

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078479968

N/A

**WOCKHARDT**

Ankleshwar

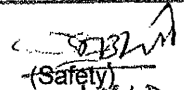

**MASTER COPY****WOCKHARDT**

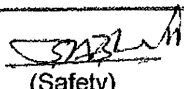
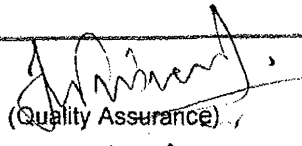
Department <b>Safety</b>	Title : <b>MATERIAL SAFETY DATA SHEET</b>  Number : <b>MSDS/300386/0</b>	Date : <b>23/06/2007</b> Supersedes : <b>MSDS-C04/1</b> Date Implemented : <b>23/06/2007</b> Review Date : <b>JUN 2010</b> Page : <b>1 of 4</b>						
<b>PRODUCT : CLARITHROMYCIN</b>								
<b>1. Identification of the Substance / preparation and the Company</b>  Wockhardt Limited, 138, GIDC Estate, Ankleshwar - 393002 District Bharuch, Gujarat, INDIA. Phone No.: 91 2646 661444 Fax No.: 91 2646 661555								
<b>2. Composition / Information on Ingredient</b>  Common Name : Clarithromycin Formula : $C_{38}H_{69}NO_{13}$ Synonyms : Not found M.W. : 747.95 Chemical Name : Erythromycin, 6-O-methyl- CAS Number : 81103-11-9 RTECS Number : KF4997000 Chemical Family : A Macrolide antibiotic Therapeutic Category : Antibacterial <table><thead><tr><th><u>Principle Components</u></th><th><u>Percent</u></th><th><u>Exposure Limits</u></th></tr></thead><tbody><tr><td>Clarithromycin</td><td>Pure Material</td><td>Not found</td></tr></tbody></table>			<u>Principle Components</u>	<u>Percent</u>	<u>Exposure Limits</u>	Clarithromycin	Pure Material	Not found
<u>Principle Components</u>	<u>Percent</u>	<u>Exposure Limits</u>						
Clarithromycin	Pure Material	Not found						
<b>3. Health Hazards Information:</b>  Usual Adult Dose : The usual adult oral dose of Clarithromycin is 250 to 500 mg every 12 hours. Adverse Effects : Adverse effects include abnormal taste, gastrointestinal disturbances, diarrhea, and headache. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects : Not found Acute : Possible eye, skin, gastrointestinal and / or respiratory tract irritation. chronic : Possible hypersensitization. Inhalation : May cause irritation. Remove to fresh air. Eye : May cause irritation. Flush with copious quantities of water. Skin : May cause irritation. Flush with copious quantities of water.								
Prepared by :  Date : <b>23/06/07</b>	Approved by :  Date : <b>23.6.07</b>							

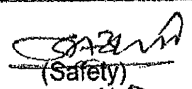
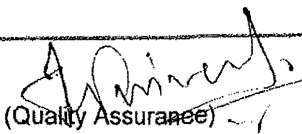
**WOCKHARDT**

Ankleshwar

**MASTER COPY****WOCKHARDT**

<b>Department</b> <b>Safety</b>	<b>Title : MATERIAL SAFETY DATA SHEET</b>  <b>Number : MSDS/300386/0</b>	<b>Date : 23/06/2007</b> <b>Supersedes : MSDS-C04/1</b> <b>Date Implemented : 23/06/2007</b> <b>Review Date : JUN 2010</b> <b>Page : 2 of 4</b>
<b>PRODUCT : CLARITHROMYCIN</b>		
<p><b>Ingestion</b> : May cause irritation. Flush out mouth with water. This material is well-absorbed from the gastrointestinal tract.</p> <p><b>Medical Conditions aggravated by exposure</b> : Hypersensitivity to the material and severely impaired kidney function.</p> <p><b>Cross sensitivity</b> : Persons sensitive to erythromycin or other macrolides may be sensitive to this material also.</p> <p><b>Pregnancy Comments</b> : The therapeutic use of clarithromycin should be avoided by pregnant women because high doses in animals have caused fetal abnormalities.</p> <p><b>Pregnancy Category</b> : C</p> <p><b>4 First Aid Measures</b></p> <p><b>General</b> : Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.</p> <p><b>Overdose Treatment</b> : Not found</p> <p><b>5 Fire fighting Measures</b></p> <p><b>Flash Point</b> : Not found      <b>Upper Flammable Limit</b> : Not found <b>Lower Flammable Limit</b> : Not found</p> <p><b>Auto-ignition Temperature</b> : Not found</p> <p><b>Extinguisher Media</b> : Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.</p> <p><b>Fire and Explosion Hazards</b> : This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.</p> <p><b>Fire Fighting Procedures</b> : As with all fires, evacuate personnel to a safe area. Fire-fighters should use self-contained breathing equipment and protective clothing.</p>		
<b>Prepared by :</b>  <b>Date :</b> 23/06/07		<b>Approved by :</b>  <b>Date :</b> 23.6.07

Department <b>Safety</b>	Title : <b>MATERIAL SAFETY DATA SHEET</b>  Number : <b>MSDS/300386/0</b>	Date : <b>23/06/2007</b> Supersedes : <b>MSDS-C04/1</b> Date Implemented : <b>23/06/2007</b> Review Date : <b>JUN 2010</b> Page : <b>3 of 4</b>
<b>PRODUCT : CLARITHROMYCIN</b>		
<b>6 Spill Response</b> Spill Response : Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.		
<b>7 Handling and Storage</b> Handling : As a general rule, when handling Clarithromycin avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling. Storage : Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.		
<b>8 Exposure control / Personnel Protection</b> Respiratory Protection : When working with small quantities in well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended. Ventilation : No special ventilation requirements. Gloves : Rubber Eye Protection : Safety Goggles Protective Clothing : Protect exposed skin		
<b>9 Physical &amp; Chemical Properties</b> Appearance and Odour : White to off-white crystalline powder. Melting Point : Approximately 220°C (decomposes) Solubility in Water : Practically insoluble      Vapor Density : Not found Boiling Point : Not found      Evaporation Rate : Not found Specific Gravity : Not found      Reactivity in Water : Not found Vapour Pressure : Not found      % Volatile by Volume : Not found		
Prepared by :  Date : 23/06/07	Approved by :  Date : 23.6.07	

<b>Department</b> <b>Safety</b>	<b>Title : MATERIAL SAFETY DATA SHEET</b>  <b>Number : MSDS/300386/0</b>	<b>Date : 23/06/2007</b> <b>Supersedes : MSDS-C04/1</b> <b>Date Implemented : 23/06/2007</b> <b>Review Date : JUN 2010</b> <b>Page : 4 of 4</b>
<b>PRODUCT : CLARITHROMYCIN</b>		
<b>10 Stability and Reactivity Data</b>  Conditions to Avoid : Not found. Incompatibilities : Oxidising agents. Decomposition Products : When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.  Stable? : Yes                      Hazardous Polymerization? No		
<b>11 Toxicological Information</b>  Oral Rat : LD50 : 1270 mg/Kg Oral Mouse : LD50 : 1230 mg/Kg Irritancy Data : Not found Target Organ(s) : Not found Listed as a Carcinogen? : NTP : No    IARC : No    OSHA : No    Other : No		
<b>12 Ecological Information</b>  Ecotoxicity : Not available      Environment toxicity : Not available  Special remarks on the product of biodegradation : Not available		
<b>13 Disposal Consideration</b>  Disposal : Dispose of waste in accordance with all applicable Federal, State and Local laws.		
<b>14 Transport Information</b>  Identification : Not applicable                      Special provision for Transport : Not applicable		
<b>15 Regulatory Information</b>  Not available		
<b>16 Other Information</b>  Product Use : Bulk Drug                      Other Special Consideration : Not available		
<b>Prepared by :</b>  <b>Date :</b>	 (Safety) 23/06/07	<b>Approved by :</b>  <b>Date :</b>
		 (Quality Assurance) 23/6/07