# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078940153

N/A

### CIPROFLOXACIN

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MANUFACTURER: WEST-WARD PHARMACEUTICAL CORP.

435 INDUSTRIAL WAY WEST EATONTOWN, NJ 07724 TELEPHONE: (908) 542-1191

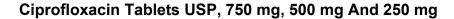
On file is a letter dated December 8, 2004 from Harold Zenenbert, Exec. Vice President Sales & Marketing, stating that this product

does not require a Material Safety Data Sheet.

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COMPAS Code: 14760070

# SAFETY DATA SHEET





### **Section 1. Identification**

**GHS** product identifier

**Chemical name** 

Other means of identification

**Product code** 

: 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid

: Not available.

: For Ciprofloxacin 750 mg:

Pack of 50's: 0143-9929-50 Pack of 100's: 0143-9929-01

: Ciprofloxacin Tablets USP, 750 mg, 500 mg And 250 mg

Bulk: 59115-028-99

For Ciprofloxacin 500 mg:

Pack of 100's: 0143-9928-01 Pack of 500's: 0143-9928-05 Pack of 30's: 0143-9928-30

Bulk: 59115-029-99

For Ciprofloxacin 750 mg:

Pack of 100's: 0143-9927-01 Pack of 500's: 0143-9927-05 Pack of 30's: 0143-9927-30

Bulk: 59115-030-99

Product type
Container information

: Solid.

: Bulk -bags:

Low density Polyethylene Food Grade

Aluminum bag

Desiccant bags tropack 4B

**Bottles of 30's** 

60 cc White HDPE Bottle Cap: 33mm Polypropylene CRC

Purified Rayon 12 g

Bottles of 50's

120 cc White HDPE Bottle Cap: 38 mm Polypropylene CRC

Purified rayon 20 g

**Bottles of 100's** 

Bottle: - 200 cc White HDPE Bottle

- 150 cc HDPE Bottle

-120 cc White HDPE Bottle

Cap: - 38 mm Polypropylene CRC

-45 mm White Polypropylene CRC

Purified rayon 20 g

Bottles of 500's

500 cc HDPE Bottle

Cap: 53 mm Polypropylene Plastic Cap

Purified rayon 20 g





### **Section 1. Identification**

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

**Identified uses** : Indicated for the treatment of infections caused by susceptible strains of microorganisms.

Manufacturer : Hikma Pharmaceuticals

Bayadar Wadi Seer , P.O Box 182400, Amman, Jordan

Tel: +96265802900 Fax: +962 6 581 7102 www.Hikma.com

Email: Ljaloukh@hikma.com

Supplier : West-Ward Pharmaceuticals Corp

401 Industrial Way West Eatontown

New Jersey (NJ) 07724 Tel: 732-542-1191, ext. 2722

Fax: 732-542-6150

Email: ctrotta@west-ward.com

Emergency telephone number (with hours of operation)

: CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887

24/7

### Section 2. Hazards identification

**OSHA/HCS status** 

: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture

: RESPIRATORY SENSITIZATION - Category 1 SKIN SENSITIZATION - Category 1 AQUATIC HAZARD (ACUTE) - Category 1 AQUATIC HAZARD (LONG-TERM) - Category 1

### **GHS label elements**

**Hazard pictograms** 





Signal word

: Danger

**Hazard statements** 

: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 - May cause an allergic skin reaction.

H410 - Very toxic to aquatic life with long lasting effects.

### **Precautionary statements**

**Prevention** 

: P280 - Wear protective gloves.

P284 - Wear respiratory protection.

P273 - Avoid release to the environment.

P261 - Avoid breathing dust.

P272 (OSHA) - Contaminated work clothing must not be allowed out of the workplace.



### Section 2. Hazards identification

Response : P391 - Collect spillage.

P304 + P341 (OSHA) - IF INHALED: If breathing is difficult, remove person to fresh air

and keep comfortable for breathing.

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or

physician.

P302 + P352 + P363 - IF ON SKIN: Wash with plenty of soap and water. Wash

contaminated clothing before reuse.

P333 + P313 - If skin irritation or rash occurs: Get medical attention.

Storage : Not applicable.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national

and international regulations.

**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 : For Ciprofloxacin 750 mg:

Pack of 50's: 0143-9929-50 Pack of 100's: 0143-9929-01

Bulk: 59115-028-99

For Ciprofloxacin 500 mg:

Pack of 100's: 0143-9928-01 Pack of 500's: 0143-9928-05 Pack of 30's: 0143-9928-30

Bulk: 59115-029-99

For Ciprofloxacin 750 mg:

Pack of 100's: 0143-9927-01 Pack of 500's: 0143-9927-05 Pack of 30's: 0143-9927-30

Bulk: 59115-030-99

Ingredient name	%	CAS number
3-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-6-fluoro-4-oxo-7-(1-piperazinyl)-, monohydrochloride	≥75 - ≤90	93107-08-5

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

There are no additional 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 if irritation occurs.

Inhalation

Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. 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 necessary, call a poison center or physician. 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. In the event of any complaints or symptoms, avoid further exposure.

Skin contact

: Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

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 if adverse health effects persist or are severe. 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 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin contact**: May cause an allergic skin reaction.

**Ingestion**: No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

Eye contact

: No known significant effects or critical hazards.

**Inhalation** : Adverse symptoms may include the following:

wheezing and breathing difficulties

asthma

Skin contact

: Adverse symptoms may include the following:

irritation redness

**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.





### Section 4. First aid measures

### Protection of first-aiders

: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

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 very toxic 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

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. Collect spillage.

### Methods and materials for containment and cleaning up

**Small spill** 

: Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.





### Section 6. Accidental release measures

### Large 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). Persons with a history of skin sensitization problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid release to the environment. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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.

## including any incompatibilities

Conditions for safe storage, : 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. 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

I	ngredient name	Exposure limits
	-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-6-fluoro-4-oxo-7- 1-piperazinyl)-,monohydrochloride	None.

### Appropriate engineering controls

: Use only with adequate ventilation. 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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.





### Section 8. Exposure controls/personal protection

### **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** 

: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

#### **Appearance**

**Physical state** 

Solid.

Color

: For Ciprofloxacin 250 mg

White round, unscored, imprinted WW927 on one side, film coated tablets

For Ciprofloxacin 500 mg

White medium capsule shape, unscored, imprinted WW928 on one side film coated tablets

For Ciprofloxacin 750 mg

White large capsule shape, unscored imprinted WW929 on one side film coated tablets

Odor : Not available.
Odor threshold : Not available.
pH : Not available.

Melting point: Not available.Boiling point: Not available.Flash point: Not available.Evaporation rate: Not available.Flammability (solid, gas): Not available.

Lower and upper explosive

(flammable) limits

octanol/water

: Not available.

Vapor pressure: Not available.Vapor density: Not available.Relative density: Not available.Solubility: Not available.Partition coefficient: n-: Not available.





### Section 9. Physical and chemical properties

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** : Not available.

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**

Product/ingredient name	Result	Species	Dose	Exposure
3-Quinolinecarboxylic acid, 1, 4-dihydro-1-cyclopropyl-6-fluoro- 4-oxo-7-(1-piperazinyl)-, monohydrochloride	LD50 Oral	Rat	>5 g/kg	-

### **Irritation/Corrosion**

There is no data available.

### **Sensitization**

There is no data available.

#### Mutagenicity

There is no data available.

### **Carcinogenicity**

### **Classification**

Product/ingredient name	OSHA	IARC	NTP	ACGIH	EPA	NIOSH
Starch	-	-	-	A4	-	-
Magnesium distearate	-	-	-	A4	-	-

### Reproductive toxicity

There is no data available.

### **Teratogenicity**

There is no data available.

### Specific target organ toxicity (single exposure)

There is no data available.

### Specific target organ toxicity (repeated exposure)

There is no data available.





# Section 11. Toxicological information

### **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 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin contact : May cause an allergic skin reaction.

: No known significant effects or critical hazards. Ingestion

Symptoms related to the physical, chemical and toxicological characteristics

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

: Adverse symptoms may include the following:

wheezing and breathing difficulties

asthma

Skin contact : Adverse symptoms may include the following:

> irritation redness

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

: No known significant effects or critical hazards.

effects

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.

Potential chronic health effects

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to

very low levels.

Carcinogenicity : No known significant effects or critical hazards. 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

There is no data available.





## **Section 12. Ecological information**

### **Toxicity**

There is no data available.

### Persistence and degradability

There is no data available.

### **Bioaccumulative potential**

There is no data available.

### **Mobility in soil**

Soil/water partition coefficient (Koc)

: 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	UN3077	UN3077	UN3077	
shipping name  SUBSTANCE, SOLID, N.O.S. (3-Quinolinecarboxylic acid, 1,4-dihydro- 1-cyclopropyl-6-fluoro-4-oxo-7- (1-piperazinyl)-,monohydrochloride).  Marine pollutant (3-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-6-fluoro- 4-oxo-7-(1-piperazinyl)-,		ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (3-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-6-fluoro-4-oxo-7- (1-piperazinyl)-,monohydrochloride). Marine pollutant (3-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-6-fluoro-4-oxo-7-(1-piperazinyl)-, monohydrochloride)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (3-Quinolinecarboxylic acid, 1,4-dihydro-1-cyclopropyl-6-fluoro-4-oxo-7-(1-piperazinyl)-,monohydrochloride)	
Transport hazard class(es)	9	9	9	
Packing group	III	III	III	
Environmental hazards	Yes.	Yes.	Yes.	



### Ciprofloxacin Tablets USP, 750 mg, 500 mg And 250 mg

### Section 14. Transport information

**Additional** information

Non-bulk packages of this product are not regulated as hazardous materials unless transported by inland waterway. This product is not regulated as a hazardous material when transported in sizes of  $\leq$ 5 L or  $\leq$ 5 kg, provided the packagings meet the general provisions of §§ 173.24 and 173.24a.

This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

**AERG** : 171

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.

## **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)**  : Not listed

Clean Air Act Section 602

**Class I Substances** 

: Not listed

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** 

Classification : Immediate (acute) health hazard

Composition/information on ingredients

Name	%	hazard	Sudden release of pressure		Immediate (acute) health hazard	Delayed (chronic) health hazard
3-Quinolinecarboxylic acid, 1,4-dihydro- 1-cyclopropyl-6-fluoro-4-oxo-7- (1-piperazinyl)-,monohydrochloride	≥75 - ≤90	No.	No.	No.	Yes.	No.

### **SARA 313**

There is no data available.

#### State regulations

**Massachusetts** : The following components are listed: Cellulose; Starch

**New York** : None of the components are listed.





## Section 15. Regulatory information

New Jersey : The following components are listed: Cellulose

Pennsylvania : The following components are listed: Cellulose; Starch

California Prop. 65

No products were found.

### Section 16. Other information

### Procedure used to derive the classification

Classification	Justification
RESPIRATORY SENSITIZATION - Category 1	Calculation method
SKIN SENSITIZATION - Category 1	Calculation method
AQUATIC HAZARD (ACUTE) - Category 1	Calculation method
AQUATIC HAZARD (LONG-TERM) - Category 1	Calculation method

#### **History**

Date of issue mm/dd/yyyy : 06/15/2016

Version : 1

Prepared by : KMK Regulatory Services Inc.

#### Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

