# MATERIAL SAFETY DATA SHEET

MANUFACTURER: AMERICAN CYANAMID COMPANY
LEDERLE LABORATORIES
MIDDLETOWN ROAD DATE:
PEARL RIVER, NY 10965

MSDS No.: 03898-03
Supersedes: 03898-02
08/06/93

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## I. PRODUCT IDENTIFICATION

PRODUCT NAME: SUPRAX\ cefixime For Oral Suspension:
(Product Code: 03898)

CAUTION! MAY CAUSE EYE AND SKIN IRRITATION.

CHEMICAL/THERAPEUTIC FAMILY: Cephalosporin derivative; antibacterial

## II. HAZARDOUS INGREDIENTS AND EXPOSURE LIMITS

| CHEMICAL AND COMMON NAMES | CAS NO. | % | RECOMMENDED AIRBORNE LEVELS OSHA | TLV (1992-93) | ACGO-TWA |
|---|---|---|---|---|---|
| Cefixime USP<br>0.4 mg/m3<br>(6R-[6a,7b(Z)]]-7-[[(2-Amino-4-thiazolyl)-[(carboxymethoxy)imino]acetyl]amino]-3-ethenyl-8-oxo-5-thia-1-azabicyclo[4.2.0]-oct-2-ene-2-carboxylic acid; SUPRAX; CL 284,635 | [79350-37-1] H4 | Not est. | Not est. | | |
| Sucrose NF<br>a-D-Glucopyranoside, b-D-fructofuranosyl-;<br>CL 139,875 | [57-50-1] | 95 | 15 mg/m3<br>5 mg/m3<br>(resp. fraction) | 10 mg/m3 (total dust)<br>STEL:<br>20 mg/m3 (total dust) | 10 mg/m3 (total dust) |

## III. PHYSICAL PROPERTIES

MOLECULAR WEIGHT: 453.44* 342.30** EMPIRICAL FORMULA: C16H15N5O7S2* C12H22O11**

APPEARANCE AND ODOR: Off-white to cream-colored powder.

BOILING POINT: Not available MELTING POINT: 200° C (decomposes)*
163-186° C (decomposes)**

VAPOR PRESSURE: Not available SPECIFIC GRAVITY: 1.587 @ 25° C**

VAPOR DENSITY: Not available PERCENT VOLATILE: Not available

*Property of Cefixime USP.
**Property of Sucrose NF.

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## III. PHYSICAL PROPERTIES



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SOLUBILITY, ORGANIC SOLVENTS: CEFIXIME is freely soluble in ethanol, glycerin, propylene glycol. SUCROSE is slightly soluble in alcohol; freely soluble in alcohol (70%); moderately soluble in glycerol, and pyridine; insoluble in chloroform and ether.

OCTANOL-WATER PARTITION COEFFICIENT (Kow): 0.024*

SOLUBILITY, AQUEOUS (WATER): CEFIXIME is very slightly soluble in water. SUCROSE is freely soluble in water.

pH: 3.2 (saturated aqueous solution 0.5 mg/ml)*

SATURATION IN AIR (BY VOLUME): Not available

EVAPORATION RATE: Not available

*Property of Cefixime USP.

## IV. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT: Not available (METHOD: Not applicable (N/A)) FLAMMABLE LIMITS: Not available LOWER: N/A UPPER: N/A

AUTOIGNITION TEMP.: Not available

HAZARDOUS COMBUSTION PRODUCTS: Not determined; combustion products will vary

with fire conditions and oxygen supply to the flame. As with other organic materials, combustion may produce carbon monoxide, carbon dioxide, nitrogen oxides, irritating aldehydes, ketones and organic acids and, possibly, hydrogen cyanide. Sulfur-containing compounds may also be generated.

EXPLOSION HAZARDS: Not available

## V. REACTIVITY DATA

STABILITY: Stable CONDITIONS TO AVOID: N/A

POLYMERIZATION: Will not occur CONDITIONS TO AVOID: N/A

INCOMPATIBLE MATERIALS: Not available

DECOMPOSITION TEMPERATURE: CEFIXIME decomposes without melting at 200° C.
SUCROSE decomposes upon melting at 160-186° C

HAZARDOUS DECOMPOSITION PRODUCTS: Not available

## VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

SIGNS AND SYMPTOMS OF OVEREXPOSURE IN THE WORKPLACE:


EYES: May cause eye irritation.

SKIN: May cause skin irritation.

INHALATION: None known or expected.

INGESTION: None known or expected.

MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE:
Clinically-observed adverse reactions caused by SUPRAX\ cefixime are mild and transient in nature. These side effects include diarrhea, loose stools, abdominal pain, dyspepsia (painful digestion), nausea, vomiting, and inflammation of the colon. Other side effects that have been reported include skin rashes, urticaria, drug fever, severe itching, liver and kidney dysfunction, headaches, and dizziness. In addition to the adverse reactions listed above, the following reactions have also been reported: hypersensitivity reactions, Stevens-Johnson syndrome (dermal eruption of dark red spots or bumps), other dermal and epidermal effects, superinfection, and effects on the blood system.

Clinical use of SUPRAX\ cefixime is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Exposure to SUCROSE may aggravate preexisting diabetes mellitus, glucose-galactose malabsorption syndrome, fructose intolerance, or sucrase-isomaltase deficiency. SUCROSE consumption increases the incidence of cavities (dental caries) and the risk of gallstones. Renal tubular damage may be caused by repeated intravenous injections of SUCROSE.

PRIMARY ROUTE(S) OF EXPOSURE/ENTRY:
Inhalation of dusts; eye or skin contact. The potential for absorption through intact or broken skin has not been evaluated. CEFIXIME is well absorbed from the gastrointestinal tract.

CANCER INFORMATION:
Neither SUPRAX\ cefixime nor SUCROSE are listed by the National Toxicology Program (NTP) as carcinogens. Neither has been evaluated for carcinogenic potential by the International Agency for Research on Cancer (IARC). Neither is regulated as carcinogens by the Occupational Safety and Health Administration (OSHA).

Lifetime studies in laboratory animals to evaluate carcinogenic potential of CEFIXIME have not been conducted.

REPORTED HUMAN EFFECTS:
Pharmacologic (drug-related) effects noted during clinical use of SUPRAX cefixime are discussed above under "MEDICAL CONDITIONS ...".

Recommended airborne limits for SUCROSE are set at levels appropriate for "nuisance dusts", indicating that it is essentially non-toxic. Exposure to excess levels of SUCROSE dusts may cause eye and skin irritation, interference with vision, and distraction from the task at hand.

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## VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

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REPORTED ANIMAL EFFECTS:
The oral LD50 of CEFIXIME in mice, rat, and rabbits were > 10 g/kg. Signs of toxicity

following oral dosing included soft to watery feces in mice and rabbits at 10 g/kg and in rats at > 3.2 g/kg; slight decreases in body weight or body-weight gain were noted in all drug-treated groups. LD50 values after intravenous (IV), intraperitoneal (IP), or subcutaneous (SC) injection were 3 to 10 g/kg, in mice and rats. Signs of toxicity following IV or IP administration included lethargy, slight body-weight decrease, clonic convulsions (5.6 or 7.5 g/kg in mice and rats, respectively), and tearing in mice (> 4.2 g/kg). A 32% solution of CEFIXIME caused a very slight irritation without corneal or iridial involvement immediately after dosing. In chronic and subchronic toxicity studies, administration of single, daily, oral doses up to 1000 mg/kg/day (rat) or 200 mg/kg/day twice a day (dog) for 1 year caused no deaths nor clinical signs of toxicity attributable to CEFIXIME. Although chronic nephropathy (spontaneously-occurring kidney toxicity) was exacerbated in the rats at these high oral doses, typical cephalosporin nephrotoxicity (characterized in animals by other, specific degenerative changes in kidney structure and function) was induced only at exaggerated IV doses of CEFIXIME.

CEFIXIME produced no adverse effects on fertility or fetal development in mice, rats and rabbits, even at oral doses of 1000 mg/kg. Similarly, CEFIXIME was not teratogenic in mice, rats, or rabbits.

The acute oral LD50 of SUCROSE is 35 g/kg in males and 27 g/kg in females (species not indicated).

OTHER:

CEFIXIME was not mutagenic in any of four different in vitro assays designed to assess mutagenicity. These tests included the Ames test, mammalian point mutation assay (with or without metabolic activation), unscheduled DNA synthesis, and in vitro cytogenetics. In addition, CEFIXIME did not exhibit clastogenic potential in vivo in the mouse micronucleus test.

## VII. EMERGENCY AND FIRST AID PROCEDURES

EYES: Immediately flush eyes with plenty of cool, low-pressure water for at least 20 minutes. Contact a physician if irritation occurs.

SKIN: Promptly wash with soap and cool running water. Remove contaminated clothing. Contaminated clothing should be washed before reuse. Destroy contaminated leather items (shoes, belts, etc.). Contact a physician if irritation occurs.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

INGESTION: Do not induce vomiting except as directed by medical personnel. Never give anything by mouth to an unconscious person. Never induce vomiting in an unconscious person. Call a physician.

## VIII. EXPOSURE CONTROL METHODS

ENGINEERING CONTROLS:



Use closed-system handling, laboratory bench hood or local exhaust ventilation to control dust or mist.

WORK PRACTICE CONTROLS:

Minimize excess handling. Keep container closed when not in use. Wash hands, face and exposed body parts at lunch and breaks, and at end of shift.

PERSONAL PROTECTION EQUIPMENT:

When engineering controls are not adequate to contain dust/mist, wear an approved air-purifying respirator with high-efficiency cartridges or a supplied-air respirator.

Rubber gloves should be worn to prevent contact with the skin. Eye protection should be worn.

## IX. SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Wearing disposable coveralls, rubber gloves and an approved full-faced air-purifying respirator with high-efficiency cartridges of a self-contained or supplied-air respirator, contain and collect spilled materials.

WASTE DISPOSAL:

Dispose of in accordance with all Federal, State, and local regulations. This is not a RCRA-regulated hazardous waste.

## X. STORAGE AND HANDLING

Maintain good housekeeping and personal hygiene procedures.

Store at controlled room temperature, 15 - 30° C (59 - 86° F).

## XI. SARA SECTION 313 INFORMATION

Not applicable.

## XII. APPENDIX

The information and statements herein are believed to be reliable but are not to be construed as a warranty or representation for which we assume legal responsibility. User should undertake sufficient verification and testing to determine the suitability for his own particular purpose of any information or products referred to herein. NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE IS MADE.