Safety Data Sheet

Product Name: Furosemide Tablets
Strength : 12.5 and 50 mg **Revision No.: 00**

Emergency Overview

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

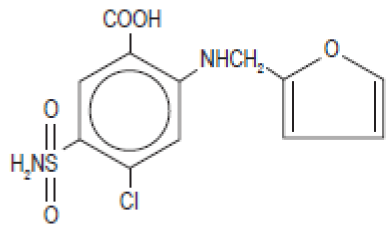
SECTION 1: IDENTIFICATION

Product Name: **Furosemide Tablets**

Formula: $C_{12}H_{11}ClN_2O_5S$

Generic Name: Furosemide (except in United Kingdom-furosemide).

Chemical Name: 4-chloro-N-furfuryl-5-sulfamoylanthranilic acid.



Molecular Weight: 330.74 g/mol

Description: Furosemide Tablets are a chemically distinct diuretic and saluretic pharmacodynamically characterized by the following:
1) A high degree of efficacy, low-inherent toxicity and a high therapeutic index.
2) A rapid onset of action and of comparatively short duration.
3) A pharmacological action in the functional area of the nephron, i.e., proximal and distal tubules and the ascending limb of the loop of Henle.
4) A dose-response relationship and a ratio of minimum to maximum effective dose range greater than tenfold.
5) It may be administered orally or parenterally.

It is readily absorbed from the intestinal tract and well tolerated.
The intravenous route produces the most rapid diuretic response.
The CAS Registry Number is 54-31-9.
Furosemide Tablets, a diuretic, is an anthranilic acid derivative with the above structural formula.

Dosage and Administration:

The usual dosage of furosemide is 1 to 2 mg/lb. body weight (approximately 2.5 to 5 mg/kg). The lower dosage is suggested for cats. Administer once or twice daily at 6 to 8 hour intervals either orally, intravenously, or intramuscularly. A prompt diuresis usually ensues from the initial treatment. Diuresis may be initiated by the parenteral administration of furosemide injection and then maintained by oral administration.
The dosage should be adjusted to the individual's response. In severe edematous or refractory cases, the dose may be doubled or increased by increments of 1 mg per pound body weight. The established effective dose should be administered once or twice daily. The daily schedule of administration can be timed to control the period of micturition for the convenience of the client or veterinarian.

Product name	Strength	Pack count	NDC Number
Furosemide Tablets	12.5 mg	HDPE bottle of 500 tablets	8611701612
	50 mg	HDPE bottle of 500 tablets	8611701712

Safety Data Sheet

Product Name: Furosemide Tablets
Strength : 12.5 and 50 mg **Revision No.: 00**

Manufacturer/supplier identification

Company	Zydus Animal Health and Investments Limited, Ahmedabad, India
Contact for information	Tel.: +91 2717-683954
Emergency Telephone No	Tel.: +91 2717-683961
Distributed by:	ZyVet Animal Health Inc. Pennington, NJ 08534

SECTION 2: HAZARD (S) IDENTIFICATION

POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s).

This product contains furosemide, a diuretic. In animals, signs of acute toxicity inhclude lethargy, prostration, diuresis, and weight loss. In humans, diuresis should be the first sign of exposure. Excessive diuresis may result in dehydration, hypokalemia, hypocalcemia, and orthostatic hypotension. Other symptoms include weakness, fatigue, and malaise. Furosemide may cause effects to the kidneys, and inhibits the absorption of sodium and chlorine in the proximal and distal tubules and in the loop of Henle.

Corn starch is a mild skin irritant and may cause dermatitis with chronic skin exposure. Inhalation of corn starch may aggravate pre-existing lung conditions. Corn starch may cause mechanical irritation to the eye and respiratory tract.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

Emergency Overview

Tablets Yellow
Odor unknown
May be irritating to eyes, skin or respiratory tract.
May cause effects to: kidney
blood electrolytes cardiovascular system

SECTION 3: INFORMATION ON THE INGREDIENTS

PRODUCT USE: Veterinary product
CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

Ingredient	**CAS Number**	**Percent**
Furosemide	54-31-9	17.9
Starch	9005-25-8	50-60
Microcrystalline cellulose	9004-34-6	<10

ADDITIONAL INFORMATION:

This MSDS is written to provide health and safety information for individuals who will be handling the final
product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4: FIRST AID MEASURES

First aid measures

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin Contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Inhalation Wash skin with soap and water. Remove to fresh air.

Ingestion Product is intended for consumption. Please see the product label for instructions for use and precautions.

Most important symptoms and effects, both acute and delayed **Symptoms**

No information available

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

FLAMMABILITY DATA:
Flash Point: Not determined (liquids) or not applicable (solids).

EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO_2), extinguishing powder or water spray.
See Section 9 for Physical and Chemical Properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7: HANDLING AND STORAGE

HANDLING:

Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:

Store at controlled room temperature, 20° to 25°C (68° to 77°F). Store in adequately sealed container. See Section 8 for exposure controls and additional safe handling information.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection: Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

Skin Protection: Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Eye Protection: Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Starch	9005-25-8	10 mg/m^3	15 mg/m^3
Microcrystalline cellulose	9004-34-6	10 mg/m^3	15 mg/m^3

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

FORM: Tablets
COLOR: Yellow
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10: STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11: TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

INHALATION:
Microcrystalline cellulose: Inhalation LC50 (4hr): >5.05 mg/L (rat)

SKIN:
Corn starch was practically not irritating to rabbits and rats.
Microcrystalline cellulose: Dermal LD50: >2000 mg/kg (rabbit) Microcrystalline cellulose was not irritating to the skin of rabbits.

EYE:
Microcrystalline cellulose: Not irritating to the eyes

ORAL:
Furosemide: Oral LD50: 2600 mg/kg (rat)
Microcrystalline cellulose: Oral LD50: >5000 mg/kg (rat)

DERMAL AND RESPIRATORY SENSITIZATION:
Microcrystalline cellulose was not a skin sensitizer in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
No data available.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Corn starch had no effect on reproduction in rats given 10% to 62% in the diet.

MUTAGENICITY / GENOTOXICITY:
No data available.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

SECTION 12: ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Microcrystalline cellulose: 96-hr LC50 (trout): >100% saturate solution
Microcrystalline cellulose: 48-hr LC50 (daphnid): >100% saturate solution
Microcrystalline cellulose: 96-hr EC50 (algae): >100% saturate solution

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

SECTION 13: DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14: TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15: REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Starch	X
Microcrystalline cellulose	X

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Starch					X
Microcrystalline cellulose			3227		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Starch	X	X		X
Microcrystalline cellulose	X	X		X

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations. X: Listed on applicable state hazardous substance or right-to-know lists.

SECTION 16: OTHER INFORMATION

References: Nil.

Issue date: 29-04-2025

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product