

SECTION 1: IDENTIFICATION

1.1 Product identifier

Product name:	Flusapex Tablets Diuretic
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None

1.2 Relevant identified uses of the substances or mixture and uses advised against

Recommended uses:	As an aid in the treatment of oedema in cats, dogs and horses.
Uses advised against:	Not for human use.

1.3 Details of the supplier of the substance or mixture

Registered company name:	Apex Laboratories Pty Ltd
Address:	Apex Laboratories Pty Ltd ACN 614 716 700 2 Cal Close Somersby NSW 2250
Telephone:	+61 2 4372 1661 (Business hours: 08:30 – 17:30)
Fax:	+61 2 4372 1668
Email:	thetvet@apexlabs.com.au
Website:	www.apexlabs.com.au

1.4 Emergency Telephone Numbers

	13 11 26 (Poisons Information Centre)
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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS classification(s):	Reproductive Toxicity – Category 1B
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2.2 Label Elements

Signal Word:	DANGER
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Hazard Statement(s)

H360	May damage fertility or the unborn child
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Additional Statement(s)

None	
Precautionary Statement(s) Prevention:	
P201	Obtain special instructions before use
P202	Do not handle until all safety precautions have been read and understood
P281	Use personal protective equipment as required
Precautionary Statement(s) Response:	
P308 + P313	If exposed or concerned: get medical advice/attention.
Precautionary Statement(s) Storage:	
P405	Store locked up
Precautionary Statement(s) Disposal:	
P501	Dispose of contents / packaging according to local regulations
2.3 Other Hazard Information	
N/a	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

Ingredient	CAS No	EC Number	Content
Frusemide	54-31-9	Not Available	25%
Other non-hazardous ingredients	N/a	N/a	To 100%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	In case of accidental contact of the product with the eyes rinse abundantly with fresh water, removing any contact lenses. Seek medical attention if irritation occurs, showing the package leaflet or the label to the medical practitioner.
Skin contact:	In case of accidental contact of the product with the skin rinse abundantly with fresh water and non-abrasive soap. Seek medical

	attention if irritation occurs, showing the package leaflet or the label to the medical practitioner.
Inhalation:	Generally not required due to the nature of the product. If concerned, remove to fresh air and seek medical advice if concerned.
Ingestion:	If swallowed do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed	
Not Available	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Dry agent, water fog, mist or spray, carbon dioxide. As appropriate for surrounding area.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Cool containers with water spray. Wear full breathing apparatus and self-contained breathing apparatus.
Fire / explosion hazard:	No known toxic hazards.
Hazchem code:	None allocated.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8.	
6.2 Environmental Precautions	
Do not allow product to reach sewage system or any water course.	

Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/surface or ground water.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	Spillage of the product is unlikely to be serious. However, avoid contact with skin and eyes.
Major Spills:	In the event of a major spill, protect drains and water courses from contamination. Wear protective clothing (overalls, gloves, goggles and boots). Shovel spillage into clean, dry, labelled containers and dispose after consulting appropriate authorities. Avoid contact with skin and eyes.

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Wear suitable protection gloves and clothing when handling the product, keeping exposure to the product to a minimum. Wash hands after handling and remove contaminated clothing and any protective equipment before entering eating areas. Prohibit eating, drinking and smoking in storage and handling areas. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Store below 25 °C (air conditioning). Storage areas and containers should be clearly marked for drug holding, protected from light, freezing or physical damage and tightly sealed when not in use.
Storage incompatibility:	Not available.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 Control parameters	
OCCUPATIONAL EXPOSURE LIMITS (OEL)	
INGREDIENT DATA:	
Not Available	
EMERGENCY LIMITS:	
Not Available	
8.2 Exposure controls	
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
Personal protection:	Not required when product used as directed.
Eye and face protection:	No special equipment needed when handling small quantities. OTHERWISE: Safety glasses with side shields / chemical goggles
Skin protection:	Skin protection is not normally necessary, however it is good practice to avoid contact with chemicals by wearing suitable gloves when handling bulk quantities.
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	Not required under normal conditions of use.
8.3 Environmental exposure controls	
See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White round tablets
Physical state: Tablet
Odour: None
Odour Threshold: Not available
pH (as supplied): Not applicable
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not application
Specific gravity/density: Not available
Solubility in water and solvents (mg/l): Disintegrates
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not applicable
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Not available
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information
 Not Available

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Mixture is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions.
10.4 Conditions to avoid:	No conditions to avoid other than extreme heat.
10.5 Incompatible materials:	No data available.

10.6 Hazardous decomposition:	No known decomposition products.
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SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Inhalation is not a great risk as this product is a tablet. The data available suggests that inhalation may cause mild irritation to the respiratory tract, especially in patients with pre-existing pulmonary disease.
Ingestion:	The data available suggests that ingestion of large quantities may result in moderate irritation of the gastrointestinal tract. Frusemide is a diuretic and so large doses may lead to fluid and electrolyte imbalance. Infrequent side effects of frusemide therapy include allergy nausea, diarrhoea, blurred vision, dizziness, headache, pancreatitis, photosensitivity, skin rashes, muscle spasm, hypotension, agranulocytosis, aplastic anaemia, thrombocytopaenia and leucopaenia, liver damage, paraesthesia, tinnitus and transient deafness.
Skin contact:	Skin contact is not a great risk as this product is a tablet. The data available suggests that skin contact may result in mild discomfort, especially to open wounds or abrasions.
Eye contact:	Eye contact is not a great risk as this product is a tablet. The data available suggests that eye contact may result in a transient irritation and associated redness and temporary vision impairment or eye damage/ulceration.
Acute toxicity:	
Frusemide	Oral (rabbit) LD ₅₀ : 800 mg/kg
Irritation	
Not expected to cause irritation.	
Respiratory or skin sensitization:	
Not expected to be a skin or respiratory sensitizer.	
Chronic toxicity	
No data available.	
Mutagenicity:	
Not expected to be mutagenic.	
Carcinogenicity:	
No ingredient in this formulation is known to be carcinogenic.	
Reproductive toxicity:	
Frusemide crosses the placenta and is found in human milk. In humans, exposure to frusemide during pregnancy has been found to be significantly associated with deafness in the neonate.	

SECTION 11: TOXICOLOGICAL INFORMATION

STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	
Frusemide:	Fish LC ₅₀ (96h): 328 mg/L Crustacea LC ₅₀ (384h): 79.3 mg/L Algae EC ₅₀ (96h): 856 mg/L
12.2 Persistence and degradability	
Frusemide:	Highly persistent in air, water and soil
12.3 Bioaccumulative potential	
Frusemide:	Low potential for bioaccumulation (LogK _{ow} = 2.03)
12.4 Mobility in Soil	
Frusemide:	Low mobility (K _{oc} = 188.3)
12.5 Other adverse effects	
Not Available	

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product / packaging disposal:	<p>Empty containers may be recycled or sent to a commercial waste disposal site. Unused product should be suitable for landfill; however, contact the relevant local Waste Disposal Authority.</p> <p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p>

Waste Treatment Options:	Do not dispose into sewers or waterways
Sewage Disposal Options:	Do not dispose into sewers or waterways

SECTION 14: TRANSPORT INFORMATION

Labels required:	None	
Marine pollutant:	NO	
Hazchem:	N/a	
Land transport (ADG):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a

Air transport (IATA / ICAO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
Sea transport (IMDG / IMO):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture	
Australian Pesticides & Veterinary Medicines Authority (APVMA) Approval No.: 35638	
Poison Schedule	Classified as a Schedule 4 (S4) Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
Classifications	Safework Australia criteria is based on the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals. The classifications and phrases listed below are based on the Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(2004)].
Hazard codes	H360: May damage fertility or the unborn child
Risk phrases	R60/61: May damage fertility or cause harm to the unborn child.
Safety phrases	Not available.
Inventory listing(s)	AUSTRALIA: AICS (Australian Inventory of Chemical Substances) All components are listed on AICS, or are exempt.

SECTION 16: OTHER INFORMATION

WORKPLACE CONTROLS AND PRACTICES:
 Unless a less toxic chemical can be substituted for a hazardous substance, ENGINEERING CONTROLS are the most effective way of reducing exposure. The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:
 The recommendation for protective equipment contained within this report is provided as a guide only. Factors such as form of product, method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

HEALTH EFFECTS FROM EXPOSURE:
 It should be noted that the effects from exposure to this product will depend on several factors including: form of product; frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

ABBREVIATIONS:
ACGIH: American Conference of Governmental Industrial Hygienists
CAS #: Chemical Abstract Service number - used to uniquely identify chemical compounds

CNS: Central Nervous System
EC No.: EC No - European Community Number **EMS:** Emergency Schedules (Emergency Procedures for Ships Carrying Dangerous Goods)
GHS: Globally Harmonized System
GTEPG: Group Text Emergency Procedure Guide
IARC: International Agency for Research on Cancer
LC50: Lethal Concentration, 50% / Median Lethal Concentration
LD50: Lethal Dose, 50% / Median Lethal Dose
mg/m³: Milligrams per Cubic Metre
OEL: Occupational Exposure Limit
pH: relates to hydrogen ion concentration using a scale of 0 (high acidic) to 14 (highly alkaline).
ppm: Parts Per Million
STEL: Short-Term Exposure Limit
STOT-RE: Specific target organ toxicity (repeated exposure)
STOT-SE: Specific target organ toxicity (single exposure)
SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons
SWA: Safe Work Australia
TLV: Threshold Limit Value
TWA: Time Weighted Average

This SDS summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user must review this SDS in the context of how the product will be handled and used in the workplace. Apex Laboratories Pty Ltd make no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers ("the product").

The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability prior to use of the product. The physical data shown herein are typical values based on material tested. These values should not be construed as guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots hereof.