Material Safety Data Sheet

MINOCYCLINE HYDROCHLORIDE CAPSULES
(50/75/100 mg)

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING	
Material	Minocycline Hydrochloride
Empirical Chemical Formula	$C_{23}H_{27}N_3O_7$.HCl
Synonyms	-
Manufacturer	Ohm Laboratories, Inc., 1385 Livingston Ave. North Brunswick, NJ, 08907, USA.
Distributor	Ranbaxy Pharmaceuticals Inc., 9431, Florida Mining Blvd. East, Jacksonville, FL, 32257

2. COMPOSITION / INFORMATION ON INGREDIENTS		
Ingredients	CAS Number	Percentage
Minocycline Hydrochloride	13614-98-7	38.50%
Non-Hazardous Ingredients	–	61.50%

3. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible.
Health	The most common effects may include photosensitivity, central nervous system effects (lightheadedness, dizziness, vertigo), superinfection, nausea, vomiting, intracranial hypertension, and hepatotoxicity. May cause cancer. May cause harm to the unborn child. May cause harm to breastfed babies
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES	
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
NOTES TO PHYSICIANS / HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocol. For additional guidance, refer to the

	current prescribing information or to the local poison control information center. Treatment of overdose should be symptomatic and supportive and may include the following: 1. Immediately dilute with milk or water. 2. Tetracyclines are of low order of toxicity and in most cases gastrointestinal decontamination will not be required. If needed, administer activated charcoal as a slurry. 3. Antacids may be useful in managing gastric irritation. 4. For milf. moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reactions, treat with oxygen, aggressive airway management, antihistamines, epinephrine, corticosteroids, ECG monitoring, and intravenous fluids. 5. Minocycline is not significantly removed by hemodialysis or peritoneal dialysis. 6. For mild pseudomembranous colitis, treatment is usually not necessary. For severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detail description of medical conditions caused by or aggravated by overexposure to this product. Hypersensitivity to material, nephrogenic diabetes insipidus, and impaired kidney function.
Antidotes	No specific antidote exists.

5. FIRE-FIGHTING MEASURES	
Fire and Explosion Hazards	No apparent fire or explosion hazard for the product.
Extinguishing Media	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Special Firefighting Procedures	Self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.
Decontamination Procedure	No specific decontamination procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE	
Safe Handling and Use	Avoid breaking or crushing capsules.
Storage	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
PERSONAL PROTECTIVE EQUIPMENT	
Eye Protection	None required for consumer use of this product. Avoid eye contact.
Respirators	None required for consumer use of this product. If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present.
Other Equipment or Procedures	None required for consumer use of this product.
Work / Hygienic Practices	Follow good Industrial and Personal Hygiene practices.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Physical Form (Appearance)	Color & Shape: 50 mg - Yellow powder filled in Size 4 white opaque cap/white opaque body hard gelatin capsules imprinted with RX694 on cap and body in black ink. 75 mg - Yellow powder filled in Size 3 gray opaque cap/grey opaque body hard

	gelatin capsules imprinted with RX695 on cap and body in black ink. 100 mg - Yellow powder filled in Size 3 gray opaque cap/white opaque body hard gelatin capsules imprinted with RX696 on cap and body in black ink.

10. STABILITY AND REACTIVITY	
Stability	Stable
Conditions to Avoid	Avoid exposure to heat and light.

11. TOXICOLOGICAL INFORMATION	
This material contains active pharmaceutical ingredient Minocycline Hydrochloride, the specific information on which is provided below.	
Oral Toxicity	Oral Rat : LD50: 2380 mg/kg Oral Mouse : LD50: 3600 mg/kg
Inhalation Toxicity	n/k
Skin Effects	Not irritating to rabbit skin.
Eye Effects	Non- irritating.
Target Organ Effects	n/k
Sensitisation	Not a dermal sensitizer in guinea pigs. Allerfic reactions have been reported following therapeutic use of Minocycline hydrochloride.
Genetic Toxicity	Mutagenicity studies of Minocycline have not been conducted; positive results in in-vitro mammalian cell assays (ie, mouse lymphoma and Chinese hamster lung cells) have been reported for related antibiotics (tetracycline hydrochloride and oxytetracycline).
Carcinogenicity	In long-term carcinogenicity studies in rats, dietary administration of this compound revealed an evidence of thyroid tumor production. Thyroid hyperplasia was also found in rats and dogs treated with this compound.
Reproductive Effects	General reproduction and fertility studies have been conducted and revealed an evidence of impaired fertility in male rats. The teratogenic potential of this compound was assessed in the mouse, rat, rabbit, dog, and monkey and revealed an evidence of adverse effects on skeletal development at maternally toxic doses. This compound crosses the placenta and may cause fetal harm.
Gastrointestinal Reactions	n/k
Hypersensitivity	n/k

Reactions	
Pharmacological Effects	Minocycline Hydrochloride has been observed to cause a dark discoloration of the thyroid in experimental animals (rats, minipigs, dogs, and monkeys). In the rat, chronic treatment with Minocycline hydrochloride has resulted in goiter accompanied by elevated radioactive iodine uptake and evidence of thyroid tumor production. Minocycline hydrochloride has also been found to produce thyroid hyperplasia in rats and dogs.
Over Dosage	In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Minocycline is not removed in significant quantities by hemodialysis or peritoneal dialysis.
Contraindications	This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.
Other information	n/k

12. ECOLOGICAL INFORMATION
This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.
Do not allow product to enter drinking water supplies, waste water or soil.

13. DISPOSAL CONSIDERATIONS	
Disposal Recommendations	Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION	
The MSDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.	
Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION	
EU Classification and Labelling	n/k
US OSHA Standard (29 CFR Part 1910.1200)	n/k
OTHER US REGULATIONS	
	n/k

16. OTHER INFORMATION
The above information and recommendations are believed to be correct as on date but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Ranbaxy shall not be held liable for any damage resulting from handling or from contact with the above product. Ranbaxy reserves the right to revise this MSDS.