

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Urilin® (40 mg/ml syrup for dogs)
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 urinary incontinence associated with acquired urethral sphincter incompetence in the bitch only. The efficacy of phenylpropanolamine has only been demonstrated in ovariohysterectomised bitches.
Uses advised against:	Not for human use. People with known hypersensitivity to phenylpropanolamine should avoid contact with the veterinary medicinal product. <ul style="list-style-type: none"> • Do not use in animals treated with non-selective monoamine oxidase inhibitors. • Do not use in cases of known hypersensitivity to the active substance or to any of the excipients. • It is not appropriate to use the product for the behavioural cause of inappropriate urination. • Do not use in pregnant or lactating bitches.
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. 154-41-6 2. 205-826-7	50	Phenylpropanolamine hydrochloride	Acute Toxicity (Oral) Category 4; H302 ¹

3. Not Available			
4. Not Available			
N/a	Proprietary	Not Available	Not Applicable
Legend: 1. Classified by Chemwatch			

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	In the event of accidental eye contact, rinse the eye with clean water for about 15 minutes and seek medical advice, showing the label or package leaflet to the physician.
Skin contact:	In the event of accidental skin contact, wash the contaminated area with soap and water. Wash hands after use of the product. To avoid accidental ingestion the product must be used and kept out of the sight and reach of children.
Inhalation:	Inhalation is unlikely due to the nature and packaging of the product. Remove to fresh air, rest and keep warm.
Ingestion:	In the event of accidental ingestion, seek immediate medical attention showing the medical practitioner the package leaflet.

4.2 Most important symptoms and effects, both acute and delayed

Hypersensitivity (allergy) to thiamphenicol may occur rarely. People with a known hypersensitivity to thiamphenicol should avoid contact with the product.
 For further information, see Section 11.

4.3 Indication of immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable:	Not applicable.
Unsuitable:	Not applicable.

5.2 Special hazards arising from the substance or mixture

Fire incompatibility:	None known
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5.3 Special protective actions for fire-fighters:

Firefighting:	Not applicable.
Fire / explosion hazard:	Not flammable.

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

N/a

6.3 Methods and material for containment and cleaning up

Minor Spills:	Flush to drain.
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Major Spills:	Flush to drain. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment.
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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	People with known hypersensitivity to phenylpropanolamine should avoid contact with the veterinary medicinal product. Always replace the cap firmly after use to ensure that the child resistant closure operates correctly. To avoid accidental ingestion the product must be used and kept out of the sight and reach of children. Wear suitable protection gloves and clothing when handling the product. When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
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Other Information:	Discard unused material. Keep out of the reach and sight of children.
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7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 3 months. Do not store above 25°C. Keep the container in the outer carton.
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Storage incompatibility:	Unknown.
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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
Phenylpropanolamine HCl	Phenylpropanolamine hydrochloride; (Propadrine hydrochloride)	4.5 mg/m ³	49 mg/m ³	300 mg/m ³

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: Urilin®: 40 mg/ml syrup for dogs
 Phenylpropanolamine HCl: white or almost white crystalline powder
Container: 50 ml or 100 ml amber type III glass bottles containing 45 ml or 100 ml of syrup, with a low density polyethylene dropper and a polypropylene child resistant screw cap.
Physical state: Liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): 194-197°C
Initial boiling point and boiling range: Not available
Flash Point: Acetone -17°C (closed cup)
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): Not available
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: Phenylpropanolamine HCl: 187.67
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	Stable under normal temperatures and conditions.

hazardous reactions:	
10.4 Conditions to avoid:	See Section 7.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	Not applicable.	
Ingestion:	Phenylpropanolamine hydrochloride is toxic when overdoses are ingested. Adverse effects may include dizziness, headache, nausea, insomnia or restlessness, and increased blood pressure. High overdose may be fatal, especially in children.	
Skin contact:	Redness and irritation may develop after skin contact with the product.	
Eye contact:	Redness and irritation may develop after eye contact with the product.	
Chronic:	<p>Estimated lethal dose for a person has been reported as 50 mg/kg bodyweight. Has been used as an aid in weight-control in humans. Small doses can cause increased blood pressure and heart rate.</p> <p>Larger doses may lead to nervousness, restlessness, nausea, insomnia, cardiac and circulatory distress and headaches. Haemorrhagic strokes have also known to occur.</p> <p>As phenylpropanolamine is a sympathomimetic agent it is possible to produce a wide range of effects most of which mimic the results of excess stimulation of the sympathetic nervous system (e.g. effects on the heart rate and blood pressure).</p>	
Urilin®:	Acute toxicity	Irritation
	Not Available	Not Available
Phenylpropanolamine hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 1490 mg/kg ²	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:		
Not expected to cause serious skin corrosion.		

SECTION 11: TOXICOLOGICAL INFORMATION

Serious eye damage / irritation:
Not expected to cause serious eye damage.
Respiratory or skin sensitization:
Not expected to cause respiratory or skin sensitization.
Germ cell mutagenicity:
Not available
Carcinogenicity:
Not expected to be carcinogenic.
Reproductive toxicity:
Not available
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity					
Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Thiamphenicol	LC ₅₀	96	Fish	1.757mg/L	1
Thiamphenicol	EC ₅₀	96	Algae or other aquatic plants	0.193mg/L	1
Acetone	LC ₅₀	96	Fish	>100mg/L	2
Acetone	EC ₅₀	48	Crustacea	>100mg/L	2
Acetone	EC ₅₀	96	Algae or other aquatic plants	20.565mg/L	2
Acetone	NOEC	96	Algae or other aquatic plants	4.950mg/L	2

Legend:		1. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 2. 4. US EPA, Ecotox database - Aquatic Toxicity Data
DO NOT discharge into sewer or waterways.		
12.2 Persistence and degradability		
Ingredient	Persistence: Water/Soil	Persistence: Air
Phenylpropanolamine hydrochloride	HIGH	HIGH
12.3 Bioaccumulative potential		
Ingredient	Bioaccumulative Potential	
Phenylpropanolamine hydrochloride	LOW (LogKOW = 0.2171)	
12.4 Mobility in Soil		
Ingredient	Mobility	
Phenylpropanolamine hydrochloride	LOW (KOC = 56.63)	
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: N/a		
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)	N/a	N/a
	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	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)	N/a	N/a
	N/a	N/a
	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	



14.6 Special precautions for user	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	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)	N/a	N/a
	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	N/a	N/a
	N/a	N/a
	N/a	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	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
	N/a	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION

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

PHENYLPROPANOLAMINE HYDROCHLORIDE (154-41-6) 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)

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Phenylpropanolamine Hydrochloride	154-41-6	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4	GHS07, Wng	H302
2	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Repr. 2, Lact.	GHS06, Dgr, GHS08	H315, H319, H332, H335, H301, H361d, H362
1	Acute Tox. 4	GHS07, Wng	H302
2	Acute Tox. 4	GHS07, Wng	H302



Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	Y
China - IECSC	N (phenylpropanolamine hydrochloride)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (phenylpropanolamine hydrochloride)
Korea - KECI	N (phenylpropanolamine hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
Legend:	<i>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)</i>

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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