

The logo for Elanco, featuring the word "ELANCO" in white, bold, uppercase letters on a blue rectangular background that is tilted slightly to the right.

MATERIAL SAFETY DATA SHEET
KEFVET 500 mg and 1000 mg TABLETS FOR DOGS AND CATS
AH0377, AH0378

Revision 3.3, 31 May 2007

STATEMENT OF HAZARDOUS NATURE:

Kefvet tablets are not considered hazardous under normal handling procedures.

The following Statement of Hazardous Nature refers to the active ingredient (cephalexin monohydrate) in the tablets:

"Hazardous according to criteria of Worksafe Australia"

Harmful; R42/43 May cause sensitisation by inhalation and skin contact.

Company Name and Address:

Elanco Animal Health
A Division of Eli Lilly Australia Pty Ltd
A.B.N. 39 000 233 992
112 Wharf Road, West Ryde, N.S.W. 2114, Australia

Contact Numbers:

Tel: (02) 9878 7777

Fax: (02) 9878 7720

Emergency Telephone Numbers:

Elanco Animal Health:
1800 226 324 (Toll free)

OR

Poisons Information Centre:
131126 (Australia-wide)

24 hour emergency contact number, CHEMWATCH **1800 039 008** (spills and accidents)

Section 1 - Identification

Product Names:

Elanco Animal HealthAH0377 Kefvet 500 mg Tablets for Dogs and Cats

Elanco Animal HealthAH0378 Kefvet 1000 mg Tablets for Dogs and Cats

Other Names: Cephalexin as the monohydrate

Manufacturer's Product Codes: AH0377 (Kefvet 500 mg)

AH0378 (Kefvet 1000 mg)

UN Number: None allocated

Dangerous Goods Class/Subsidiary Risk: None allocated

Hazchem Code: None allocated

Poisons Schedule Number: S4

Pack Size and Container Type: Kefvet 500 mg: Pack of 12 tablets, 100 tablets
Kefvet 1000 mg: Pack of 8 tablets, 100 tablets

Use:

Major Recommended Uses: For the treatment of susceptible infections of the respiratory tract, urogenital tract, the skin, localised infections in soft tissues, and treatment and prophylaxis of osteomyelitis in dogs and cats, and for the treatment of susceptible infections of the gastrointestinal tract in dogs.

Major Recommended Method(s) of Application: Oral

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Cephalexin monohydrate	23325-78-2	91-92
Excipients	NA	8-9

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines: Cephalexin monohydrate - LEG <100 micrograms/m³ TWA for 12 hours.

Section 3 - Hazards Identification

Appearance: Peach coloured capsule-shaped tablets

Physical State: Solid

Odor: Odorless

Emergency Overview

Primary Physical and Health Hazards: Not hazardous if intact. Severe Allergen.

Caution Statement: Intact Kefvet Tablets are not considered to be a health hazard. Kefvet Tablets contain cephalexin which causes severe allergic reactions.

Routes of Entry: Inhalation and skin contact.

Potential Signs and Symptoms of Occupational Exposure: Tablets are intended for animal consumption under guidance of a veterinarian. Tablets are not considered hazardous under normal handling procedures. Allergic reactions to cephalexin monohydrate have been reported. Allergic reactions to the powder used to make the tablets may include rash, nasal congestion, cough, dry throat, and eye irritation.

Medical Conditions Aggravated by Exposure: Penicillin or cephalosporin hypersensitivity.

Carcinogenicity: Cephalexin monohydrate - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or Poisons Information Centre. Phone 13 1126 (Australia-wide). If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: Not applicable.

UEL: No applicable information found.

LEL: No applicable information found.

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Contain dry material by lightly misting with water, followed by sweeping up or vacuuming. Vacuuming may disperse dust if appropriate dust collection filter is not part of the vacuum. Be aware of potential for dust explosion when using electrical equipment. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage: Store below 30°C (Room Temperature).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to contents may occur:

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Other Handling Precautions: In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

CAUTION! - ANIMAL

This product is contraindicated in animals that are hypersensitive to cephalosporins and penicillins.

Some dogs may exhibit nausea and vomiting. As with other antibiotics which are excreted by the kidneys, accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced.

Section 9 - Physical and Chemical Properties

Boiling Point: Not applicable.

Melting Point: No applicable information found.

Specific Gravity: No applicable information found.

pH: No applicable information found.

Evaporation Rate: No applicable information found.

Water Solubility: Slightly soluble.

Vapor Density: No applicable information found.

Vapor Pressure: No applicable information found.

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Animal Toxicity Data Single Exposure

No data are available for Kefvet Tablets. Toxicity data for cephalexin monohydrate and cephalexin hydrochloride are presented.

Oral: Cephalexin monohydrate - Rat, 5000 mg/kg, no deaths, increased urine output, weight loss.

Monkey, 1000 mg/kg, no deaths, diarrhea.

Skin: Cephalexin monohydrate - Rabbit, 153 mg/kg, no deaths or toxicity.

Inhalation: Cephalexin hydrochloride - Rat, 1990 mg/m³ for 4 hours, no deaths.

Intravenous: Cephalexin monohydrate - Rat, 700 mg/kg, no deaths or toxicity.

Dog, 100 mg/kg, no deaths, vomiting, tarry stools.

Skin Contact: Cephalexin monohydrate - Rabbit, nonirritant.

Eye Contact: Cephalexin monohydrate - Rabbit, slight irritant.

Animal Toxicity Data Repeat Exposure

No data are available for Kefvet Tablets. Toxicity data for cephalexin monohydrate are presented.

Target Organ Effects: Cephalexin monohydrate - No effects identified in animal studies.

Other Effects: Cephalexin monohydrate - Salivation and vomiting.

Reproduction: Cephalexin monohydrate - No effects identified in animal studies.

Sensitization: Cephalexin monohydrate - No applicable information found.

Mutagenicity: Cephalexin monohydrate - Not mutagenic in bacterial cells.

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Disposal: Dispose of empty container by wrapping with paper and putting in garbage.

Section 14 - Transport Information

No special transport requirements necessary.

Section 15 - Other Information

Sections revised: Removed automatic print date from header.

Section 15: Added Chemwatch details to Contacts

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

GLOSSARY

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline

STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)