

# NEULAND LABORATORIES LIMITED

1 / 4

## SAFETY DATA SHEET

Status: Current	Ciprofloxacin Hydrochloride	Valid from: 28.10.2003
Evid. num.: --		Replace: 25.01.2003

Elaborated by: TVVS Rayudu Dy. Manager-QA	Date of issue: 28.10.2003	Approved by: Dr. V.N. Iyer Manager-QC & QA	Date prepared: 27.10.2003
Signature: <i>[Signature]</i>		Signature: <i>[Signature]</i>	

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/ SUPPLIER:

PRODUCT NAME:	Ciprofloxacin Hydrochloride
Manufacturer/supplier:	NEULAND LABORATORIES LIMITED
Identification (Product):	CP
COMPANY ADDRESS:	204, 6-3-853/1, Meridian Plaza, Ameerpet, Hyderabad - 500016 Andhra Pradesh, INDIA. Telephone Nos. (091) - 40 - 23412934/36/37 Fax : (091) - 40 - 23412957 e-mail : dr Rao@neulandlabs.com
URGENT INFORMATION AVAILABLE AT.:	Corporate Office
	Factory (Unit-II)
	Phones: (091) - 40 - 23412934/36/37
	Phones: (091) - 8455 - 226017 / 26

### 2. COMPOSITION/INFORMATION ON HAZARDOUS INGREDIENTS:

CHEMICAL NAME:	3-Quinolincarboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-, monohydrochloride, monohydrate.
CONTENT:	98.00 - 102.00% w/w
CAS NO.:	86393-32-0
EC NO.:	--
INDEX NO.:	--
MOLECULAR FORMULA:	$C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_2O$
(HILL)	
MOLECULAR WEIGHT:	385.82
SYNONYM:	--

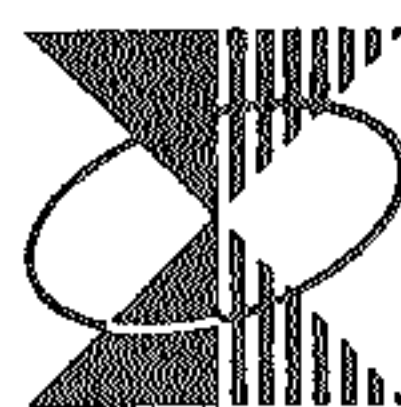
### 3. HAZARDS IDENTIFICATION:

SPECIAL HEALTH HAZARDS:	Inhalation : Causes irritation. Skin contact : Causes irritation. Eye contact : Causes irritation Swallowing : Causes may include nausea or vomiting, mild diarrhea, dizziness, drowsiness, abdominal pain, headache, nervousness or restlessness, and skin rash. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
ECOLOGICAL HAZARDS:	Not known
CHEMICAL AND PHYSICAL HAZARDS:	Label precautionary statements: Harmful, harmful if swallowed Target organs: Liver, G.I. System Wear suitable protective clothing.

### 4. FIRST AID MEASURES:

IF INHALED :	Remove to fresh air. If not breathing give artificial respiration.
IN CASE OF SKIN CONTACT:	Flush with plenty of water.
IN CASE OF CONTACT WITH EYES :	Flush with plenty of water. Call a physician
IF SWALLOWED :	Wash out mouth with water provided person is conscious. Call a physician.





# NEULAND LABORATORIES LIMITED

## SAFETY DATA SHEET

2 / 4

Status: Current	Ciprofloxacin Hydrochloride	Valid from: 28.10.2003 Replace: 25.01.2003
Evid. num.: --		

### 5. FIRE-FIGHTING MEASURES:

EXTINGUISHING MEDIA:	Water spray, dry chemical powder, carbon dioxide or foam as appropriate for surrounding fire and materials.
SPECIAL FIRE FIGHTING PROCEDURE	As with all fires, evacuate personnel to a safe area. Fire-fighters should use self contained breathing equipment and protective clothing.
UNUSUAL FIRE AND EXPLOSIONS HAZARDS	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.
SPECIAL PROTECTIVE EQUIPEMENT FOR FIRE-FIGHTING:	Wear appropriate NIOSH/MSHA approved respirator, chemical-resistant gloves, safety goggles, other protective clothing.

### 6. ACCIDENTAL RELEASE MEASURES:

PERSON-RELATED PRECAUTIONARY MEASURES:	Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Safety Glasses.
ENVIRONMENTAL-PROTECTION MEASURES:	Ventilate area and wash spill site after material pickup is complete.
PROCEDURES FOR CLEANING/ ABSORPTION:	Sweep up, place in a bag and hold for waste disposal. Avoid raising dust.

### 7. HANDLING AND STORAGE:

HANDLING:	Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.
STORAGE:	Preserve in a tight-light resistant container, should be handled and stored as per label instructions.

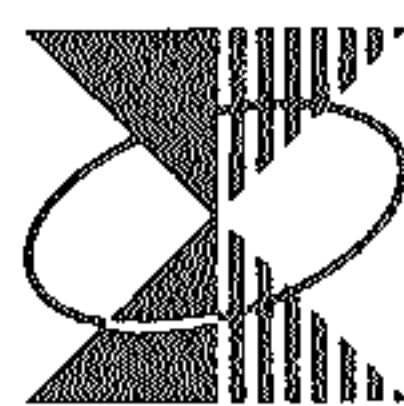
### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION:

SPECIFIC CONTROL PARAMETER -MDK:	Keep tightly closed being light and moisture sensitive .
INDUSTRIAL HYGIENE:	Wash thoroughly after handling.
RESPIRATORY PROTECTION:	When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.
HAND PROTECTION:	Wear appropriate protective rubber gloves (Chemical resistant).
EYE PROTECTION:	Wear safety glasses.
SKIN PROTECTION:	Wear Apron and protect exposed skin

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

FORM / COLOUR:	Faintly yellowish crystalline powder and odourless..
ODOUR:	Practically odourless.
BOILING POINT (°C):	Not applicable
MELTING POINT (°C):	About 310° C.
VAPOUR PRESSURE:	Not applicable
FLASH POINT:	Not applicable





# NEULAND LABORATORIES LIMITED

## SAFETY DATA SHEET

3 / 4

Status: Current	Ciprofloxacin Hydrochloride	Valid from: 28.10.2003 Replace: 25.01.2003
Evid. num.: --		

IGNITION TEMPERATURE:	Not applicable
EXPLOSION LIMITS:	Not applicable
DENSITY:	Not applicable
PH VALUE:	3.0-4.5
SOLUBILITY IN WATER:	Sparingly soluble
SOLUBILITY IN OTHER SUBSTANCES:	Slightly soluble in methanol. Very slightly soluble in ethanol, practically insoluble in acetone, in ethyl acetate and in methylene chloride.
Log P(oct):	
OTHER INFORMATION:	When heated to decomposition material emits toxic fumes of HCL, HF and NOx. Emits toxic fumes under fire conditions.

### 10. STABILITY AND REACTIVITY:

Incompatibility	
STABILITY:	Material is stable for 60 months.
HAZARDOUS REACTIONS:	
CONDITIONS TO BE AVOIDED:	Avoid exposure to light.
CHEMICALS TO BE AVOIDED:	Oxydizing agents and iron
HAZARDOUS DECOMPOSITION PRODUCTS:	When heated to decomposition material emits toxic fumes of HCL, HF and NOx. Emits toxic fumes under fire conditions

### 11. TOXICOLOGICAL INFORMATION:

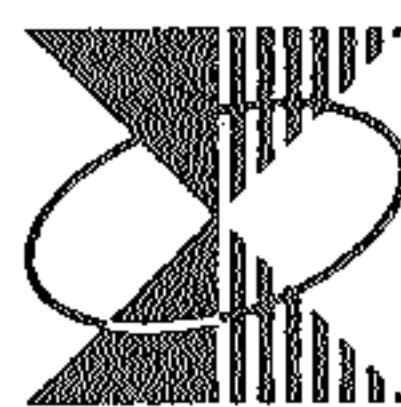
LD <sub>50</sub> (ORAL, RAT):	>5000mg/kg
LD <sub>50</sub> (ORL, MUS):	> 5000 mg/kg
SHORT-TERME EXPOSURE EFFECTS (EFFECTS AND SYMPTOMS):	--
LONG-TERME EXPOSURE EFFECTS (EFFECTS AND SYMPTOMS):	--

### 12. ECOLOGICAL INFORMATION:

DISTRIBUTION:	} Data not yet available
BIOLOGIC DEGRADATION:	
ACCUMULATION:	
ECOTOXCIC EFFECTS:	

### 13. DISPOSAL CONSIDERATIONS:

Method of disposal:	Dispose of waste in accordance with state / central laws..
---------------------	--



# NEULAND LABORATORIES LIMITED

## SAFETY DATA SHEET

4 / 4

Status: Current	Ciprofloxacin Hydrochloride	Valid from: 28.10.2003 Replace: 25.01.2003
Evid. num.: --		

### 14. TRANSPORT INFORMATION:

PROPER SHIPPING NAME:  
ROAD TRANSPORT  
ADR, UN NO.:  
RAIL TRANSPORT  
RID, UN NO.:  
SEA TRANSPORT  
IMDG, UN NO.:  
AIR TRANSPORT  
IATA / ICAO, UN NO.:

Safe for transportation by any mode. No hazard known.

### 15. REGULATORY INFORMATION:

HAZARD SYMBOL:

Harmful

R-PHRASES:

R-36/37/38

S-PHRASES:

S-26-36

LAWS AND REGULATIONS:

Local, State, Central / Federal Laws is applicable.

### 16. OTHER INFORMATION:

TRAINING:

On handling, storage and disposal.

USAGE:

As anti-bacterial

LITERATURE:

Various reliable sources.

This Safety Data Sheet is provided in compliance with Directives concerning Safety Data Sheets (91/155/EEC and 93/112/EEC). Data was gathered from acknowledged expert sources and are also based on our knowledge on safe use of the product. The stated data alone are not yet a sufficient basis for safe use of the product under any circumstances. To insure safe use of the product other legal regulations and instructions from technical-technological documentation should be observed.