

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

GHS Product identifier: Pharmachem Kefvet 500 mg Tablets for Dogs and Cats
Pharmachem Kefvet 1000 mg Tablets for Dogs and Cats

Other means of identification: Not applicable

Recommended use of the product and restrictions on use: 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.

Supplier's Details: Pharmachem
Unit 6, 70 Fison Ave West
Eagle Farm QLD 4009
Telephone: (07) 3868 0333
Facsimile: (07) 3868 0344

Contact Person: Mr Gray Boston
Emergency Telephone: (07) 3630 1654

SECTION 2 HAZARDS IDENTIFICATION

Classification of Product:
These products are classified as health hazards in accordance with the following classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition.

Health hazards: Respiratory sensitizer, skin sensitizer

Respiratory sensitizer: Category 1

GHS label elements, including precautionary statements:

Pictogram:



Signal word: Danger

Hazard statement: May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statement: Prevention: Avoid breathing vapour
Response: If inhaled call a doctor or Poisons Information Centre

Skin sensitizer: Category 1

GHS label elements, including precautionary statements:

Pictogram:



Signal word: Warning

Hazard statement: May cause an allergic skin reaction

Precautionary statements:

Prevention: Wear protective gloves and clothing.
Response: If on skin wash with plenty of soap and water.
If skin irritation or rash occurs get medical advice.
Wash contaminated clothing before re-use.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

| Ingredients | Cas No. | Proportion (%) |
|---------------------------------------|----------------|----------------|
| Cephalexin monohydrate | 23325-78-2 | 91-92 |
| Non-hazardous, proprietary excipients | Not applicable | 8-9 |

SECTION 4 FIRST AID MEASURES

The following First Aid directions have been set for these products by the Australian Pesticides and Veterinary Medicines Authority (APVMA) as part of the registration process:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

However, the following information is provided for further assistance while implementing the approved First Aid directions.

Eyes: Flush eyes with plenty of water.
Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water.
Inhalation: Move individual to fresh air. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.
Ingestion: Do not induce vomiting. 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.
Advice to doctor: Treat symptomatically

SECTION 5 FIRE FIGHTING MEASURES

Suitable extinguishing media: Water, carbon dioxide, dry chemical or foam
Hazards from combustion products: May emit toxic fumes when exposed to heat or fire.
Special protective precautions and equipment for fire fighters: Firefighters should wear full protective clothing including self-contained breathing apparatus.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Emergency procedures: Sweep or vacuum up spilled tablets. Take care to avoid generation of dust by breaking tablets when cleaning up spillages. Vacuuming may disperse dust if appropriate dust collection filter is not part of the vacuum. Wear protective equipment, including eye protection, to avoid exposure to dust.
Methods and materials for containment and clean up: Collect contained material in drums or other receptacles for transport to an approved local authority disposal facility.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling: Avoid tablet damage and generation of dust or tablet particles. Clean up any spillages immediately
Conditions for safe storage, including any incompatibilities: Store below 30°C (Room Temperature).

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards: No value assigned for cephalexin monohydrate by NOHSC
Engineering Controls: Use with adequate ventilation
Personal Protective Equipment: Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required.

However, the following equipment and/or procedures are recommended for manufacturing or other situations where exposure to contents or dust 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.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Peach coloured capsule-shaped tablets
Physical State: Solid
Odor: Odorless
Water Solubility: Slightly soluble.

SECTION 10 STABILITY AND REACTIVITY

Chemical stability: Stable
Conditions to avoid: None known
Incompatible materials: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).
Hazardous decomposition products: May emit toxic fumes when heated to decomposition.
Hazardous reactions: Hazardous polymerization will not occur.

SECTION 11 TOXICOLOGICAL INFORMATION

Routes of Exposure:

These products are in tablet form and are for veterinary use, so exposure is possible by accidental ingestion or skin contact. It is also possible that dust from tablets may be inhaled where tablet damage has occurred.

Signs and symptoms of exposure

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.

Summary of Toxicology

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: Non-irritant.
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: No effects identified in animal studies.
Other Effects: Salivation and vomiting.
Reproduction: No effects identified in animal studies.
Sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction
Mutagenicity: Not mutagenic in bacterial cells.

Medical Conditions Aggravated by Exposure:

Penicillin or cephalosporin hypersensitivity.

SECTION 12 ECOLOGICAL INFORMATION

No applicable ecological information available.

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods:

The APVMA has approved the following container disposal directions for Kefvet 500 / 1000 as part of the registration process:

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

Unused product or product which has been contained and retrieved from spillages should be disposed of in an approved local authority landfill or as indicated above if no approved local authority landfill is available.

SECTION 14 TRANSPORT INFORMATION

Kefvet products are not defined as dangerous goods by the Australian Code for the Transport of Dangerous Goods by Road and Rail. No special transport arrangements or provisions are required for this material.

SECTION 15 REGULATORY INFORMATION

These product have been registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). In granting registration to any product, the APVMA has exercised its legislative responsibility to ensure that the product is suitably formulated and properly labelled and, when used according to instructions is:

- safe to the host, the user, consumers and the environment;
- efficacious (that is, the product does the job it claims it shall do); and
- not unduly prejudicial to trade.

The APVMA uses the services of a number of Australian and State government agencies as advisers to help with some of these evaluations of applications for registration of agricultural and veterinary chemical products. These include:

- the Office of Chemical Safety (OCS) of the Commonwealth Department of Health and Ageing which:
 - evaluates and reports on toxicology and metabolism studies; proposes first aid and safety directions; determines poison schedule classifications; and establishes acceptable daily intakes (ADIs) and acute reference doses (ARfD); and
 - evaluates the occupational health and safety aspects of an application and recommends safety directions and occupational controls on use and advises on a Material Safety Data Sheet (MSDS);

- the Commonwealth Department of the Environment and Heritage (DEH) which evaluates environmental data and recommends appropriate use controls and instructions for the product that will protect the environment; and
- State and Territory departments responsible for agricultural and primary industries which evaluate and reports on efficacy and target crop or animal safety data for new agricultural chemicals and new uses of registered products. In some cases the APVMA contracts this work out to other agencies such as universities, the CSIRO or to other experts.

Although all ingredients appear in the Australian Inventory of Chemical Substances (AICS), they have not been assessed by NICNAS (National Industrial Chemicals Notification and Assessment Scheme).

These products are categorised as Schedule 4 poisons under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) by virtue of the presence of cephalexin monohydrate.

SECTION 16 OTHER INFORMATION

| | |
|---------------------|--------------|
| MSDS version: | 3 |
| Date of Revision: | May 2019 |
| Update of sections: | All sections |

CONTACT POINT

Mr Gray Boston, General Manager
B/Hrs Phone (07) 3868 0333 A/Hrs (07) 3630 1654

References:

References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, <https://apvma.gov.au/node/26586>, (as updated)
2. Code of Practice – Preparation of safety data sheets for hazardous chemicals, Safe Work Australia, May 2018
3. AICS (Australian Inventory of Chemical Substances), NICNAS (National Industrial Chemicals Notification and Assessment Scheme), Commonwealth Department of Health
4. Australian Pesticides and Veterinary Medicines Authority (APVMA) Guidelines, <https://apvma.gov.au/node/1060>, (as updated)
5. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health, TGA, (as updated)
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 7th Edition
7. The Poisons Standard (as updated), Therapeutic Goods Administration (TGA), Commonwealth Department of Health
8. Hazardous Chemical Information System (HCIS), Safe Work Australia (as updated)
9. Chemical Classification and Information Database (CCID), Environmental Protection Authority, New Zealand (as updated)
10. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition, United Nations, New York and Geneva, 2017

All information contained in this Safety Data Sheet is as accurate and up to date as possible. Since Pharmachem cannot anticipate or control the conditions under which this information may be used, each user should review the information in the specific context of the intended application. Pharmachem will not be responsible for damages of any nature resulting from use of or reliance upon the information. No expressed or implied warranties are given other than those implied as mandatory by Commonwealth State or Territory legislation.