

## SECTION 11

### INFORMATION ON TOXICOLOGICAL EFFECTS

#### - Exposure routes:

- Inhalation:
- Ingestion:
- Skin contact:
- Eye contact:

SI	NO
X	
X	
X	
X	

#### - Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):

- Inhalation: may be irritating or sensitizing
- Ingestion: not harmful if swallowed
- Skin contact: may be irritating or sensitizing
- Eye contact: may be irritating

#### - Toxicokinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion):

data not available in the literature search carried out

#### - Acute toxicity effects:

- Oral: LD50 guinea pig = >15.000 mg/kg <sup>(3)</sup>  
LD50 mouse = 3.250 mg/kg <sup>(4)</sup>  
LD50 rabbit > 2.000 mg/kg <sup>(5)</sup>  
LD50 rat > 2.000 mg/kg <sup>(6)</sup>
- Dermal: Data not available in the literature search carried out
- Inhalation: Data not available in the literature search carried out
- Other effects: -

#### - Corrosion/Irritation effects:

skin: data not available in the literature search carried out  
eye: data not available in the literature search carried out  
by inhalation : data not available in the literature search carried out

#### - Severe ocular lesion : Data not available in the literature search carried out

#### - Sensitisation:

- Dermal: data not available in the literature search carried out
- Respiratory: data not available in the literature search carried out

#### - Repeated dose toxicity (experimental.): NOAEL not available

#### - CMR effects:

- Germinal cell mutagenicity: no mutagenic
- Carcinogenicity: data not available in the literature search carried out
- Reproductive toxicity: data not available in the literature search carried out

#### - Specific Target Organ Toxicity (STOT)-single exposure:

Data not available in the literature search carried out

#### - Specific Target Organ Toxicity (STOT)- repeated exposure :

Data not available in the literature search carried out

#### - Aspiration hazards: Data not available in the literature search carried out

#### - Epidemiological information: studies on nursing mothers who had received orally 5-10 mg of glyburide shown that the substance was undetectable in the milk <sup>(7)</sup>

## SECTION 12 ECOLOGICAL INFORMATION

### 12.1. Toxicity

- Acute toxicity to algae (*Scenedesmus subspicatus*)(72 ore):  $EC_{50} > 100$  mg/L
- Acute toxicity to fish (Guppy)(96 ore):  $LC_{50} > 100$  mg/L
- Acute toxicity to *Daphnia magna* (48 ore):  $EC_{50} > 100$  mg/L
- Acute toxicity to sludge: strong adsorption to activated sludge

### 12.2. Persistence and degradability

Not readily biodegradable : 0% 28days

### 12.3. Bioaccumulative potential

$\log Pow = 4,790$  very high bioaccumulation potential

### 12.4. Mobility in soil

Data not available in the literature search carried out

### 12.5. Results of PBT e vPvB assessment

Assessment is not available - on the basis of the  $\log Pow$  value and the experimental data the substance could present a bioaccumulation and persistency potential; studies on daphnia, algae and fish did not show a danger for the environment

### 12.6. Other adverse effects

Not known

## SECTION 13 DISPOSAL CONSIDERATION

### 13.1. Waste treatment methods

- Mixture wastes:
- Contaminated packaging:

Incineration	Recycling	Landfilling
X		
	X	

The substance must be incinerated in a suitable incinerator authorized by the Competent Authorities. Should never be disposed through wastewater.

Refers to Community/National/Local requirements concerning the waste disposal.

## SECTION 14 TRANSPORT INFORMATION

The substance is not classified for transport.

## SECTION 15 REGULATORY INFORMATION

### 15.1 Safety, Health and Environmental regulation/legislation specific for the mixture or its ingredients

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and following amendment and National reinforcements.

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 - 0023

Regulation (EC) no 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals

## 15.2. Chemical Safety Assessment

- Exposure scenario attached
- Chemical Safety Assessment (CSA) attached

YES	NO
	X
	X

## SECTION 16 OTHER INFORMATION

### Revisions:

- **Revision n. 02 dated** October 2010 (regarding all sections in according to Regulation no. 453/2010).

### Bibliographic sources:

- (1) Data bank ChemID plus Lite, Glyburide full record, Physical properties
- (2) GLP Compliant Laboratories, Beta House, Chilworth Science Park, Southampton UK, Report no. 32701, issue 1, 28/09/2001
- (3) Arzneimittel-Forschung. Drug research. Vol.19, pag. 1404, 1969
- (4) Arzneimittel-Forschung. Drug research. Vol.19, pag. 1640, 1966
- (5) Oyo Yakuri. Pharmacometrics. Vol 4, pag. 247, 1970
- (6) Arzneimittel-Forschung. Drug research. Vol.19, pag. 1413, 1969
- (7) Feig DS, Briggs GG, Kraemer JM et al. Transfer of glyburide and glipizide into breast milk. Diabetes

### Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Exposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society)
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for reproduction substances
- EINECS: European Inventory of existing Commercial Substances
- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE : Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative

**Information related to the regulation CE/1272/2008****List of hazards statements****H413:** May cause long lasting harmful effects to aquatic life.**List of P statements****P273** Avoid release to the environmentPrevention -Reaction -Storage -Disposal -**P501:** Dispose of contents/container in accordance with local/regional/ national/international regulation.**Information related to the Directive 67/ 548/ CEE, Directive 1999/45/CE and Regulation (CE) n. 1907/2006***R phrases* none*S phrases* none**Information on workers training**

Follow criteria of Directive 98/24/CE, its amendments and National reinforcements

**Restriction of use :** None**Substance under authorisation :** no**DISCLAIMER**

This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material. The provider of this document can not provide any warnings about the dangers of use or interaction with other chemicals or materials. And 'the user's safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Annex I of Regulation No 453/2010/EU.

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and by Cambrex Profarmaco Milano S.r.l -Health & Safety Office and R&D.



## MATERIAL SAFETY DATA SHEET HALOPERIDOL

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

Commercial product name Haloperidol  
Company: Farmabase Pharmaceutical Raw Materials  
Campiello del Trivio, 12  
38068 Rovereto  
Italy  
Phone: 0464/421996  
Fax: 0464/421985  
CAS nr. 52-86-8

2. Chemical Characterisation & physical form

Chemical formula  $C_{21}H_{23}ClFNO_2$   
Molecular weight 375.87  
Physical form Haloperidol is a white or almost white powder

3. Hazards Identification

Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation. Severe over-exposure can result in death.  
Repeated exposure to an highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

4. First aid measures

Eye contact: check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.

Skin contact: after contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

Ingestion: do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Inhalation: allow the victim to rest in a well ventilated area. Seek immediate medical attention.

5. Fire fighting measures

Flammability of the product: may be combustible at high temperature

Products of combustion are: carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO, NO<sub>2</sub>), halogenated compounds.

Fire fighting media and instructions:

Small fire: use dry chemical powder

Large fire: use water spray, fog or foam. Do not use water jet.

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VAT/P.I.: IT 01285580229  
C.F.: CCH FBA 62T18 II6121E  
C.C.I.A.A.: 127370  
Pos.Mec.: TN 011775

# F A R M A B A S E

## PHARMACEUTICAL RAW MATERIALS

### 6. Accidental release measures

Small spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container.

Large spill:

Use a shovel to put the material into a convenient waste disposal container.

### 7. Handling and storage

Precautions:

Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. In ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

Storage:

Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Highly toxic or infectious materials should be stored in a separate locked safety storage cabinet or room.

### 8. Exposure controls / personal protection

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 limits.

Personal protection:

Splash goggles, lab coat, gloves, dust respirator. Be sure to use an approved/certified respirator or equivalent. Consult a specialist before handling this product.

### 9. Physical and chemical properties

Physical state	powder
Colour	white or almost white
Boiling point	decomposes
Melting point	148 °C (298.4 °F)
Solubility	practically insoluble in water

### 10. Stability and reactivity

The product is stable and non-corrosive in presence of glass.

### 11. Toxicological information

Toxicity to animals: acute oral toxicity (LD50): 71 mg/kg (Mouse)

Toxic effects on humans: hazardous in case of skin contact (irritant), of ingestion, of inhalation.

### 12. Ecological information

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise. The products of biodegradation are more toxic.

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

13. Disposal considerations

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

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):

R25-toxic if swallowed

R36/38-irritating to eyes and skin

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

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**MATERIAL SAFETY DATA SHEET** (Directive 1907/2006/CE)Substance: **FERRIC HYDROXIDE POLYMALTOSE COMPLEX**

Revision Date: 27/05/2009

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## 1. CHEMICAL AND COMPANY IDENTIFICATION

## 1.1 Substance Identification

1.1.1 Commercial Name Ferric Hydroxide Polymaltose Complex

1.2 Substance Use Pharmaceutical

## 1.3 Company Identification

1.3.1 Company Identification: BIOFER S.p.A.

Via Canina, 2

41036 Medolla (MO)

Tel. + 39 053552214

Fax +39 053551323 (52204)

e-mail [info@bioferspa.com](mailto:info@bioferspa.com)

1.3.2 Emergency telephone number : +39 053552214

## 2. HAZARDS IDENTIFICATION

2.1 Hazards classification according to Directive 67/548/CEE: not classified substance.

2.2 Further hazards indication for human health and environment: none.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Chemical Name: Ferric hydroxide polymaltose complex

CAS N. 53858-86-9

EINECS N. -

INDEX N. -

Formula -

Molecular Weight From 30000 Da to 1000000 Da

## 4. FIRST AID MEASURES

4.1 Inhalation If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

4.2 Skin contact In case of skin contact, immediately wash skin with soap and copious amounts of water.

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4.3	Eyes contact	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. In case of persistent irritation call a physician.
4.4	Ingestion	If swallowed, wash out mouth with copious amount of water. In case of ingestion of a significant amount of substance, call a physician.
5.	FIRE FIGHTING MEASURES	
5.1	Extinguishing suitable media	Water spray, resistant alcohol foam, carbon dioxide, dry chemical powder.
5.2	Forbidden extinguishing media	None
5.3	Hazards from combustion	Under fire conditions emits irritant fumes for eyes and for breathing organs.
5.4	Special protective equipment for Fire fighters	Wear self-contained breathing apparatus and protective clothing and chemical safety goggles
6.	MEASURES IN CASE OF ACCIDENTAL LEAKAGE	
6.1	Personal precautions	Avoid raising dust
6.2	Environmental precautions	Avoid the substance dissipates in the ground or stream or sewers.
6.3	Cleaning procedure	Use suitable mechanical equipments in order to pick the substance in suitable containers for disposal. Wash with copious amount of water.
7.	HANDLING AND STORAGE	
7.1	Handling	Keep a suitable ventilation system in rooms where dust could raise. Usual fire fighting measures
7.2	Storage	Storage in a fresh room. Keep tightly closed in a dry and ventilated area.

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8 EXPOSURE CONTROL / PERSONAL PROTECTION

8.1	Maximum professional exposure	not defined
8.2	Environmental exposure control	Suitable local aspiration system with a suitable filter for dust pulling down.
8.3	Personal protection	Only for special conditions in case of uncontrolled exposure.
8.3.1	Breathing protection	Dust mask type P1 (EN 143).
8.3.2	Hands protection	Chemical safety gloves for dust. Permeation time to be fixed according to type and time of exposure.
8.3.3	Eyes protection	Safety box or cup goggles.
8.3.4	Skin protection	Fully protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Aspect and colour:	Brown red powder
Odour:	odourless
pH (sol. 5% Fe <sup>3+</sup> w/v)	5.5 ÷ 7.5
Fusion point/range	not defined
Boiling point/range	not applicable
Flash point	not defined
Flammability (solid/gas)	not defined
Self Flammability	not defined
Explosive properties	not defined
Explosive limits	not defined
Oxidant properties	not defined
Vapor pressure	not applicable
Vapor density	not applicable
Evaporation rate	not applicable
Density	not defined
Water solubility	not defined
Liposolubility	not defined
Partition coefficient n-oct/water	not defined

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## 10. STABILITY AND REACTIVITY

- |      |                                  |  |
|------|----------------------------------|--|
| 10.1 | Stability                        | Stable in standard usage and storage conditions. |
| 10.2 | Reactivity                       | Not reactive.                                    |
| 10.2 | Materials to avoid               | Strong oxidizing agents.                         |
| 10.3 | Hazardous decomposition products | Unknown  |

## 11. TOXICOLOGICAL INFORMATION

- |      |   |  |
|------|---|--|
| 11.1 | Acute toxicity  | DL50 (IPR-rat) > 5 mg/kg<br>DL50 (ORL-rat) 1516 mg(Fe)/kg  |
| 11.2 | Irritation and corrosiveness                            | no available data  |
| 11.3 | Sensitization   | no available data  |
| 11.4 | Carcinogenicity, mutagenicity and reproduction toxicity | The toxicological properties have not been thoroughly investigated<br>Health damages following the correct use of the substance are unknown. |

## 12. ECOLOGICAL INFORMATION

- |      |                               |                   |
|------|-------------------------------|-------------------|
| 12.1 | Water toxicity                | no available data |
| 12.2 | Mobility                      | no available data |
| 12.3 | Persistence and degradability | no available data |
| 12.4 | Bioaccumulative potential     | no available data |
| 12.5 | PBT Valutation                | no available data |
| 12.6 | Other harmful effects         | no available data |
- Use according to the good working practices and avoiding to dissipate the substance in environment.

## 13. DISPOSAL CONSIDERATIONS

Dispose of the waste, the surplus, the contaminated packaging according to national and local existing regulations.

## 14. TRANSPORT INFORMATION

- |      |                         |                |
|------|-------------------------|----------------|
| 14.1 | RID/ADR (road/railway): | not prescribed |
|------|-------------------------|----------------|

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14.2 IMDG (sea): not prescribed

14.3 IATA (airway): not prescribed

15. REGULATORY INFORMATION

15.1 Labelling (directive 67/548/CEE)

15.1.1 Hazards symbols none

15.1.2 R codes none

15.1.3 S codes

S-22 Do not breathe dust

S-36 Wear suitable protective clothing

15.2 Specific community regulation none

16. OTHER INFORMATION

The above information goes by our best present knowledge but does not purport to be all inclusive and it shall be considered purely as an indication. BIOFER S.p.A. shall not be held liable for any damage resulting from handling or from contact with the above substance.

The present Material Safety Data Sheet replaces and cancels every previous version.

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**MATERIAL SAFETY DATA SHEET****OF****KETOCONAZOLE****Aarti Drugs Ltd.****PLOT NO: G:60, MIDC, TARAPUR****1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY INFORMATION****Product Name:** Ketoconazole**CAS#:** 65277-42-1**RTECS:** TK7912300**TSCA:** TSCA inventory: No products were found.**CI#:** Not available.**Synonym:** Piperazine, 1-acetyl-4-(4-((2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl)methoxy)phenyl)-,cis-**Chemical Name:** Ketoconazole**Chemical Formula:** C<sub>26</sub>-H<sub>28</sub>-CL<sub>2</sub>-N<sub>4</sub>-O<sub>4</sub>**2. COMPOSITION/INFORMATION ON INGREDIENTS****Composition:****CAS #** 65277-42-1**3. HAZARDS IDENTIFICATION****Potential Acute Health Effects:**

Slightly hazardous in case of skin contact (irritant), of eye contact (irritant). Severe over-exposure can result in death.

**Potential Chronic Health Effects:****CARCINOGENIC EFFECTS:** Not available.**MUTAGENIC EFFECTS:** Not available.**TERATOGENIC EFFECTS:** Not available.**DEVELOPMENTAL TOXICITY:** Classified Reproductive system/toxin/female, Reproductive system/toxin/male**[POSSIBLE].** Classified Development toxin [NONE].**The substance is toxic to liver, endocrine.**

#### 4. FIRST AID MEASURES

**Eye Contact:** NO known EFFECT on eye contact, rinse with water for a few minutes.

**Skin Contact:**

After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

**Serious Skin Contact:** Not available.

**Inhalation:** Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

**Serious Inhalation:**

Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek medical attention.

**Ingestion:**

Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

**Serious Ingestion:** Not available.

#### 5. FIRE FIGHTING MEASURES

**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, CO<sub>2</sub>), nitrogen oxides (NO, NO<sub>2</sub>...).

**Fire Hazards in Presence of Various Substances:** Not available.

**Explosion Hazards in Presence of Various Substances:**

Risks of explosion of the product in presence of mechanical impact: Not available.

Risks of explosion of the product in presence of static discharge: Not available.

**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:** Not available.

**Special Remarks on Explosion Hazards:** Not available.



## 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.

## 7. HANDLING AND STORAGE

### Precautions:

Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents.

### Storage:

Keep container dry. Keep in a cool place. Ground all equipment containing material. Carcinogenic, teratogenic or mutagenic materials should be stored in a separate locked safety storage cabinet or room.

## 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.

### 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state and appearance** : Solid.

**Odor** : Not available

**Taste** : Not available

**Molecular Weight** : 531.48 g/mole

**Color** : White Crystal powder

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

**Boiling Point** : Not available.

**Melting Point** : Not available

**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** : Not available

## 10. STABILITY AND REACTIVITY

**Stability** : The product is stable.

**Instability Temperature:** Not available.

**Conditions of Instability:** Not available.

**Incompatibility with various substances:** Not available

**Corrosivity:** Non-corrosive in presence of glass

**Special Remarks on Reactivity:** Not available.

**Special Remarks on Corrosivity:** Not available.

**Polymerization:** No.

## 11. TOXICOLOGICAL INFORMATION

**Routes of Entry:** Absorbed through skin. Eye contact. Ingestion.

**Toxicity to Animals:** Acute oral toxicity (LD50): 166 mg/kg [Rat].

### **Chronic Effects on Humans:**

**DEVELOPMENTAL TOXICITY:** Classified Reproductive system/toxin/female, Reproductive system/toxin/male

[POSSIBLE]. Classified Development toxin [NONE].

The substance is toxic to liver, endocrine.

**Other Toxic Effects on Humans:** Slightly hazardous in case of skin contact (irritant).

**Special Remarks on Toxicity to Animals:** Not available.

**Special Remarks on Chronic Effects on Humans:** Not available.

**Special Remarks on other Toxic Effects on Humans:** Not available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity:** Not available.

**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 less toxic than the product itself.

**Special Remarks on the Products of Biodegradation:** Not available.

## 13. DISPOSAL CONSIDERATIONS

**Waste from residues / unused products:** Waste disposal must be in accordance with appropriate local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous.

**Contaminated packaging:** Do not re-use empty containers

## 14. TRANSPORT INFORMATION

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

**Identification:** Not applicable.

**Special Provisions for Transport:** Not applicable.

### 15. REGULATORY INFORMATION

15.1 Name of firm: M/s Aarti Drugs Ltd.

15.2 Mailing address: G-60  
MIDC, Tarapur  
INDIA

15.3 Telephone & Fax: 952525 271241

**State Notification:** The above information is your notice as to the Right-to-Know listings of the stated product(s). Individual states will list chemicals for a variety of reasons including, but not limited to, the compounds toxicity; carcinogenic, tumorigenic and/or reproductive hazards; and the compounds environmental impact if accidentally released.

### 16. OTHER INFORMATION

The information contained in this material data sheet is believed to be reliable but no representation, guarantee or Warranties, of any kind are made as to its accuracy, suitability for a particular application or results to be obtained from them. It is whoever ensure that the information contained in the material safety data sheet is relevant to the product manufactured / handled or sold as the case may be by us.

**M/s AARTI DRUGS LTD.** makes no warranties expressed or implied in respect of the adequacy of this document for any particular purpose.



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# LORATADINE

## 1. Product Identification

**Synonyms:** 4-(8-Chloro-5,6-dihydro-11-H-benzo-(5,6)cyclohepta(1,2-b)Pyridine-11-ylidene-1-piperidine carboxylic acid ethyl ester; Loratadine Related Compounds: 8-Chloroazatadine ARS

**CAS No.:** 79794-75-5

**Molecular Weight:** 382.9

**Chemical Formula:** C<sub>22</sub>H<sub>23</sub>ClN<sub>2</sub>O<sub>2</sub>

**Product Codes:** 3060, 3061, 4330, 4390

## 2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Loratadine	79794-75-5	100%	Yes

## 3. Hazards Identification

### Emergency Overview

**WARNING! MAY BE HARMFUL IF SWALLOWED OR INHALED. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT.**

### Potential Health Effects

#### Inhalation:

May cause irritation to the respiratory tract. Symptoms may include coughing, sore throat, labored breathing, and chest pain.

#### Ingestion:

Symptoms from overexposure include: headache, insomnia, dry mouth, somnolence, nervousness, dizziness, fatigue, dyspepsia, nausea, pharyngitis, anorexia and thirst.

#### Skin Contact:

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May cause irritation with redness and pain.

**Eye Contact:**

May cause irritation, redness and pain.

**Chronic Exposure:**

No information found.

**Aggravation of Pre-existing Conditions:**

No information found.

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## 4. First Aid Measures

**Inhalation:**

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:**

Give large amounts of water to drink. Never give anything by mouth to an unconscious person. Get medical attention.

**Skin Contact:**

Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

**Eye Contact:**

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

---

## 5. Fire Fighting Measures

**Fire:**

As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

**Explosion:**


Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Maximum Explosion Pressure (P<sub>max</sub>, bar-g): 8.3 Maximum Rate of Pressure Rise (R<sub>max</sub>, bar/s): 929 Maximum Scaled Rate of Pressure Rise (K<sub>st</sub>, bar-m/s): 252 Minimum Explosible Concentration, (MEC, g/m<sup>3</sup>): 53 Minimum Spark Ignition Energy, (MIE, mJ): <9 Minimum Ignition Temperature of a Dust Clouds, (T<sub>c</sub>): 370C Hot Surface Ignition Temperature of Dust Layers, (T<sub>s</sub>): Loratadine melted Dust Class: St-2.

**Fire Extinguishing Media:**

Water spray, dry chemical, alcohol foam, or carbon dioxide.

**Special Information:**

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus

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with full facepiece operated in the pressure demand or other positive pressure mode. Follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7).

## 6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8, and follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7). Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Spills: Carefully sweep up material into an appropriate container and save for reclamation or disposal. Do not flush to sewer!

## 7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

Loratadine has potent pharmacological activity and is classified as an OEB-2\* material. Handling practices for OEB-2 substances are described below:

### Laboratory

- \*Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices.
- \*No local exhaust ventilation required for transfer/handling of quantities of powder less than 100 g (total weight transferred or handled). However, if the source container contains 2 kg or more, pilot plant practices apply.
- \*No local exhaust ventilation required for solutions of these compounds.
- \*Quantities of solid above 100 g require use of a powders weighing hood or other approved containment/ventilation system.
- \*High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system.
- \*Develop cleaning procedures and techniques that limit potential exposure.

### Pilot Plant and Production

- \*Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses and safety shoes. Use good manufacturing practices (i.e., cGMPs).
- \*Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders.
- \*Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.
- \*Protective garments (coveralls, Tyveks, lab coat) are not to be worn in common areas (e.g., cafeterias) or out-

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of-doors.

\*High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system.

\*Develop cleaning procedures and techniques that limit potential exposure.

\*OEB - Occupational Exposure Band: The classification of a compound or pharmaceutical ingredient into one of four ordinal categories of increasing potency and toxicity. This rating assigns a set of pre-determined handling and containment practices to a compound until a quantitative OEL is established.

## 8. Exposure Controls/Personal Protection

### Airborne Exposure Limits:

None established.

### Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

### Personal Respirators (NIOSH Approved):

Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.

### Skin Protection:

Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

### Eye Protection:

Use chemical safety goggles and/or a full face shield where splashing is possible. Maintain eye wash fountain and quick-drench facilities in work area.

### Other Control Measures:

See Section 7 for additional information on occupational control measures appropriate for OEB-2 potent compounds.

## 9. Physical and Chemical Properties

### Appearance:

White powder.

### Odor:

No information found.

### Solubility:

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Insoluble in water.

**Specific Gravity:**

No information found.

**pH:**

No information found.

**% Volatiles by volume @ 21C (70F):**

0

**Boiling Point:**

No information found.

**Melting Point:**

131 - 135C (268 - 275F)

**Vapor Density (Air=1):**

No information found.

**Vapor Pressure (mm Hg):**

No information found.

**Evaporation Rate (BuAc=1):**

No information found.

## 10. Stability and Reactivity

**Stability:**

Stable under ordinary conditions of use and storage.

**Hazardous Decomposition Products:**

May produce carbon monoxide, carbon dioxide, nitrogen oxides and hydrogen chloride when heated to decomposition.

**Hazardous Polymerization:**

Will not occur.

**Incompatibilities:**

Strong oxidizing agents, strong acids, strong bases.

**Conditions to Avoid:**

Incompatibles.

## 11. Toxicological Information

-----\Cancer Lists\-----			
Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Loratadine (79794-75-5)	No	No	None

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## 12. Ecological Information

### Environmental Fate:

No information found.

### Environmental Toxicity:

No information found.

## 13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7). Dispose of container and unused contents in accordance with federal, state and local requirements.

## 14. Transport Information

Not regulated.

## 15. Regulatory Information

Ingredient	TSCA	EC	Japan	Australia
Loratadine (79794-75-5)	Exempt	No	No	No

Ingredient	Korea	--Canada-- DSL	NDSL	Phil.
Loratadine (79794-75-5)	No	No	No	No

Ingredient	-SARA 302- RQ	TPQ	-SARA 313- List	Chemical Catg.
Loratadine (79794-75-5)	No	No	No	No

Ingredient	CERCLA	-RCRA- 261.33	-TSCA- 8(d)
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Loratadine (79794-75-5)

-----  
No

-----  
No

-----  
No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No  
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No  
Reactivity: No (Pure / Solid)

**Australian Hazchem Code:** None allocated.

**Poison Schedule:** S4

**WHMIS:**

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

## 16. Other Information

**NFPA Ratings:** Health: 2 Flammability: 1 Reactivity: 0

**Label Hazard Warning:**

WARNING! MAY BE HARMFUL IF SWALLOWED OR INHALED. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT.

**Label Precautions:**

Avoid contact with eyes, skin and clothing.

Avoid breathing dust.

Keep container closed.

Use with adequate ventilation.

Wash thoroughly after handling.

INTENDED FOR FDA REGULATED USE ONLY.

NOT ON THE TSCA INVENTORY.

**Label First Aid:**

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, give large amounts of water to drink. Never give anything by mouth to an unconscious person. In all cases, get medical attention.

**Product Use:**

Bulk Drug.

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**\*\*\*\* MATERIAL SAFETY DATA SHEET \*\*\*\***

**Section 1 - Chemical Product and Company Identification**

**MSDS Name** Metamizole sodium  
**Synonyms** Metamizole sodium  
**Company name** Optyphar Ltd.  
**Company address** B-5F, 271 LvKeRoad, Shanghai 201204, China  
**Company telephone** (86-21)-61024511, 61052101  
**Company facsimile** (86-21)-6105 2120

**Section 2 - Composition, Information on Ingredients**

CAS#	Chemical Name	%	EINECS#	Haz Symbols	Risk Phrases
5907-38-0	Metamizole sodium	99.0 % ~ 101.0%			

**Section 3 - Hazards Identification**

**EMERGENCY OVERVIEW**

Harmful if swallowed. Air sensitive.

**POTENTIAL HEALTH EFFECTS**

The toxicological properties of this material have not been investigated. Use appropriate procedures to prevent opportunities for direct contact with the skin or eyes and to prevent inhalation.

**Section 4 - First aid Measures**

**Eyes** Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids.  
**Skin** Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
**Ingestion** Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water.  
**Inhalation** Remove from exposure and move to fresh air immediately.

**Notes to Physician**

**Section 5 - Fire Fighting Measures**

**General Information** As in any fire, 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.  
**Extinguishing Media** In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam.

**Section 6 - Accidental Release Measures**

**General Information** Use proper personal protective equipment as indicated in Section 8.  
**Spills/Leaks** Clean up spills immediately, observing precautions in the Protective



Equipment section. Sweep up, then place into a suitable container for disposal.

### Section 7 - Handling and Storage

**Handling** Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.

**Storage** Store in a cool, dry place. Keep container closed when not in use.

### Section 8 - Exposure Controls, Personal Protection

**Engineering Controls** Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels.

#### PERSONAL PROTECTIVE EQUIPMENT

**Eyes** Wear safety glasses and chemical goggles if splashing is possible.

**Skin** Wear appropriate protective gloves and clothing to prevent skin exposure.

**Clothing** Wear appropriate protective clothing to minimize contact with skin.

**Respirators** Wear a NIOSH/MSHA or European Standard EN 149 approved full-facepiece airline respirator in the positive pressure mode with emergency escape provisions.

### Section 9 - Physical and Chemical Properties

<b>Physical State</b>	Powder
<b>Color</b>	White or almost white crystalline
<b>Odor</b>	Not available.
<b>pH</b>	Not available.
<b>Vapor Pressure</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Boiling Point</b>	Not available.
<b>Freezing/Melting Point</b>	144 - 145.5 deg C.
<b>Autoignition Temperature</b>	Not available.
<b>Flash Point</b>	Not available.
<b>Explosion Limits, lower</b>	Not available.
<b>Explosion Limits, upper</b>	Not available.
<b>Decomposition Temperature</b>	
<b>Solubility in water</b>	soluble
<b>Specific Gravity/Density</b>	
<b>Molecular Formula</b>	C <sub>13</sub> H <sub>16</sub> N <sub>3</sub> NaO <sub>4</sub> S·H <sub>2</sub> O
<b>Molecular Weight</b>	351.4

### Section 10 - Stability and Reactivity

**Chemical Stability** Stable under normal temperatures and pressures.

**Conditions to Avoid** Incompatible materials, strong oxidants.

**Incompatibilities with Other** Strong oxidizing agents - air.

#### Materials

**Hazardous Decomposition Products** Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, nitrogen.

**Hazardous Polymerization** Has not been reported.

### Section 11 - Toxicological Information

**RTECS#** CAS# 5907-38-0: XH5600000

**LD50/LC50** CAS#5907-38-0: Oral, mouse: LD50 = 150 mg/kg; Oral, rat: LD50 = 243

mg/kg.

**Carcinogenicity** Metamizole sodium - Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.

See actual entry in RTECS for complete information.

#### **Section 12 - Ecological Information**

#### **Section 13 - Disposal Considerations**

Dispose of in a manner consistent with federal, state, and local regulations.

#### **Section 14 - Transport Information**

	<b>IATA</b>	<b>IMO</b>	<b>RID/ADR</b>
<b>Shipping Name:</b>	No information available.	No information available.	No information available.
<b>Hazard Class:</b>	-	-	-
<b>UN Number:</b>	-	-	-
<b>Packing Group:</b>	-	-	-

#### **Section 15 - Regulatory Information**

##### **European/International Regulations**

European Labeling in Accordance with EC Directives

Hazard Symbols: XN

Risk Phrases: R 22 Harmful if swallowed.

Safety Phrases: S 22 Do not breathe dust.

S 24/25 Avoid contact with skin and eyes.

##### **WGK (Water Danger/Protection)**

CAS# 5907-38-0: No information available.

##### **United Kingdom Occupational Exposure Limits**

##### **United Kingdom Maximum Exposure Limits**

##### **Canada**

CAS# 5907-38-0 is listed on Canada's NDSL List.

CAS# 5907-38-0 is not listed on Canada's Ingredient Disclosure List.

##### **Exposure Limits**

CAS# 5907-38-0 OEL-RUSSIA:STEL 0.5 mg/m3

##### **US FEDERAL**

##### **TSCA**

CAS# 5907-38-0 is listed on the TSCA inventory.

#### **Section 16 - Additional Information**

##### **Warranty**

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 way shall the company 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, howsoever arising, even if the company has been advised of the possibility of such damages.



## MATERIAL SAFETY DATA SHEET-RISPERIDONE

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Product details:**

Trade Name : Risperidone

**Manufacturer :**

JUBILANT ORGANOSYS LIMITED

No. 56,

KIADB Industrial Area

Nanjangud - 571 302

Mysore district

Karnataka state, INDIA

Tel : 0091-821-228402 TO 228408

Fax : 0091-821-228410

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

**Chemical Characterization :**

CAS No. : 106266-06-2

Risperidone Pure Material

Formula:  $C_{23}H_{27}FN_4O_2$

Molecular Weight : 410.5

Therapeutic category : Antipsychotic

*Shree*



### 3. HAZARD IDENTIFICATION

#### Hazard Description :

Risperidone is reported to be less likely to cause sedation or extrapyramidal effect but agitation may occur more frequently.

#### Additional information:

Orthostatic hypotension, hypertension has been reported infrequently

### 4. FIRST AID MEASURES

#### General information:

Take affected persons out into the fresh air.

Immediately remove any clothing soiled by the product

After inhalation: Supply fresh air, consult doctor in case of complaints

#### After skin contact:

Wash with water and soap and rinse with plenty of water  
May cause irritation.

#### After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor, may cause irritation.

#### After swallowing:

Rinse out mouth with water and then drink plenty of water  
Never give anything by mouth to an unconscious person.  
Do not induce vomiting  
Seek immediate medical advice

#### Information for doctor:

The following symptoms may occur

- Headache
- fatigue
- Dizziness



## 5. FIRE FIGHTING MEASURES

### Suitable extinguishing agents:

Use fire fighting measures that suit the environment

Carbon dioxide, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam

### Protective equipment:

Wear self-contained respiratory protective device

### Additional information:

Dispose of contaminated fire fighting extinguishing powder by collecting separately. It must not enter the sewage system

## 6. ACCIDENTAL RELEASE MEASURES

### Person related safety precautions:

Ensure adequate ventilation  
Avoid formation of dust

### Measures for environmental protection:

Do not allow product to reach sewage system or any water course  
Do not allow to penetrate the ground / soil

### Measures for cleaning /collecting:

Ensure adequate ventilation  
Pick up mechanically  
Avoid dust formation absolutely. If necessary pick up with a tested and approved industrial vacuum cleaner.  
Send for recovery or disposal in suitable receptacles

*Shilp*



## 7. HANDLING AND STORAGE

### Handling:

#### Information for safe handling:

Ensure good ventilation / exhaustion at the workplace  
Prevent formation of dust  
Any deposit of dust which cannot be avoided must be regularly removed  
Avoid contact with eye and skin  
Avoid inhalation of dust

#### Information about protection against explosions and fires:

Keep ignition sources away-do not smoke

### Storage:

#### Requirements to be met by storerooms and receptacles:

Store container tightly sealed at a dry place with sufficient ventilation

#### Further information about storage conditions:

- Store in a cool place
- Protect from humidity and water
- Protect from contamination

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Component with limit values that require monitoring at the work place :** Not required

**Additional occupational exposure limit values for possible hazards during processing:** Observe general threshold limit for dust

### Personal protective equipment:

#### General protective and hygienic measures:

The usual precautionary measures should be adhered to when handling chemicals  
Vacuum clean contaminated clothing, do not blow or brush off contamination  
Avoid contact with eye and skin  
Do not inhale dust / smoke / mist  
Wash hands before breaks and at the end of work

**Breathing equipment :** Not necessary if room is well-ventilated

**Protection of hands :** Protective gloves

**Eye protection:** At formation of dust or insufficient ventilation: Tightly sealed goggles

**Body protection:** Protective work clothing





## 9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Crystalline Powder  
Colour : A white or almost white powder

### Change in condition :

Melting point : 170°C  
Flash point : Not applicable  
Danger of explosion : Product is not explosive  
Density : 0.4-0.6g/cc  
Solubility : Soluble in alcohol and freely soluble in MDC

## 10. STABILITY AND REACTIVITY

### Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to documented norms  
Stable upto melting point

**Dangerous reactions :** No dangerous reactions known

## 11. TOXICOLOGICAL INFORMATION

### Acute toxicity:

Not available

### Primary irritant effect:

**On the skin :** Irritation to skin

**On the eye :** Eye irritation is possible after mechanical influence (dust)

### Additional toxicological information:

When used and handled according to specified norms, the product does not have any harmful effects according to our experience

*shub*



## 12. ECOLOGICAL INFORMATION

Elimination data : Aerobiotic : < 60%

Ecotoxicological data : EC 50 (Iepomis mactochirus) : 5.8 mg/L

EC 50 (daphnia) : 6 mg/L

## 13. DISPOSAL CONSIDERATION

Incinerate in an approved facility

## 14. TRANSPORT INFORMATION

Pack in air tight containers

NOT RESTRICTED AS PER IATA DGR REGULATION

UN NOT APPLICABLE

## 15. REGULATORY INFORMATION

Wash immediately with plenty of water if contact with skin, wear suitable clothing, gloves and eye

## 16. OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

(For Research & Development  
Purpose Only  
Not for human consumption  
or for any commercial sale

On the skin, wash with plenty of water  
For Jubilant Organosys Limited  
*[Signature]*  
Authorized Signatory

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

**MATERIAL SAFETY DATA SHEET**  
**ROXITHROMYCIN**

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

Commercial product name    Roxithromycin  
Company:                      Farmabase Pharmaceutical Raw Materials  
                                    Campiello del Trivio, 12  
                                    38068 Rovereto  
                                    Italy  
                                    Phone: 0464/421996  
                                    Fax: 0464/421985  
CAS nr.                        80214-83-1

2. Chemical Characterisation & physical form

Chemical formula             $C_{41}H_{76}N_2O_{15}$   
Molecular weight            837.0  
Physical form                Roxithromycin is a white or off-white crystal powder

3. Hazards Identification

Label precautionary statements

Harmful

Harmful is swallowed.

Irritating to eyes, respiratory system and skin.

Target organ(s):

Liver, kidneys.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable protective clothing.

4. First aid measures

Eye contact: in case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes.

Skin contact: in case of contact, immediately wash skin with soap and copious amounts of water.

Ingestion: if swallowed, wash out mouth with water provided person is conscious. Call a physician.

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

5. Fire fighting measures

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

Special firefighting procedures: wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Unusual fire and explosion hazards: emits toxic fumes under fire conditions.

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 62118 11612E  
C.C.I.A.A.: 127370  
Pos.Mec.: TN 011775

# F A R M A B A S E

## PHARMACEUTICAL RAW MATERIALS

### 6. Accidental release measures

Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves.

Sweep up, place in a bag and hold for waste disposal.

Avoid raising dust.

Ventilate area and wash spill site after material pickup is complete.

### 7. Handling and storage

Refer to section 8.

### 8. Exposure controls / personal protection

Wear appropriate Niosh/Msha-approved respirator, chemical-resistant gloves, safety goggles, other protective clothing.

Safety shower and eye bath.

Mechanical exhaust required.

Do not breathe dust.

Avoid contact with eyes, skin and clothing.

Avoid prolonged or repeated exposure.

Wash thoroughly after handling.

Harmful solid.

Irritant.

Keep container closed.

Store in a cool dry place.

### 9. Physical and chemical properties

Appearance and odour

Solid.

Physical properties

Melting point 115 to 120°C

Solubility Water – insoluble

Ethanol – soluble

Acetone - soluble

Methylene Chloride – soluble

Dimethyl Formamide – soluble

Chloroform - soluble

### 10. Stability and reactivity

Incompatibilities: strong oxidizing agents.

Hazardous combustion or decomposition products:

Toxic fumes of:

Carbon monoxide, carbon dioxide, nitrogen oxides.

### 11. Toxicological information

Acute effects:

Harmful if swallowed. May be harmful if inhaled. May be harmful if absorbed through the skin. Cause eye and skin irritation. Material is irritating to mucous membranes and upper respiratory tract.

Chronic effects: target organ(s): liver, kidneys. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Rtecs: KF4990000

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.E. IT 01285580229  
C.F.E. CCH FBA 62118 11612E  
C.C.I.A.A.: 127370  
Pos.Mec.: TN 011775

# F A R M A B A S E

## PHARMACEUTICAL RAW MATERIALS

Erythromycin, 9-O-((2-Methoxyethoxy)Methyl)Oxime

Toxicity data:

ORL-Rat LD50: 830 mg/kg

IPR-Rat LD50: 171 mg/kg

ORL-Mus LD50: 665 mg/kg

IPR-Mus LD50: 148 mg/kg

ORL-Dog LD50: .2 mg/kg

Target organ data:

Behavioural (change in motor activity). Lungs, thorax or respiration (other changes).

Nutritional and gross metabolic (weight loss or decreased weight gain).

Only selected registry of toxic effects of chemical substances (Rtecs) data is presented here. See actual entry in Rtecs for complete information.

### 12. Ecological information

Data not yet available.

### 13. Disposal considerations

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

### 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

European information:

Caution: substance not yet fully tested.

Harmful

R22-harmful if swallowed

R36/37/38-irritating to eyes, respiratory system and skin

S26-in case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S36-wear suitable protective clothing

TLV and source

For acetone:

ACGIH TLV-TWA: 750 ppm (1780 mg/m<sup>3</sup>); STEL 1000 ppm (2380 mg/m<sup>3</sup>).

OSHA PEL: 8H TWA 750 ppm (1800 Mg/M<sup>3</sup>); stel 1000 ppm (2400 mg/m<sup>3</sup>).

### 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

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

Phone: 0464 421996 - 424246  
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C.F.: CCH FBA 62118 11612E  
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# SAFETY DATA SHEET

In compliance with Regulation (CE) n. 1907/2006 and (UE)n. 453/2010 (Annex I)

Issuing Date 26-Aug-2009

Revision Date 08-Jan-2011

Revision Number 1

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

### 1.1. Product identifier

Product Name

TERAZOSIN HCL DIHYDRATE

Chemical Name:

Piperazine, 1-(4-amino-6,7-dimethoxy-2-quinazoliny)-4-((tetrahydro-2-furanyl)carbonyl)-, monohydrochloride, dihydrate

Synonyms

Abbott-45975; 1-(4-Amino-6,7-dimethoxy-2-furanyl)carbonyl)piperizine, hydrochloride dihydrate; Adecur; Benaprost; Blavin; Deflox; Dysalfa; Eglidon; Ezosina; Flotrin; Flumarc; Fosfomic; Hyron; Hytrin; Isontyn; Kornam; Magnuro; Olyster; Sedegis; Sinalfa; Sutif; Terafluss; Teraprost; Teraumon; Unoprost; Uroflo; Vicard; Zayasel, (Heitrin, Hytracin, Hyttrinix, Vasocard, Vasomet)

Formula

$C_{19}H_{25}N_5O_4 \cdot HCl \cdot 2H_2O$

CAS

70024-40-7

EINECS

Not available

Index Number

Not available

Reach Registration Number

Not available

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use

Active Pharmaceutical Ingredient

Uses advised against

No information available

### 1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier

Assia Chemical Industries Ltd. - Teva Tech site  
API Production  
Ramat Hovav, PO Box 2049  
Emek Sara, Be'er Sheva 84874  
Tel: 972 (8) 650-9555  
Fax: 972 (8) 650-9500

For further information, please contact

E-mail Address

moked.tevatech@teva.co.il

### 1.4. Emergency telephone number

Emergency Telephone Number

972 (8) 6509442

## SECTION 2. Hazards identification

### 2.1. Classification of the substance or mixture

#### REGULATION (EC) No 1272/2008

Chemical Name	CLP/GHS classification
Piperazine, 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-((tetrahydro-2-furanyl)carbonyl)-, monohydrochloride, dihydrate	Repr. 2 H361fd

#### Classification according to EU Directives 67/548/EEC or 1999/45/EC

Chemical Name	EU Classification
Piperazine, 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-((tetrahydro-2-furanyl)carbonyl)-, monohydrochloride, dihydrate	Repr. Cat. 3; R63, R62

Full text of phrases reported in section 16

### 2.2. Label Elements

#### Signal Word



#### Warning

#### Hazard Statements

H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

#### Precautionary Statements

P260 - Do not breathe dust  
P402 + P404 - Store in a dry place. Store in a closed container  
P262 - Do not get in eyes, on skin, or on clothing  
P280 - Wear protective gloves/protective clothing/eye protection/face protection

### 2.3. Other hazards

Not available

## SECTION 3. Composition/information on ingredients

### 3.1. Substances

Chemical Name	EC No.	REACH Reg. No.	CAS-No	Weight %
Piperazine, 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-((tetrahydro-2-furanyl)carbonyl)-, monohydrochloride, dihydrate	-	Not available	70024-40-7	100

### 3.2. Mixtures

N.A.

## SECTION 4. First aid measures

### 4.1. Description of first-aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes
Ingestion	Get medical attention. Clean mouth with water, only if the person is in conscious.
Inhalation	Remove from exposure, lie down. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.

### 4.2. Most important symptoms and effects, both acute and delayed

#### Most Important Symptoms/Effects

Irritation:	No information available.
Corrosivity:	No information available
Sensitization	No information available
Eyes:	May cause: Blurred vision
Skin:	N/A
Inhalation:	May cause: Dyspnea, Nasal congestion/Rhinitis.
Ingestion:	May cause: Nausea

### 4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician	Treat symptomatically
--------------------	-----------------------

## SECTION 5. Fire-fighting measures

### 5.1. Extinguishing media

#### Suitable Extinguishing Media

Water spray. Carbon dioxide (CO<sub>2</sub>). Foam. Dry powder.

#### Unsuitable extinguishing media

No information available.

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

### 5.3. Advice for firefighters

#### Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## SECTION 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

### 6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.

### 6.3. Methods and materials for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). If emergency, enforce internal emergency plan.

### 6.4. Reference to other sections

See sections 8 and 13 for additional information.

## SECTION 7. Handling and storage

### 7.1. Precautions for Safe Handling

#### Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

#### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

### 7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat. Keep in light-resistant containers. Keep tightly closed in a dry and cool place. Keep at temperatures between 20 °C and 25°C. Store in accordance with local regulations.

### 7.3. Specific end use(s)

#### Exposure Scenario

No information available

#### Other Guidelines

No information available

## SECTION 8. Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

#### Biological occupational exposure limits

Not Available

#### Derived No Effect Level (DNEL)

No information available.

#### Predicted No Effect Concentration (PNEC)

No information available.

### 8.2. Exposure controls

#### Engineering Measures

Provide engineering control, according to Teva Guidelines

#### Special Requirements

Employment of pregnant women is permitted subject to protective measures required by local regulations and Teva policy .

#### Personal protective equipment

##### Eye Protection

Approved safety goggles/glasses

##### Skin and Body Protection

Long sleeved clothing

##### Hand Protection

Rubber/latex/neoprene or other suitable chemical resistant gloves

##### Respiratory Protection

Approved full face respirator P3 or airline respirator

#### Environmental exposure controls

No information available

## SECTION 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	White Pale , . crystalline powder.		
Odour	Odourless		
Odour Threshold	No information available		
pH	No information available.	Melting Point/Range	271-274 °C 278-279 for Terazosin hydrochloride
Boiling Point/Range	No information available.	Flash Point	No information available.
Evaporation Rate	No information available	Flammability (solid, gas)	No information available.
Flammability Limits in Air		Vapor Pressure	No information available.
Upper	No information available.		
Lower	No information available.		
Vapor Density	No information available.	Relative Density	No information available.
Solubility	Soluble in Methanol Isotonic saline solution. Slightly soluble in Chloroform. Practically Insoluble in Acetone, Hexanes	Water Solubility	Freely soluble
Autoignition Temperature	No information available	Decomposition Temperature	No information available
Viscosity	No information available	Explosive Properties	No information available
Oxidizing Properties	No information available		
<b>9.2 Other information</b>			
Molecular Weight	459.9 (423.9 for Terazosin hydrochloride)		

## SECTION 10. Stability and reactivity

### 10.1. Reactivity

No data available

### 10.2. Chemical stability

Stable under normal conditions

### 10.3. Possibility of hazardous reactions

Hazardous polymerization does not occur.

### 10.4. Conditions to avoid

Excessive heat. Moisture. Exposure to light.

### 10.5. Incompatible materials

Oxidizing agents.

### 10.6. Hazardous decomposition products

Toxic fumes of: Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride (Trazodone HCl).



## SECTION 11. Toxicological information

### 11.1. Information on toxicological effects

#### Acute Toxicity

##### Product Information

LD50 Oral rat 5500 mg/kg  
LD50 Oral mouse >8000 mg/kg

Irritation: No information available.  
Corrosivity: No information available  
Sensitization: No information available  
Eyes: May cause: Blurred vision  
Skin: N/A  
Inhalation: May cause: Dyspnea, Nasal congestion/Rhinitis.  
Ingestion: May cause: Nausea

#### Chronic toxicity

##### Carcinogenicity

Rats (male) 250 mg/kg/day: statistically significant increase in benign adrenal medullary tumors (175 times the MRHD). Female rats were unaffected. Mice doses of 32 mg/kg/day: not oncogenic. This effect does not support evidence for carcinogenicity in man.

##### Reproductive Toxicity

Rats, 30 and 120 mg/kg/day: less sperm in 20% of animal tested (good correlation between sperm count and subsequent pregnancy). Rat, 40 mg/kg/day, 1-2Y: increased testicular atrophy.

Rats or rabbits (oral) up to 280 and 60 times, respectively, the maximum recommended human dose: not teratogenic; but increased fetal resorptions, and in rabbits decreased fetal weight and increased skeletal variations

##### Mutagenic Effects

Devoid of mutagenic potential when evaluated in vivo and in vitro (the Ames test, in vivo cytogenetics, the dominant lethal test in mice, in vivo Chinese hamster chromosome aberration test and V79 forward mutation assay)

##### STOT - repeated exposures

No information available

##### STOT - single exposure

No information available

#### Other information

##### Target Organ Effects

Blood Central nervous system (CNS) Bladder Lungs Thorax

##### Central nervous system:

May cause dizziness, May cause somnolence, May cause vertigo

##### Cardiovascular system:

May cause, Hypotension, Palpitations, Postural hypotension, Syncope

##### Body as a whole

May cause: Asthenia, Flu syndrome, Headache

## SECTION 12. Ecological information

### 12.1. Toxicity

Ecotoxicity effects

### 12.2. Persistence and degradability

No information available

### 12.3. Bioaccumulative potential

Half-Life Elimination in Human: half life in plasma is about 12h

### 12.4. Mobility in soil

No information available

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

Endocrine Disruptor Information

Not available for data lacking

## SECTION 13. Disposal considerations

### 13.1. Waste treatment methods

Waste from Residues/Unused  
Products

Dispose of in accordance with local regulations.

Contaminated Packaging

Empty containers should be taken for local recycling, recovery or waste disposal

## SECTION 14. Transport information

<u>14.1.</u> UN-No	Not hazardous for transport
<u>14.2.</u> Proper Shipping Name	Not hazardous for transport
<u>14.3 Transport hazard class(es)</u> ADR / RID / ADN	Not hazardous for transport
IMDG	Not hazardous for transport
IATA / ICAO	Not hazardous for transport
<u>14.4.</u> Packing Group	Not hazardous for transport
<u>14.5. Environmental hazards</u> Marine Pollutant	No information Available
<u>14.6. Special precautions for users</u> Subsidiary Class	No information available.
EmS No.	No information available.
ADR/RID-Labels	No information available.
<u>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</u> Technical name	Not available
Ship type	Not Available
Annex II	Not available

## SECTION 15. Regulatory information

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

- Dir. 67/548/CE and 1999/45/CE and successive modifications
- Regulation 1907/2006/CE (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- Regulation 453/2010/CE Annex I
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/UE

### **International Inventories**

All of the components in the product are on the following Inventory lists.

TSCA	Listed
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

### **Legend**

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

### 15.2. Chemical Safety Assessment

No information available

**SECTION 16. Other information****EU Directive 2001/58/EC****R-phrase(s)**

R63 - Possible risk of harm to the unborn child

R62 - Possible risk of impaired fertility

**S-phrase(s)**

S22 - Do not breathe dust

S 7/8 - Keep container tightly closed and dry

S24/25 - Avoid contact with skin and eyes

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection

**CLP/GHS - Regulation****Hazards Statements**

H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

**Precautionary Statements**

P260 - Do not breathe dust

P402 + P404 - Store in a dry place. Store in a closed container

P262 - Do not get in eyes, on skin, or on clothing

P280 - Wear protective gloves/protective clothing/eye protection/face protection

Training appropriate for workers is required to ensure protection of human health and environment.

**Source of data**

SAX'S - DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS

VERSCHUEREN - HANDBOOK OF ENVIRONMENTAL DATA ON ORGANICS CHEMICALS

THE MERCK INDEX

KLEEMANN - PHARMACEUTICAL SUBSTANCES

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

STN DATA BANK

BRETHERRICK'S - HANDBOOK OF REACTIVE CHEMICAL HAZARDS

A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

N.L.M. - NATIONAL LIBRARY OF MEDICINE

H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK

N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

N.T.P. - NATIONAL TOXICOLOGY PROGRAM

I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

Chemspider database

ChemAdvisor

**Issuing Date**

26-Aug-2009

**Revision Date**

08-Jan-2011

**Revision Note**

Not applicable

**Disclaimer**

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, and disposal of the designated material and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet