Exposure controls / personal protection

Chemical splash goggles in compliance with OSHA regulations are advised; however, OSHA regulations also permit other type safety glasses. Wear chemical resistant gloves. To prevent repeated or prolonged skin contact, wear impervious clothing and boots.

Use NIOSH/MSHA approved respirator appropriate for exposure of concern.

8. Physical and chemical properties

Physical state	crystalline powder
Colour	off-white
Melting point	142 - 147°C
Solubility	sparingly soluble in water

9. Stability and reactivity

Hazardous reaction	not known when used appropriately
Hazardous decomposition	not known
Incompatibilities:	strong oxidizing agents

10. Toxicological information

LD 50 (skin)	not known
LD 50 (inhalation)	not known

11. Ecological information

Not available.

12. Disposal considerations

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

13. Transport information

The material is non hazardous according to current regulations for transportation of hazardous goods. These codes are not applicable as the material is not hazardous.

Campiello del Trivio, 12
38068 Rovereto (Italy)
P.O.Box 120

Phone: 0464 421996 - 424246
Fax: 0464 421985
Email: fabioec@tin.it

VAT/P.I.: IT 01285580229
C.F.: CCIT FBA 62T18 H612E
C.C.I.A.A.: 127370
Pos.Mec.: TN 011775

F A R M A B A S E
PHARMACEUTICAL RAW MATERIALS

14. Other information

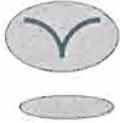
The information herein is believed to be correct as of the date but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws & guidelines as applicable.

FARMABASE Pharmaceutical
Raw Materials

Campiello del Trivio, 12
38068 Rovereto (Italy)
P.O.Box 120

Phone: 0464 421996 - 424246
Fax: 0464 421985
Email: fabioec@tin.it

VAT/P.I.: IT 01285580229
C.F.: CCII FBA 62T18 H612E
C.C.I.A.A.: 127370
Pos.Mec.: TN 011775



CADILA
PHARMACEUTICALS
LIMITED

Corporate Office:

"Cadila Corporate Campus" Sarkhej Dholka Road, Bhat, Ahmedabad -382210, India
Tel. 91-2718 225001 - 15 Fax. 91-2718 225039

Material Safety Data Sheet Fluoxetine Hydrochloride MSDS

Section 1: Chemical Product and Company Identification

Product Name: Fluoxetine Hydrochloride

CAS#: 59333-67-4 or 56296-78-7

RTECS: UI4050000

CI#: Not available.

Synonym: (+-)-Methyl-gamma-(4-(trifluoromethyl)phenoxy)benzenepropanamine hydrochloride

Chemical Name:

Propylamine, N-methyl-3-phenyl-(p-trifluoromethylphenoxy)-, hydrochloride

Chemical Formula: C₁₇H₁₈F₃N.O.HCl

Contact Information:

CADILA PHARMACEUTICALS LTD.

294, GIDC ESTATE,

ANKLESHWAR – 393 002

GUJARAT, INDIA

TEL : +91-2646-223846

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Fluoxetine Hydrochloride	59333-67-4	100

Toxicological Data on Ingredients: Fluoxetine Hydrochloride: ORAL (LD50): Acute: 452 mg/kg [Rat]. 248 mg/kg [Mouse].

Section 3: Hazards Identification

Potential Acute Health Effects:

Hazardous in case of eye contact (irritant), of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation.

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Not available.

TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Not available.

The substance may be toxic to liver, central nervous system (CNS).

Repeated or prolonged exposure to the substance can produce target organs damage.

Section 4: First Aid Measures

Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

Serious Skin Contact: Not available.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:

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Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.
Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...), halogenated compounds.

Fire Hazards in Presence of Various Substances:

Slightly flammable to flammable in presence of heat.

Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:

Slightly explosive in presence of open flames and sparks.

Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:

Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Section 6: Accidental Release Measures

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:

Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.

Storage:

Keep container tightly closed. Keep container in a cool, well-ventilated area. Store at temperatures between 15 and 30 deg. C. Do not store above 30°C (86°F).

Section 8: Exposure Controls/Personal Protection

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

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Personal Protection:

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent.

Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline powder.)

Odor: Not available.

Taste: Not available.

Molecular Weight: 345.79 g/mole

Color: Yellow.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: 193°C (379.4°F) - 197 C

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

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:

Very slightly soluble in methanol.

Freely soluble in Dichloromethane, Chloromform, DMF, DMSO.

Springly soluble in Ethanol, Methanol, Isopropanol, Ethyl Acetate, Acetonitrile

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents.

Corrosivity: Not available.

Special Remarks on Reactivity: Incompatible with oxidizing agents (e.g. peroxides, permanganates, nitric acid, etc.)

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 248 mg/kg [Mouse].

Chronic Effects on Humans: May cause damage to the following organs: liver, central nervous system (CNS).

Other Toxic Effects on Humans:

Hazardous in case of ingestion.

Slightly hazardous in case of skin contact (irritant), of inhalation.

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Special Remarks on Toxicity to Animals:

Lowest Published Toxic Dose/Conc:

TDL [Human] - Route: Oral; Dose: 7.8 mg/kg

TDL [Woman] - Route: Oral; Dose: 0.4 mg/kg

TDL [Child] - Route: Oral; Dose: 26 mg/kg

Special Remarks on Chronic Effects on Humans: May cause adverse reproductive effects and birth defects (teratogenic)

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects:

Skin: Causes skin irritation.

Eyes: Causes eye irritation.

Inhalation: May cause respiratory tract irritation.

Section 12: Ecological Information

Ecotoxicity: Ecotoxicity in water (LC50): 1.6 ppm 96 hours [Fish (Trout)]. 0.9 ppm 48 hours [Daphnia (daphnia)].

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are as toxic as the product itself.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: No products were found.

Other Regulations: OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

Other Classifications:

WHMIS (Canada): CLASS D-1B: Material causing immediate and serious toxic effects (TOXIC).

DSCL (EEC):

R22- Harmful if swallowed.

R36- Irritating to eyes.

R43- May cause sensitization by skin contact.

R50- Very toxic to aquatic organisms.

S46- If swallowed, seek medical advice immediately and show this container or label.

S56- Dispose of this material and its container at hazardous or special waste collection point.

HMIS (U.S.A.):

Health Hazard: 2

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Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:

Gloves.

Lab coat.

Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.

Splash goggles.

Section 16: Other Information

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Cadila Pharmaceuticals Ltd. be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages.

For, CADILA PHARMACEUTICALS LTD.


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SAFETY DATA SHEET

In accordance with Regulation (CE) 1907/2006, (CE) 1272/2008 and (EU) 453/2010 (Annex I)

SECTION 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Substance identifier

Substance name:	GLIBENCLAMIDE
Other names (if available):	Glyburide 5-chloro-N-(2-(4-(((cyclohexylamino)carbonyl)amino) sulphonyl)phenyl)ethyl)-2-methoxybenzamide 1-((p-(2-(5-chloro-o-anisamido)ethyl)phenyl)sulphonyl)-3-cyclohexylurea
Name in Annex VI-CLP; Name reported in the inventory of harmonized classification and labelling:	unlisted
CAS number	10238-21-8
REACH registration number	Exempt of registration

1.2. Relevant identified uses of the substance and uses advised against

Relevant use(s)	Active Pharmaceutical Ingredient for the preparation of pharmaceuticals (drug products)
Uses advised against	none

1.3. Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Company name: CAMBREX PROFARMACO MILANO Srl

Address : Via Curiel, 34 20067 Paullo (MI) - ITALY

Phone number : 02 9062601

Fax number: 02 90630995

Competent person responsible for the safety data sheet:

Sig. Luciano Albani

e-mail: luciano.albani@cambrex.com

1.4. Emergency telephone number

Location:

Address: Via Curiel, 34 20067 Paullo (MI) - ITALY

Phone number (24 hours): +39 02 906260/1

**SECTION 2
HAZARDS IDENTIFICATION**

2.1 Classification of the substance

- Classification of the substance in accordance with Regulation (CE) n. 1272/2008:

Hazard class	Class code and hazard category	Hazard statement	Hazard warning
Aquatic environment toxicity	Aquatic Chronic 4	H413	May cause long lasting harmful effects to aquatic life.

- Classification in accordance with Directive 67/548/CEE:

Classification	Risk phrases	Safety phrases
none	none	none

Main adverse effects

Physico-chemical effects

Health effects

Environmental effects

See also sections from 9 to 12

No adverse effect known.

No adverse effect known.

May cause long lasting harmful effects to aquatic life.

2.2 Label elements

- Labelling in accordance with regulation n. 1272/2008/EC

Hazard pictogram/s	none
Signal Word	none
Hazard indication (H) ^[1]	H413
Safety statements (P) ^[1]	
- <i>Prevention</i>	P273
- <i>Reaction</i>	-
- <i>Storage</i>	-
- <i>Disposal</i>	P501

^[1] For the explanation of H and P statements: see Section 16

2.3 Other hazards (which do not results in the classification)

The substance satisfies the PBT criteria

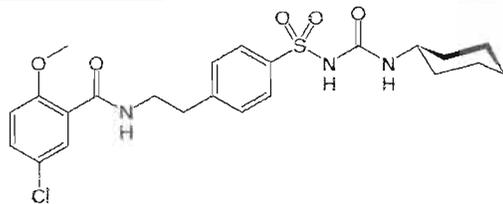
- PBT
- vPvB

YES	NO
	X
	X

- Health hazards not known
- Environmental hazards not known
- Physico-chemical hazards not known
- Specific effects unknown

**SECTION 3
COMPOSITION/INFORMATION ON INGREDIENTS**

Description: active pharmaceutical ingredient

Name of the component	Glibenclamide
Concentration	Pure substance
Structural formula	
Chemical formula	C ₂₃ H ₂₈ Cl N ₃ O ₅ S
Molecular weight	494,0 g/mol
Substance with Community OEL	No
CAS name	5-chloro-N-(2-(4-(((cyclohexylamino) carbonyl)amino) sulphonyl) phenyl)ethyl)-2-methoxybenzamide
CAS number	10238-21-8
IUPAC name	5-chloro-N-[2-[4-(cyclohexylcarbamoylsulfamoyl)phenyl]ethyl]-2-methoxybenzamide
EC number	EINECS 233-570-6
Index number	not assigned
Impurity/ies (if classified)	-
Additive/ies (if classified)	-

**SECTION 4
FIRST AID MEASURES**

4.1 Description of the first aid measures

- *Eye contact* Wash immediately with large amounts of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms will appear.
- *Skin contact* Remove contaminated clothes and shoes immediately. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical advice if adverse symptoms will appear.
- *Ingestion* If swallowed wash mouth with water provided person is conscious. Treat symptomatically and supportively. Get medical advice if adverse symptoms will appear.
- *Inhalation* Avoid breathing aerosols and dusts that may be generated by handling of the product. Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms will appear.

4.2 Most important symptoms and effects (acute and delayed)

- *Acute effects* not known
- *Delayed effects:* not known

4.3 Indication of any immediate medical attention and special treatment needed

- *Medical monitoring:* none
- *Antidotes, if known* unknown
- *Contraindications* unknown
- *Immediate treatment at workplace* not known

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

- *Suitable extinguishing media* Water spray or regular foam, dry powder, CO₂.
- *Unsuitable extinguishing media* not known

5.2 Special hazards arising from the substance

- *Hazardous combustion products* Thermal decomposition or combustion may generate toxic and hazardous fumes (CO_x, SO_x, NO_x) and compounds containing chlorine.
- *Other special hazards* not known

5.3 Advice fo firefighters

- *Technical actions for protection* Keep containers cool with water.
- *Special protective equipment for firefighters* Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in highest condition of protection on the basis of the information reported in the previous sub-sections

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel

Wear appropriate protective equipment (see Section 8) to prevent contamination of the skin, eyes and personal clothing.
In case of fire and/or explosions avoid breathing fumes and vapors. Use a self-contained breathing apparatus (SCBA) and appropriate protective clothing. The fumes can be eliminated by spraying with water.
See also section 8

- For emergency responders

See section 8.

6.2 Environmental precautions

In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water. Contact local Authorities in case of environmental release.

6.3 Methods and material for containment and clearing up

- *Containment procedures:* Coverage of the discharges
- *Cleaning up procedures:* Recover the substance for suction or other mechanical means and wash the area with plenty of water and detergents. Store the material into a company that specializes pending disposal. Containers must be cleaned up and disposed of as waste remediation above.

6.4 Reference to other sections

See also section 8 and 13.

**SECTION 7
HANDLING AND STORAGE**

7.1. Precautions for safe handling

- *Recommendation for handling:* Handle away from sparkles and flames - sources of ignition
Handle in a well ventilated place
Avoid contact with incompatible materials
Wear suitable Personal Protection Equipment (see section 8)
Keep the substance away from drains, surface or ground waters
- *Recommendation for personal hygiene:* Do not eat, drink and smoke in the working areas
Wash hands after handling the substance
Remove contaminated clothing and protective equipment before entering eating areas

7.2. Condition for safe storage including any incompatibilities

The substance is not classified for any physical and chemical properties and no risk management is foreseen.

Other advice

- *Ventilation requirements* Use in a well ventilated place at room temperature (preferably less than 40°C)
- *Containers* Keep containers tightly closed and with correctly labeled.
- *Specific design of storage rooms* Not requested on the based of the classification
- *Quantity limits for storage* Not requested on the based of the classification
- *Packaging compatibilities* See also section 10.5

7.3. Specific end use(s)

- Recommendation for specific final use(s):
the substance is an Active Pharmaceutical Ingredient which shall be used only for professional purposes for the preparation of pharmaceuticals (drug products)

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Industry or sector specific guidance available and attached		X

**SECTION 8
EXPOSURE CONTROLS/PERSONAL PROTECTION**

8.1. Control parameters

- National/European Occupational Exposure Limits General exposure limit: N.A.
- Other National/European Occupational Exposure Limits unknown
- Recommended monitoring procedures The measurement of substances in the workplace must be carried out with standardized methods (eg EN 689:1997: Workplace atmospheres - Guide for assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; UNI EN 482:2006: atmospheres in the workplace - General requirements for the provision of procedures for the measurement of chemical agents) or, failing that, with appropriate methods.
- DNEL values (components) unknown
- PNEC values (components) unknown

8.2. Exposure controls

	SI	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

8.2.1. Appropriate engineering controls

The adoption of the most appropriate technical controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance) when a unique and standardized exposure scenario described in a dossier registered REACH is not available.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

- a) Eye and Face protection Safety goggles as for EN 166; facial shield
- b) Skin protection
 - *hands protection* Wear protective gloves.
Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/CEE.
The glove material has to be made of rubber or polyethylene impermeable and resistant to the substance.
Make the choice of the glove material on consideration of the penetration times, rates of diffusion and degradation.
The selection of suitable gloves not only depends on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
 - *other, body protection* Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 13982.
- c) Respiratory protection Dust mask with approved dust filter.
Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU)
In the case of brief exposure or minimal exposure use respiratory filter; in case of intensive and sustained exposition wear self-contained breathing.
- d) Thermal hazards Not foreseen in the standard use. Assess possible Personal Protection Equipment on the basis of specific uses of the substance.

8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

Avoid to release in the environment.

**SECTION 9
PHYSICAL AND CHEMICAL PROPERTIES**

9.1. Information on basic physical and chemical properties

- Appearance: off white or white solid (crystalline powder)
- Odor: -
- Odour threshold: -
- pH: Data not available in the literature search carried out
- Melting point/freezing point: 169 °C ⁽¹⁾
- Initial boiling point and boiling range: Data not available in the literature search carried out
- Flash point: Sensibility to ignition (tested):