

SAFETY DATA SHEETS

This SDS packet was issued with item:

078940153

N/A

CIPROFLOXACIN

MANUFACTURER: WEST-WARD PHARMACEUTICAL CORP.

435 INDUSTRIAL WAY WEST

EATONTOWN, NJ 07724

TELEPHONE: (908) 542-1191

On file is a letter dated December 8, 2004 from Harold Zenenbert,
Exec. Vice President Sales & Marketing, stating that this product
does not require a Material Safety Data Sheet.

COMPAS Code: 14760070

SAFETY DATA SHEET

Ciprofloxacin Tablets, 500mg

Section 1. Identification

GHS product identifier	: Ciprofloxacin Tablets, 500mg
Chemical name	: 1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid
Synonyms	: Not available.
Product code	: Not available.
Chemical family	: Not available.
Product type	: Regulated prescription drug.
Container information	: Not available.

Identified uses

Indicated for the treatment of infections caused by susceptible strains of microorganisms.

Supplier's details	: West-Ward Pharmaceutical Corp. 465 Industrial Way West Eatontown NJ 07724 USA
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Emergency telephone number (with hours of operation)	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7
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Section 2. Hazards identification

OSHA/HCS status	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
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Classification of the substance or mixture	: CARCINOGENICITY - Category 2 AQUATIC HAZARD (LONG-TERM) - Category 3
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GHS label elements

Hazard pictograms



Signal word : Warning

Hazard statements : Suspected of causing cancer.
Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Avoid release to the environment.

Response : IF exposed or concerned: Get medical attention.

Storage : Store locked up.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.



Section 2. Hazards identification

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Chemical name : 1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid
Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.
Product code : Not available.

Ingredient name	%	CAS number
3-Quinolinecarboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-	60 - 100	85721-33-1
Cellulose	5 - 10	9004-34-6
Starch, carboxymethyl ether, sodium salt	1 - 5	9063-38-1
Silicon dioxide	0.1 - 1	7631-86-9
Starch	5 - 10	9005-25-8
Hydrogenated Vegetable Oil	0.1 - 1	150409-10-2
Magnesium distearate	1 - 5	557-04-0
Talc	1 - 5	14807-96-6
Titanium dioxide	0.1 - 1	13463-67-7
Ethanediol	0.1 - 1	107-21-1
Cellulose, 2-hydroxypropyl methyl ether	0.1 - 1	9004-65-3
Simethicone	0.1 - 1	8050-81-5
Polyacrylate Dispersion (Eudragit NE 30D)	0.1 - 1	1439374-06-7

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Section 4. First aid measures

- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

- Specific hazards arising from the chemical** : This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds
metal oxide/oxides

Section 5. Fire-fighting measures

Special protective actions for fire-fighters : No special measures are required.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and materials for containment and cleaning up

Spill : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid release to the environment. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Titanium dioxide	OSHA PEL (United States, 6/2010). TWA: 15 mg/m ³ 8 hours. Form: Total dust ACGIH TLV (United States, 3/2012). TWA: 10 mg/m ³ 8 hours.

Appropriate engineering controls : If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state	: Solid.
Color	: Not available.
Odor	: Not available.
Odor threshold	: Not available.
pH	: Not available.
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not applicable.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials and acids. Non-reactive or compatible with the following materials: reducing materials, combustible materials, organic materials, metals, alkalis and moisture.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Titanium dioxide	Skin - Mild irritant	Human	-	72 hours 300 µg Intermittent	-

Sensitization

There is no data available.

Carcinogenicity

Classification

Product/ingredient name	OSHA	IARC	NTP
Titanium dioxide	-	2B	-

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Long term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Section 11. Toxicological information

Potential chronic health effects

- General** : No known significant effects or critical hazards.
- Carcinogenicity** : Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	50000 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
3-Quinolinecarboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-	Acute EC50 1 mg/L Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute IC50 6700 µg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
	Chronic NOEC 5000 µg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
Titanium dioxide	Acute EC50 5.83 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
	Acute LC50 3 mg/L Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 5.5 ppm Fresh water	Daphnia - Daphnia magna - Juvenile (Fledgling, Hatchling, Weanling)	48 hours
	Acute LC50 1000 mg/L Fresh water Chronic NOEC 0.984 mg/L Fresh water	Fish - Pimephales promelas Algae - Pseudokirchneriella subcapitata - Exponential growth phase	96 hours 72 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
3-Quinolinecarboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-	0.28	-	low
Titanium dioxide	-	352	low

Mobility in soil

- Soil/water partition coefficient (K_{oc})** : Not available.

- Other adverse effects** : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed

Clean Air Act Section 602 Class I Substances : Not listed

Section 15. Regulatory information

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Titanium dioxide	0.1 - 1	No.	No.	No.	No.	Yes.

SARA 313

	Product name	CAS number	%
Form R - Reporting requirements	Ethanediol	107-21-1	0.1 - 1
Supplier notification	Ethanediol	107-21-1	0.1 - 1

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

Massachusetts : The following components are listed: Cellulose; Starch; Talc; Silicon dioxide; Titanium dioxide; Ethanediol

New York : The following components are listed: Ethanediol

New Jersey : The following components are listed: Cellulose; Talc; Titanium dioxide; Ethanediol

Pennsylvania : The following components are listed: Cellulose; Starch; Talc; Silicon dioxide; Titanium dioxide; Ethanediol

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
Titanium dioxide	Yes.	No.	No.	No.

International regulations

Section 15. Regulatory information

International lists	: Australia inventory (AICS): Not determined. China inventory (IECSC): Not determined. Japan inventory: Not determined. Korea inventory: Not determined. Malaysia Inventory (EHS Register): Not determined. New Zealand Inventory of Chemicals (NZIoC): Not determined. Philippines inventory (PICCS): Not determined. Taiwan inventory (CSNN): Not determined.
Chemical Weapons Convention List Schedule I Chemicals	: Not listed
Chemical Weapons Convention List Schedule II Chemicals	: Not listed
Chemical Weapons Convention List Schedule III Chemicals	: Not listed

Section 16. Other information

History

Date of issue mm/dd/yyyy	: 02/15/2014
Version	: 1
Revised Section(s)	: Not applicable.
Prepared by	: KMK Regulatory Services Inc.
Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) UN = United Nations

Notice to reader

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