

BRISTOL-MYERS SQUIBB, PHARMACEUTICAL GROUP,
P.O. BOX 191, NEW BRUNSWICK, NJ 08903
EMERGENCY CONTACTS:
Dr. E. Hayes (Toxicology) (908) 519-2385

DATE: 11-6-92

CHEMTREC (800) 424-9300

The information below is believed to be accurate and represents the best information currently available. However, we make no warranty express or implied, with respect to such information, and we assume no liability resulting from its use.

SUBSTANCE IDENTIFICATION

SUBSTANCE: VELOSEF FOR ORAL SUSPENSION
Velosef '125' for Oral Suspension (125 mg/5 ml)
Velosef '250' for Oral Suspension (250 mg/5 ml)

CAS NUMBER: 38821-53-3* RTECS: XI0336000*

OTHER NAMES: Cephradine for Oral Suspension; 5-Thia-1-azabicyclo(4.2.0)oct-2-ene-2-carboxylic acid, 7-((amino-1,4-cyclohexadien-1-ylacetyl)amino)-3-methyl-8-oxo, (6R-(6-alpha, 7-beta(R*)))-*.

MOLECULAR FORMULA: C₁₆H₁₉N₃O₄S* MW: 349.44*

* Information pertains only to Cephradine.

COMPONENTS

SUBSTANCE	WT%	HAZARD	EXPOSURE LIMIT
Cephradine	4 - 8	sensitizer	none
Sucrose	> 1	nuisance dust	10 mg/m ³ (TLV-TWA); 15 mg/m ³ (total dust, PEL-TWA)
Flavor, Natural & Artificial Blood Orange	1	may be irritant	none

Inactive Ingredients:

Citric Acid; Colorants (FD&C Red No. 40 for '250' only; FD&C Yellow No. 6 for '125' only); Flavors; Guar Gum; Methylcellulose; Sodium Citrate.

PHYSICAL DATA

APPEARANCE: Granular Powder
MELTING POINT: Not available.
VAPOR PRESSURE: Not applicable.
SOLUBILITY IN WATER: When mixed with water, part of the formulation will dissolve and part will form a suspension.

ODOR: Fruit

BOILING POINT: Not available.

FIRE AND EXPLOSION DATA

FLASH POINT: Not available. FLAMMABILITY LIMITS: Not available.

EXTINGUISHING MEDIA: Use water.

As with most organic solids, fire may be possible at elevated temperatures or

by contact with an ignition source. Although material has not been

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FIRE AND EXPLOSION DATA (CONTINUED)

specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. As with all fires evacuate personnel to safe area. When this material is involved in a fire a self-contained breathing apparatus and full protective clothing should be worn by firefighters. Use water to keep fire-exposed containers cool. Fight fire from maximum safe distance or use an unmanned monitor. Move containers of chemicals from fire area if this can be done without risk. Divert runoff to a safe area. See Reactivity Data.

REACTIVITY DATA

STABILITY: Stable under normal conditions.

HAZARDOUS POLYMERIZATION: Will not occur.

DECOMPOSITION: Thermal decomposition or burning may produce noxious products including: CO, CO₂, NO_x, SO_x.

INCOMPATIBILITY: None known.

SPILL, LEAK & DISPOSAL PROCEDURES

SPILL: Wearing suitable protective clothing, sweep material onto paper and place into an appropriate fiber drum for disposal. Latex gloves, eye protection and a NIOSH-approved dust/mist respirator should be worn as a minimum precaution. Additional protective clothing/equipment, may be needed depending on the extent of the spill. The spill area should be ventilated and decontaminated after material has been picked up.

DISPOSAL: Dispose of in accordance with all local, state and federal regulations or with the regulations of the country in which the material is used.

HEALTH EFFECTS & FIRST AID

EXPOSURE LIMITS: See Components.

ROUTES OF ENTRY:

Oral: Approximately 100% of orally administered cephadine is absorbed from the gastrointestinal tract and its absorption is unaffected by food intake.

Dermal: No information.

Inhalation: No information.

SYMPTOMS OF EXPOSURE:

Oral Route: Velosef contains cephadine, a cephalosporin antibiotic drug intended for oral administration. Therapeutic oral doses of cephalosporins may produce nausea, vomiting, and diarrhea. There have been some reports of nervous systems reactions following oral exposure to cephalosporins, including dizziness, headache, malaise, fatigue, and vertigo. Hypersensitivity reactions have been reported in approximately 5% of patients receiving cephalosporins. These reactions include urticaria, pruritus, rash, wheezing, fever and chills, reactions resembling serum sickness, eosinophilia, joint pain, edema, erythema, and other symptoms. Anaphylaxis, which may involve

difficulty in breathing, respiratory distress, and may be fatal, has been rarely reported with oral cephalosporins. If an allergic reaction should occur, seek medical attention immediately.

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HEALTH EFFECTS & FIRST AID (CONTINUED)

Inhalation Route: Cephalosporins may also cause allergic reactions (as described above under Oral Route) in susceptible persons after inhalation. Most dusts may cause mechanical irritation (sneezing, tearing of the eyes) after high exposures. A NIOSH-approved dust/mist respirator should be worn when handling large quantities of this product.

Dermal: Possibility of allergic skin reaction if suspension contacts the skin. Use gloves and protective clothing. Additional protective clothing may be needed when handling large quantities of this product.

Eye Contact: This product contains a sensitizer and eye contact may result in tearing, redness, swelling or other allergic reactions. Most dusts may cause mechanical irritation (sneezing, tearing of the eyes) after high exposures. Goggles should be worn when handling large quantities of this product.

MEDICAL CONDITIONS AGGRAVATED: Hypersensitivity to any penicillin or cephalosporin. Therapeutic doses may aggravate gastrointestinal disease, hepatic disorders, hematologic disorders, renal disorders.

CARCINOGEN LISTS: IARC: no NTP: no OSHA: no

TOXICITY:

Cephadrine:

Acute oral LD50 (rat) > 12,000 mg/kg; Acute oral LD50 (mouse) = 3,549 mg/kg; Acute oral ip LD50 (mouse) = 597 mg/kg; Acute sc LD50 (mouse) = 2,890 mg/kg; Acute iv LD50 (mouse) = 3,539 mg/kg.

Cephadrine would be considered essentially nontoxic after acute oral administration. It was moderately toxic via the other routes tested. See RTECS for reproductive toxicity data. Additional information about therapeutic use and effects of this product may be found in the package insert supplied with this product.

TARGET ORGANS: Gastrointestinal tract.

FIRST AID FOR OVEREXPOSURE

Eye Contact: Flush with large amounts of water for 15-20 minutes.

Skin Contact: Wash with soap and water for 15-20 minutes.

Ingestion: Get medical attention immediately.

Inhalation: Remove to fresh air; if difficulty in breathing administer oxygen. If a person is not breathing artificial respiration can be attempted. Get medical attention immediately.

SPECIAL PROTECTION INFORMATION

If material has spilled, workers should avoid skin or eye contact with, and inhalation of the powder. Chemical safety goggles and latex gloves should be worn when handling this formulation. Spilled powder may be wetted to minimize dust generation. In the event of a large spill, a NIOSH-approved dust/mist

respirator should be used.

Workers should wash their hands and face after handling this compound.

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SPECIAL PROTECTION INFORMATION (CONTINUED)

Promptly remove contaminated clothing should contact occur. Wash contaminated clothing before reuse.

Personnel who handle this material in a manufacturing facility should wear protective clothing, including latex gloves, eye protection, a gown, hair and shoe covers and a NIOSH-approved dust/mist respirator. Personnel who handle this formulation in a non-manufacturing setting (e.g. at a clinical facility) should use latex gloves and eye protection if there is potential for the material to contact the skin or eyes.

SPECIAL PRECAUTIONS & COMMENTS

Velosef for Oral Suspension should be stored at 15-30 degrees C.

Persons who are allergic to this substance or any penicillin or cephalosporin should avoid contact with this substance.

Therapeutic agents are intended for use under direction of a physician and/or under the conditions of use described on the label. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities. It does not address the therapeutic use of this material. Information concerning the therapeutic use of this drug substance should be obtained from formulated product package inserts and other appropriate references.

DOT Shipping Classification: None.
