



## MATERIAL SAFETY DATA SHEET-OXCARBAZEPINE

Version: R<sub>1</sub>

Effective Date: 11.05.11

### 1. Identification of the Substance/Preparation and of the Company/Undertaking

#### Product Information

Designation : Active Pharmaceutical Ingredient  
Synonyms : 10,11-Dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide.  
Use : Anticonvulsant.  
Company : Jubilant Life Sciences Limited, # Plot No.18, 56, 57&58 KIADB,  
Industrial Area, Nanjangud-571302, Mysore, India.  
Telephone : +91 8221 228402-08  
Telefax number : +91 8221 228410-11  
Emergency information : Mr. Biswajit Mitra, Site Head  
Telephone-91-8221 228402-08  
Email: Biswajit Mitra@jubl.com

### 2. Hazards Identification

GHS Classification : Acute toxicity (dermal), Category 4, H312  
Acute toxicity (inhalation), Category 4, H332

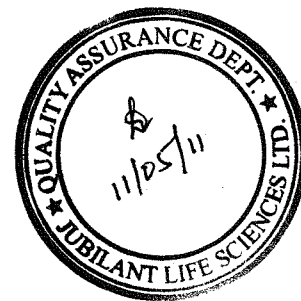
Classification : Harmful by inhalation. (R20)  
Harmful in contact with skin. (R21)  
Do not breathe dust. (S22)  
Avoid contact with skin. (S24)  
Avoid contact with skin and eyes. (S24/25)

The product used is a pharmaceutical active substance. All precautions for drugs and pharmaceuticals should thoroughly be observed.

### 3. Composition/Information on Ingredients

#### Hazardous Ingredients

Chemical Name	Classification	GHS Classification	Concentration
10,11-Dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide	R20	H312	100%
	R21	H332	
	S22		
	S24		
	S24/25		
Molecular formula: C <sub>15</sub> H <sub>12</sub> N <sub>2</sub> O <sub>2</sub>		CAS No. [28721-07-5]	
Molecular weight: 252.27		Index No. Not available	



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### 4. First-aid Measures

- General advice : Remove affected person from danger area. Do not leave affected persons unsupervised. Seek medical treatment  
First aid personnel should pay attention to their own safety.
- Eye contact : Flush with copious amounts of water for at least 15 minutes. If pain, blinking, tears, redness or irritation persists, get medical attention.
- Skin contact : Wash off immediately with plenty of water and mild soap. Remove contaminated clothing and shoes. Get medical attention if irritation develops.
- Inhalation : Supply fresh air or oxygen and call a physician immediately.
- Ingestion : Wash out mouth with water provided person is conscious. Call a physician.

#### Notes to physician

- Symptoms : Headache, vomiting, mild nausea, blurred vision, skin rashes etc.
- Hazards : Difficulty in breathing, body aches, chest pain, unusual bleeding etc.
- Treatment : Call the doctor immediately and medical monitoring.

### 5. Fire-fighting Measures

- Hazards during fire-fighting : Emit toxic fumes under fire condition.
- Protective equipment for fire-fighting : Wear self contained breathing apparatus for fire fighting if necessary.
- Extinguishing media : Use extinguishing measures to suit surroundings, water spray, dry chemical powder, carbon dioxide or appropriate foam.
- Further Information : Dispose of contaminated fire fighting extinguishing powder by collecting separately. It must not enter the sewage system.

### 6. Accidental Release Measures

- Personal precautions : Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.
- Environmental precautions : Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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Methods for cleaning-up or taking up : Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

### 7. Handling and Storage

#### Handling

Advice on safe handling : Handle in accordance with good industrial hygiene and safety procedures. Avoid prolonged or repeated exposure. Take precautionary measures against electrostatic discharge.

Hints for protection against fire and explosion : Material should be handled in a laboratory hood whenever possible.

Dust explosion class : Not available.

#### Storage

Requirements for storage and vessels : Preserve in well-closed containers and store at room temperature.

Further information : Store in a cool place. Protect from contamination.

Advice on storage compatibility : Keep away from all heat sources, including direct sun-light, open flame, sources of ignition, sparks etc.

Storage class according to VCI : Not available

### 8. Exposure Controls and Personal Protection

Additional information on : Use with local exhaust ventilation.

The layout of technical plants

Components	Basis	Factor	BIEL-Group	Values	Remarks
10,11-Dihydro-10-oxo-5H-dibenz[b,f]azepine-5-carboxamide	NA	NA	NA	NA	
NA = Not available					

#### Personal protective equipment

Respiratory protection : Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

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Hand protection	:	Wear suitable gloves resistant to chemical penetration.
Eye protection	:	Chemical safety goggles.
Body protection	:	Wear suitable protective clothing.
Additional information	:	Only use protective equipment in accordance with national/international regulations. Follow the national regulation about wearing personal protective equipment and the warranty given by the manufacturer for the safe function
Hygienic measures	:	General industrial hygiene practice.
General protective measures	:	Handle in accordance with good industrial hygiene and safety practice. Provide local exhaust or general room ventilation. Avoid contact with skin, eyes and clothing. Do not breathe dust.

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### **9. Physical and chemical properties**

Form	:	Powder
Color	:	Light orange to creamish-white or off-white
Odor	:	Not available
Melting Point/range	:	216-226° C
Flammability	:	Not available
Flash point	:	Not available
Ignition temperature	:	Not available
Bulk density	:	Not available
Solubility (quantitative)	:	Soluble in acetic acid, sparingly soluble in chloroform, slightly soluble in dichloromethane, acetone and methanol, very slightly soluble in ethanol, insoluble in ether.
Solubility in water	:	Practically insoluble
pH value	:	Not available
Viscosity, dynamic	:	Not available

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### **10. Stability and Reactivity**

Thermal decomposition	:	Not available
Condition to avoid	:	Not available
Hazardous reaction	:	Not available
Substances to avoid	:	Strong oxidizing agents.

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### **11. Toxicological Information**

RTECS nr	:	HN8445000
Rat oral LD50 [mg/kg]	:	Not available
Rabbit dermal LD50 [mg/kg]	:	Not available
Rat inhalation LC50 [mg/L/4h]	:	Not available
Acute toxicity	:	Not available
Chronic toxicity	:	Not available
Sensitization	:	Not available
Ames-test	:	Positive

### **12. Ecological Information**

LC50-96 Hour - fish [mg/L]	:	Not available
EC50-48 Hour-Daphnia magna [mg/L]	:	Not available
IC50-72 Hour - Algae [mg/L]	:	Not available
Persistence - degradability	:	Not available
Log P octanol / water at 20°C	:	Not available
Biodegradation [%]	:	Not available
Environmental precautions	:	Not available

### **13. Disposal Considerations**

Product	:	Contact a licensed professional waste disposal service to dispose of this material. Dispose in a safe manner in accordance with local/national regulations. Observe all federal, state and local environmental regulations.
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### **14. Transport Information**

#### **Land transport**

UN-No	:	Not available
ADR Class	:	Not available
ADR Packing group	:	Not available
TRC	:	Not available
Hazard ID-No.	:	Not available
Label (s)	:	Not available
Designation of goods	:	Oxcarbazepine (API)

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### Air transport Passenger Aircraft

UN-No : Not available  
 IATA-Class or division : Not available  
 IATA Packing group : Not available  
 IATA-Label (s) : Not available  
 Correct technical name : Oxcarbazepine (API)

### Air transport Cargo Aircraft


UN-No : Not available  
 Class : Not available  
 Packaging group : Not available  
 ICAO-Label (s) : Not available  
 Correct technical name : Oxcarbazepine (API)

### Sea transport

UN-No : Not available  
 Class : Not available  
 Packaging group : Not available  
 ICAO-Label (s) : Not available  
 Correct technical name : Oxcarbazepine (API)

## 15. Regulatory Information

### Labeling according to CLP-/GHS

Symbol(s) : 

GHS07

Hazard Statement(s) : Harmful in contact with skin. (H312)  
 Harmful if inhaled. (H332)


Safety precautions(s) : Avoid breathing dust/fume/gas/mist/vapours/spray.  
 (P261)  
 Wear protective gloves/protective clothing/eye  
 protection/face protection. (P280)  
 IF ON SKIN: Wash with plenty of soap and water. (P302 +  
 P352)  
 Wash contaminated clothing before reuse. (P363)

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### Labeling according to EEC Directive

Symbol(s)	:	
R phrase(s)	:	Harmful by inhalation. (R20) Harmful in contact with skin. (R21)
S phrase(s)	:	Do not breathe dust. (S22) Avoid contact with skin. (S24) Avoid contact with skin and eyes. (S24/25)

### National legislation/regulation

Water hazard class	:	Not available
Other regulations	:	Not available

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### 16. Other particulars

Not available

The information provided in this Safety Data Sheet is correct to the best of our knowledge information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process unless specified in the text.