



## cefdinir

cefdinir (REVIEW)  
Issue Date: 10-Apr-2011  
NC618TCP

Hazard Alert Code: MODERATE

CHEMWATCH 9404382  
Version No:2.0  
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### Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME**  
cefdinir

**OTHER NAMES**

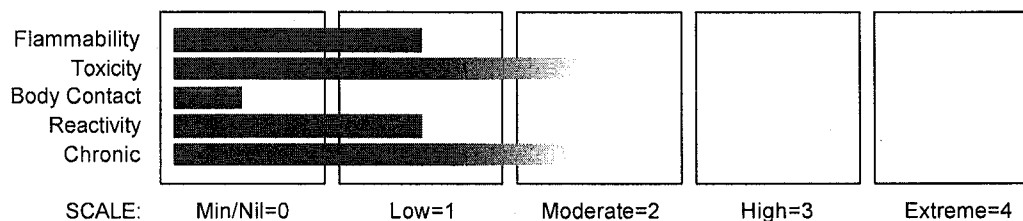
C14-H13-N5-O5-S2, "8-[2-(2-amino-1, 3-thiazol-4-yl)-1-hydroxy-2-nitroso-ethenyl]amino-4-ethenyl-7-oxo-2-thia-6-azabicyclo[4.2.0]oct-4-ene-5-carboxylic acid", "5-thia-1-azabicyclo(4.2.0)oct-2-ene-2-carboxylic acid, 7-(((2-amino-4-thiazolyl)(hydroxyimino acetyl)amino)-3-ethenyl-8-oxo-, (6R-(6-alpha, 7-beta(Z))))", "[6R-[6alpha, 7beta (Z)]]-7-[[2-(2-amino-4-thiazolyl)(hydroxyimino)acetyl]amino]-3-ethenyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid", "syn-7-[2-(2-amino-4-thiazolyl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid", BMV-28488, Cefdinyl, FK-482, Omnicef, Kefnir

**PRODUCT USE**

A semi-synthetic, broad-spectrum antibiotic in the third generation of the cephalosporin class, proven effective for common bacterial infections of the ear, sinus, throat, and skin. Therapeutic uses of cefdinir include otitis media, soft tissue infections, and respiratory tract infections, including sinusitis, strep throat, community-acquired pneumonia and acute exacerbations of bronchitis. Cefdinir is a bacteriocidal antibiotic. It can be used to treat infections caused by several Gram-negative and Gram-positive bacteria. Given by mouth. Structurally related to cefixime.

### Section 2 - HAZARDS IDENTIFICATION

**CHEMWATCH HAZARD RATINGS**



**EMERGENCY OVERVIEW**  
Not hazardous

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## Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

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NAME	CAS RN	%
cefdinir	91832-40-5	>98

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## Section 4 - FIRST AID MEASURES

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### SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

### EYE

- If this product comes in contact with the eyes:
  - Wash out immediately with fresh running water.
  - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
  - Seek medical attention without delay; if pain persists or recurs seek medical attention.
  - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

### SKIN

- If skin or hair contact occurs:
  - Flush skin and hair with running water (and soap if available).
  - Seek medical attention in event of irritation.

### INHALED

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

### NOTES TO PHYSICIAN

- Treat symptomatically.
- In acute rodent toxicity studies, a single oral 5600-mg/kg dose produced no adverse effects. Toxic signs and symptoms following overdose with other beta-lactam antibiotics have included nausea, vomiting, epigastric distress, diarrhoea, and convulsions. Haemodialysis removes cefdinir from the body. This may be useful in the event of a serious toxic reaction from overdose, particularly if renal function is compromised.

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## Section 5 - FIRE FIGHTING MEASURES

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### EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

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Section 5 - FIRE FIGHTING MEASURES

## FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

## FIRE/EXPLOSION HAZARD

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
  - Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
  - In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL), are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
  - A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
  - Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type.
  - Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
  - Build-up of electrostatic charge may be prevented by bonding and grounding.
  - Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
  - All movable parts coming in contact with this material should have a speed of less than 1-meter/sec
  - A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source
  - One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours).
  - Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.
- Combustion products include: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>), other pyrolysis products typical of burning organic material.
- May emit poisonous fumes.

## FIRE INCOMPATIBILITY

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

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Section 5 - FIRE FIGHTING MEASURES

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## PERSONAL PROTECTION

Glasses:

Chemical goggles.

Respirator:

Particulate

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## Section 6 - ACCIDENTAL RELEASE MEASURES

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### MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

### MAJOR SPILLS

- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise Emergency Services.

**Personal Protective Equipment advice is contained in Section 8 of the MSDS.**

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## Section 7 - HANDLING AND STORAGE

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### PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handling; DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working

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Section 7 - HANDLING AND STORAGE

conditions are maintained.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

## SUITABLE CONTAINER

- Glass container is suitable for laboratory quantities.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

## STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents.

## STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry area protected from environmental extremes.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations

For major quantities:

- Consider storage in banded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).
- Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.

## SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+: *May be stored together*

O: *May be stored together with specific preventions*

X: *Must not be stored together*

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

The following materials had no OELs on our records

- cefdinir:

CAS:91832- 40- 5

### MATERIAL DATA

CEFDINIR:

■ It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as

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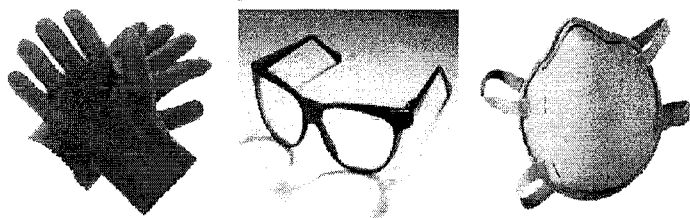
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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply. Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

### PERSONAL PROTECTION



#### EYE

- When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
  - Chemical goggles
  - Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
  - Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent].

#### HANDS/FEET

- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:
  - frequency and duration of contact,
  - chemical resistance of glove material,
  - glove thickness and
  - dexteritySelect gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).
  - When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
  - When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
  - Contaminated gloves should be replaced.Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
  - Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
  - Double gloving should be considered.

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

- PVC gloves.
- Protective shoe covers. [AS/NZS 2210]
- Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

### OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

### RESPIRATOR

- Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)
- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

### ENGINEERING CONTROLS

- Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/containment technology.

Manufacturing and pilot plant operations require barrier/containment and direct coupling technologies.

Barrier/containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, etc. evaporating from tank (in still air)	0.25- 0.5 m/s (50- 100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5- 1 m/s (100- 200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1- 2.5 m/s (200- 500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

10; high efficiency particulate (HEPA) filters or cartridges

10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.

25-50; a full face-piece negative pressure respirator with HEPA filters

50-100; tight-fitting, full face-piece HEPA PAPR

100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### APPEARANCE

White to slightly brownish-yellow solid; does not mix well with water.  
pKa 9.7

### PHYSICAL PROPERTIES

State	Divided Solid	Molecular Weight	395.42
Melting Range (°C)	170 (decomposes)	Viscosity	Not Applicable
Boiling Range (°C)	Not Applicable	Solubility in water (g/L)	Partly Miscible
Flash Point (°C)	Not Available	pH (1% solution)	Not Applicable
Decomposition Temp (°C)	170	pH (as supplied)	Not Applicable
Autoignition Temp (°C)	Not Available	Vapour Pressure (kPa)	Negligible
Upper Explosive Limit (%)	Not Available	Specific Gravity (water=1)	Not Available
Lower Explosive Limit (%)	Not Available	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

## Section 10 - CHEMICAL STABILITY

### CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

*For incompatible materials - refer to Section 7 - Handling and Storage.*

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## Section 11 - TOXICOLOGICAL INFORMATION

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### POTENTIAL HEALTH EFFECTS

#### ACUTE HEALTH EFFECTS

##### SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- The most common side effects of cephalosporins include acute, life-threatening kidney failure. Neurological symptoms may occur. There may be a generalised sensitivity reaction characterised by itch, wheal, skin rash, fever and chills, blood changes, joint pain, swelling and redness. Healing and clotting may be slowed. Cephalothin can cause changes in white cell distribution, loss of platelets and anaemia due to immune reaction. Cross sensitivity may occur between cephalosporins, cephamycins and penicillins. Other effects may include disturbances in taste and smell, low blood pressure and headache. If alcohol is taken during therapy, nausea and vomiting may result. Allergic reactions may cause breathing distress and death.

##### EYE

- Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

##### SKIN

- The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

##### INHALED

- The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

##### CHRONIC HEALTH EFFECTS

- Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray. Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e. super-infection).

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## Section 11 - TOXICOLOGICAL INFORMATION

Prolonged use of cephalosporins may result in resistance and super-infection of non-susceptible organisms, rarely resulting in intestinal inflammation. Loss of white blood cells and platelets have been reported; side effects are more common in those with pre-existing liver and kidney damage. Skin rashes, anaemia and gallstones have been seen. Cephalosporins are distributed in the milk of lactating women; however there is no information about their effect on the foetus and infant.

### TOXICITY AND IRRITATION

#### CEFDINIR:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

#### TOXICITY

Oral (Rat) LD50: >5600 mg/kg  
Intraperitoneal (Rat) LD50: >5600 mg/kg  
Subcutaneous (Rat) LD50: >5600 mg/kg  
Intravenous (Rat) LD50: >2000 mg/kg  
Oral (Mouse) LD50: >5600 mg/kg  
Intraperitoneal (Mouse) LD50: >5600 mg/kg  
Subcutaneous (Mouse) LD50: >5600 mg/kg  
Intravenous (Mouse) LD50: >2000 mg/kg  
Oral (Dog) LD50: >1000 mg/kg

#### IRRITATION

In clinical trials, 5093 adult and adolescent patients (3841 US and 1252 non-US) were treated with the recommended dose of cefdinir capsules (600 mg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. One hundred forty-seven of 5093 (3%) patients discontinued medication due to adverse events thought by the investigators to be possibly, probably, or definitely associated with cefdinir therapy

The discontinuations were primarily for gastrointestinal disturbances, usually diarrhea or nausea. Nineteen of 5093 (0.4%) patients were discontinued due to rash thought related to cefdinir administration.

In both cefdinir- and control-treated patients, rates of diarrhea and rash were higher in the youngest pediatric patients. The incidence of diarrhea in cefdinir-treated patients = 2 years of age was 17% (95/557) compared with 4% (51/1226) in those 2 years old. The incidence of rash (primarily diaper rash in the younger patients) was 8% (43/557) in patients = 2 years of age compared with 1% (8/1226) in those 2 years old.

Other adverse effects include shock, anaphylaxis with rare cases of fatality, facial and laryngeal oedema, feeling of suffocation, serum sickness-like reactions, conjunctivitis, stomatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme, erythema nodosum, acute hepatitis, cholestasis, fulminant hepatitis, hepatic failure, jaundice, increased amylase, acute enterocolitis, bloody diarrhoea, haemorrhagic colitis, melena, pseudomembranous colitis, pancytopenia, granulocytopenia, leukopenia, thrombocytopenia, idiopathic thrombocytopenic purpura, haemolytic anemia, acute respiratory failure, asthmatic attack, drug-induced pneumonia, eosinophilic pneumonia, idiopathic interstitial pneumonia, fever, acute renal failure, nephropathy, bleeding tendency, coagulation disorder, disseminated intravascular coagulation, upper GI bleed, peptic ulcer, ileus, loss of consciousness, allergic vasculitis, possible cefdinir-diclofenac interaction, cardiac failure, chest pain, myocardial infarction, hypertension, involuntary movements, and rhabdomyolysis

The paediatric version of cefdinir can bind to iron in the digestive tract. In rare cases, this creates a discolouration of the stool to a rust or red colour. Some patients may interpret this as blood in the stool, although in reality blood appears dark brown or black in the stool. If the reddish stool is accompanied by abdominal pain, weight loss, diarrhea, etc., it could be a *Clostridium difficile* infection caused by the antibiotic. This infection can occur as a result of taking an antibiotic.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of cefdinir has not been evaluated. No mutagenic effects were seen in the bacterial reverse mutation assay (Ames) or point mutation assay at the hypoxanthine-guanine phosphoribosyltransferase locus (HGPRT) in V79 Chinese hamster lung cells. No clastogenic effects were observed in vitro in the structural chromosome aberration assay in V79 Chinese hamster lung cells or in vivo in the micronucleus assay in mouse bone marrow

Reproductive and developmental toxicity:

continued...

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## Section 11 - TOXICOLOGICAL INFORMATION

In rats, fertility and reproductive performance were not affected by cefdinir at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m<sup>2</sup>/day). Cefdinir was not teratogenic in rats at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m<sup>2</sup>/day) or in rabbits at oral doses up to 10 mg/kg/day (0.7 times the human dose based on mg/kg/day, 0.23 times based on mg/m<sup>2</sup>/day). Maternal toxicity (decreased body weight gain) was observed in rabbits at the maximum tolerated dose of 10 mg/kg/day without adverse effects on offspring. Decreased body weight occurred in rat fetuses at = 100 mg/kg/day, and in rat offspring at = 32 mg/kg/day. No effects were observed on maternal reproductive parameters or offspring survival, development, behavior, or reproductive function.

## Section 12 - ECOLOGICAL INFORMATION

### CEFDINIR:

■ First generation cephalosporins are "relatively susceptible" to beta-lactamase (cephalosporinase) produced by Gram-negative bacteria, whereas second and particularly third generation cephalosporins have greater stability against Gram-negative beta-lactamases. Thus various micro-organisms present in soil and water are likely to be able to degrade cephalosporins in the environment, but at an unknown rate. Cephalosporins contain ionic species (a pyridylthio-N and a carboxylic group), and are likely to be adsorbed onto clay particles in the soil although the strength of adsorption is unknown. DO NOT discharge into sewer or waterways.

### Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
cefdinir	No Data Available	No Data Available		

## Section 13 - DISPOSAL CONSIDERATIONS

■ Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for

continued...

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Section 13 - DISPOSAL CONSIDERATIONS

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disposal if no suitable treatment or disposal facility can be identified.

- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

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## Section 14 - TRANSPORTATION INFORMATION

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HAZCHEM:

None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG

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## Section 15 - REGULATORY INFORMATION

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### REGULATIONS

No data for cefdinir (CAS: , 91832-40-5)

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## Section 16 - OTHER INFORMATION

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■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:  
[www.chemwatch.net/references](http://www.chemwatch.net/references).

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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