SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Frusedale® (40mg oral tablets)
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:	For the treatment of oedema associated with cardiac insufficiency, renal dysfunction and trauma in cats and dogs. In animals with pulmonary oedema of cardiac origin, combined therapy with other medicinal products may be indicated.
Uses advised against:	Not for human use. Do not use in animals with acute glomerular nephritis, renal failure with anuria, electrolyte deficiency disease or in animals that have received an overdosage of digitalis. Do not use concurrently with aminoglycoside antibiotics. Do not use in animals weighing less than 4 kg.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
Telephone:	+44 (0) 1756 791311
Fax:	+44 (0) 1756 798604
Email:	Not available
1.4 Emergency Telephone Numbers	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
DSD Classification (EU):	Not Available

DPD Classification (EU)[1]:	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)[1]:	Not Available
2.2 Label Elements	
Signal Word:	Not Available
Hazard Statement(s)	
Not Available	
Additional Statement(s)	
Not Available	
Precautionary Statement(s) Prevention:	
Not Available	
Precautionary Statement(s) Response:	
Not Available	
Precautionary Statement(s) Storage:	
Not Available	
Precautionary Statement(s) Disposal:	
Not Available	
2.3 Other Hazard Information Not Available	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% w/w	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 54-31-9 2. 200-203-6 3. Not Available 4. Not Available	40	Furosemide (Frusemide)	Reproductive Toxicity Category 1B; H360[1]
Legend:	*1. Classified by Chemwatch*		

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 copious amounts of fresh water. Seek medical attention, 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. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner. Gloves should be worn when handling the tablets.
Inhalation:	Remove to fresh air and seek medical attention.
Ingestion:	Following accidental ingestion, seek medical advice, showing the package leaflet to the medical practitioner. Treatment is symptomatic and includes replacement of fluid and electrolytes.
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 N/a	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	All systems may be used.
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. Wear full breathing apparatus and self-contained breathing apparatus.

Fire / explosion hazard:	Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard. • Combustion products include: • carbon monoxide (CO) • carbon dioxide (CO2) • hydrogen chloride • phosgene • nitrogen oxides (NOx) • sulfur oxides (SOx) • other pyrolysis products typical of burning organic material. Emits toxic fumes.

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:	Flush residues and small spillages to waste with copious quantities of water.
Major Spills:	Clean up all spills immediately. Large spills should be collected into an appropriate container for waste disposal. Control personal contact with the substance, by using protective equipment. 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. Wash hands after use. Avoid contact and inhalation of dust/fumes associated with the product. When handling, **DO NOT** eat, drink or smoke. 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:	Do not store above 25°C. Protect from light. Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Storage incompatibility:	No major incompatibilities known.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION
8.1 Control parameters
DERIVED NO EFFECT LEVEL - DNEL
Not Available
PREDICTED NO EFFECT LEVEL - PNEC
Not Available
OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:
Not Available

EMERGENCY LIMITS:				
Ingredient	**Material Name**	**TEEL-1**	**TEEL-2**	**TEEL-3**
Not Available				

Ingredient	Original IDLH	Revised IDLH
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:		
Eye and face protection:	Safety glasses with side shields / chemical goggles	
Skin protection:	See hand protection below	
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 applicable	
8.3 Environmental exposure controls See Section 12		

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Frusedale®: White, circular, biconvex, flat-faced tablets with bevelled edges and a breakline.
Furosemide: A white or almost white, crystalline powder
Container: Polypropylene containers containing 1000 white, circular, biconvex, flat-faced tablets with bevelled edges, a breakline and which are embossed F40 on one face, CP or DP on the reverse.
Physical state: Solid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Furosemide 210°C with decomposition
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 available
Solubility in water and solvents (mg/l): Furosemide practically insoluble
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Furosemide 330.7
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:	Product is considered stable.
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions.
10.4 Conditions to avoid:	Avoid excessive heat.

	Exposure to light may cause discolouration.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	Can be irritating to the respiratory tract.	
Ingestion:	Diuretic. Diuresis may result in dehydration, hypokalemia, hypocalcemia and orthostatic hypotension. Other symptoms include weakness, fatigue, nausea, vomiting, dryness of mouth, increased thirst, weak pulse, muscle cramp, pain, irregular heartbeat and mood/mental changes. Possible hypersensitisation.	
Skin contact:	Irritating to skin. Possible hypersensitisation.	
Eye contact:	Possible allergic reaction.	
Chronic:	Most adverse effects of furosemide occur with high doses, and serious effects are uncommon. Administration at the recommended dosage level is not normally associated with undesirable effects.	
Frusedale®:	**Acute toxicity**	**Irritation**
	Not Available	Not Available
Furosemide:	**Acute toxicity**	**Irritation**
	Oral (rat) LD50: 2600 mg/kg[1] Mouse – 1050 mg/kg^{-1} Rabbit – 720 mg/kg^{-1} Dog – 1000 mg/kg^{-1}	Not Available
1. Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances*		
Skin corrosion/irritation:		
Can be irritating to the skin; there is a possibility for hypersensitisation.		
Serious eye damage/irritation:		
There is a risk of allergic reaction.		
Respiratory or skin sensitization:		
Not available		
Germ cell mutagenicity:		

SECTION 11: TOXICOLOGICAL INFORMATION
Not available
Carcinogenicity:
There has been some concern that Furosemide can cause cancer or mutations but there is not enough data to make an assessment.
Reproductive toxicity:
Not contraindicated in pregnant or lactating animals.
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION		
Not expected to be an environmental hazard.		
12.1 Toxicity		
Not Available		
12.2 Persistence and degradability		
Ingredient	**Persistence: water/soil**	**Persistence: air**
Furosemide	HIGH	HIGH
12.3 Bioaccumulative potential		
Ingredient	**Bioaccumulation**	
Furosemide	LOW (LogKOW = 2.03)	
12.4 Mobility in Soil		
Ingredient	**Mobility**	
Furosemide	LOW (KOC = 188.3)	

12.5 Results of PBT and vPvB assessment
Not Available
12.6 Other adverse effects
Not Available

SECTION 13: DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
Product / packaging disposal:	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION	
Labels required:	None
Marine pollutant:	NO
Hazchem:	Not Applicable

Land transport (ADR):		
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
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA / DGR):		
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

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee):		
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
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Inland waterways transport (ADN):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
14.6 Special precautions for user	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in	N/a	

bulk according to Annex II of MARPOL73/78 and the IBC Code	

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

FUROSEMIDE (54-31-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
- International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Furosemide	54-31-9	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Repr. 1B	GHS08, Dgr,	H360
2	Repr. 1B, Repr. 1A, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Carc. 2, Repr. 2, Acute Tox. 3, Acute Tox. 4, Carc. 1B, Muta. 2, Lact., Aquatic Chronic 3, STOT RE 2	GHS08, Dgr, GHS06	H315, H319, H335, H301, H360Df, H350, H341, H373, H312, H332, H362, H412
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (furosemide)
China - IECSC	N (furosemide)

Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	N (furosemide)
Legend:	*Y = All ingredients are on the inventory* *N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)*

SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:
EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

Definitions and abbreviations
PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
IDLH: Immediately Dangerous to Life or Health Concentrations

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